In the Matter of the Accusation Against:

SANTA CLARA DRUG
"THE COMPOUNDING SHOP"
2453 Forest Avenue
San Jose, CA 95128

Pharmacy License No. PHY 39079
Sterile Compounding License No. LSC 99114

and

LIONEL FRANCIS JARA
19745 Lamar Drive
Cupertino, CA 95014

Pharmacist License No. RPH 21273

Respondents.

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 (Board).

2. On or about September 2, 1993, the Board issued Pharmacy License No. PHY 39079 to Santa Clara Drug Pharmacy Inc. dba Santa Clara Drug "The Compounding Shop" (Respondent Santa Clara). On or about July 24, 2003, the Board issued Sterile Compounding License No. LSC 99114 to Respondent Santa Clara. Both licenses were in full force and effect at all times relevant to the charges herein and will expire on September 1, 2012, unless renewed.
3. On or about July 25, 1959, the Board issued Pharmacist License Number RPH 21273 to Lionel Francis Jara (Respondent Jara). The Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on March 31, 2012, unless renewed. Since on or about January 1, 1994, Respondent Jara has served and/or been reflected in Board records as the Pharmacist in Charge (PIC) for Respondent Santa Clara.

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

7. Section 118(b) of the Code provides, in pertinent part, that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated. Section 4402(a) of the Code provides that any pharmacist license that is not renewed within three years following its expiration may not be renewed, restored, or reinstated and shall be canceled by operation of law at the end of the three-year period. Section 4402(e) of the Code provides that any other license issued by the Board may be canceled by the Board if not renewed within 60 days after its expiration, and any license canceled in this fashion may not be reissued but will instead require a new application to seek reissuance.

STATUTORY AND REGULATORY PROVISIONS

8. 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:

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(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.

9. Section 4113, subdivision (b) 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."

10. Section 4342 of the Code provides, in pertinent part, that the Board may institute any action or actions provided by law and deemed necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform to expected quality or strength.

11. California Code of Regulations, title 16, section 1716, states 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. . . ."

12. California Code of Regulations, title 16, section 1735.3, sets forth the record-keeping requirements for all forms of pharmacy compounding, and mandates the minimum records with regard to each drug product compounded in the pharmacy that must be maintained and retained in the pharmacy in a readily retrievable form for a period of at least three years. These records must include, pursuant to section 1735.3, subdivision (a)(6), the name of the manufacturer and the lot number of each component used in the compounded drug product.

13. California Code of Regulations, title 16, section 1751.1, subdivision (a), requires that pharmacies compounding sterile injectable drug products for future use keep, in addition to those records required by section 1735.3, records indicating the name, lot number, amount, and date on which products were provided to a prescriber. Subdivision (c) requires that these records be kept and maintained in the pharmacy in a readily retrievable form for at least three years.

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14. California Code of Regulations, title 16, section 1751.7, subdivision (c), requires that batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

15. Health and Safety Code section 11165 provides, in pertinent part, for establishment and maintenance of a Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of prescribing and dispensing of Schedule II, III, and IV controlled substances, and requires, in pertinent part, that for each prescription for a Schedule II, III, or IV controlled substance, the dispensing pharmacy or clinic transmit a report with certain information on the patient, prescriber, controlled substance, and prescription, to the California Department of Justice, on a weekly basis in a format prescribed by the California Department of Justice.¹

16. 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 of the licensing act to pay a sum not to exceed its reasonable costs of investigation and enforcement.

CONTROLLED SUBSTANCES / DANGEROUS DRUGS

17. Section 4021 of the Code provides that a “controlled substance” means any substance listed in Schedules I through V contained in Health and Safety Code section 11053 et seq.

18. 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.”

¹ Health and Safety Code section 11165 was first amended to impose CURES reporting requirements effective January 1, 2005. As of that date prescriptions for Schedule II and III drugs had to be reported. Effective January 1, 2007, Schedule IV prescriptions also had to be reported.
19. **Alprostadil** is a dangerous drug as designated by Business and Professions Code section 4022. It is a drug used to treat sexual dysfunction.

20. **Phentolamine** is a dangerous drug as designated by Business and Professions Code section 4022. It is a drug used to treat sexual dysfunction.

21. **Papaverine** is a dangerous drug as designated by Business and Professions Code section 4022. It is a drug used to treat sexual dysfunction.

**CAUSES FOR DISCIPLINE, AS TO BOTH RESPONDENTS**

**FIRST CAUSE FOR DISCIPLINE**

(Dispensing of Preparations or Drugs Deviating from Expected Quality or Strength)

22. Respondents are each and severally subject to discipline under section(s) 4301, 4301(j), 4301(o), 4113(b), and/or 4342 of the Code, in that between on or about July 28, 2010 and September 7, 2010, Respondents dispensed, furnished, caused to be dispensed or furnished, attempted to dispense or furnish, assisted or abetted the dispensing or furnishing of, and/or conspired to dispense or furnish, preparations or drugs that deviated from the expected quality or strength. Namely, Respondents dispensed Alprostadil 10mcg/ml, to patients, where the strength of the active ingredient Alprostadil was tested to be actually 13.5mcg/ml (135% potency). In addition, a Trimix product with labeled strengths of Alprostadil 10mcg/ml, Papaverin 30mg/ml, Phentolamine 1mg/ml was dispensed to patients, where the strengths of the active ingredients were tested to be: Alprostadil 14.289mcg/ml (142.9% potency); Papaverine 28.92 mg/ml (96.4% potency); and Phentolamine 1.71mg/ml (171% potency).

**SECOND CAUSE FOR DISCIPLINE**

(Deviation from Prescription)

23. Respondents are each and severally subject to discipline under section(s) 4301, 4301(j), 4301(o), and/or 4113(b) of the Code, and/or California Code of Regulations, title 16, section 1716, in that as described in paragraph 21 above, Respondents dispensed, furnished, caused to be dispensed or furnished, attempted to dispense or furnish, assisted or abetted the dispensing or furnishing of, and/or conspired to dispense or furnish drug(s) to patient(s) in a strength or strengths that varied from the prescribed and labeled strength(s).
THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Accurate Lot Numbers for Records of Compounded Drug Products)

24. Respondents are each and severally subject to discipline under section(s) 4301, 4301(j), 4301(o), and/or 4113(b) of the Code, and/or California Code of Regulations, title 16, section 1735.3, subdivision (a)(6) in that on or about August 5, 2010 and/or August 24, 2010, Respondents failed to record accurate lot numbers for two ingredients, Phentolamine Mesylate Powder and Papaverine HCL 30mg/ml injectable, that were used in the compounding of two lots of Alprostadil 10mcg/Papaverin 30mg/Phentolamine 1mg/ml.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Compounding for Future Furnishing)

25. Respondents are each and severally subject to discipline under section(s) 4301, 4301(j), 4301(o), and/or 4113(b) of the Code, and/or California Code of Regulations, title 16, section(s) 1735.2, 1735.3, and/or 1751.1, in that on or about August 11, 2010 and/or September 8, 2010, Respondents were unable to produce or retrieve adequate compounding records for an Alprostadil 500 mcg/ml compound and/or solution that was found in the freezer on or about August 11, 2010, or for another Alprostadil 500mcg/ml solution that was sent for end product and potency testing on or about August 17, 2010.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Quarantine Batch-Produced Products for End Product Testing)

26. Respondents are each and severally subject to discipline under section(s) 4301, 4301(j), 4301(o), and/or 4113(b) of the Code, and/or California Code of Regulations, title 16, section 1751.7, subdivision (c), in that between on or about July 22, 2010 and on or about September 7, 2010, Respondents dispensed, furnished, caused to be dispensed or furnished, attempted to dispense or furnish, assisted or abetted the dispensing or furnishing of, and/or conspired to dispense or furnish sterile injectable products compounded from one or more non-sterile ingredients, including Alprostadil 10mcg/ml, Lot 07282010#3956-01, compounded on or about July 28, 2010, Alprostadil 20mcg/ml, Lot 07222010#0913-01, compounded on or about July 22, 201, Trimix 10mcg/30mg/1mg/ml, Lot 08052010#2283-01, compounded on or about
August 5, 2010, and/or Trimix 10mcg/30mg/1mg/ml, Lot 082402010#2283-01, compounded on or about August 24, 2010, without quarantining the products to conduct end-product testing.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Report Controlled Substance Prescriptions to CURES)

27. Respondents are each and severally subject to discipline under section(s) 4301, 4301(j), 4301(o), and/or 4113(b) of the Code, and/or Health and Safety Code section 11165, in that between in or about July 2007 and on or about May 11, 2010, Respondents failed to transmit any dispensing data to CURES for Schedule II through IV controlled substances dispensed.

DISCIPLINE CONSIDERATIONS

28. To determine the level of discipline, if any, to be imposed on Respondent Santa Clara and/or Respondent Jara (collectively, “Respondents”), Complainant further alleges that:

a. On or about November 17, 1990, in a prior disciplinary action titled In the Matter of the Accusation Against Lionel F. Jara and Barron Park Pharmacy, Case No. 1494 filed April 30, 1990 before the Board of Pharmacy, Respondent Jara’s Pharmacist License No. RPH 21273 was subjected to prior discipline. By way of a Decision and Order of the Board adopting a Proposed Stipulation and Decision effective November 17, 1990, Respondent Jara admitted to misconduct including: failure(s) to maintain a current inventory of drugs and shortages and overages of Demerol, Dilaudid, M.D. Contin, Percocet, and Tylox; filling prescriptions for the drug Darvon without authorization of the prescriber; and refilling prescriptions for Darvon more than five times and more than six months after issuance. Respondent admitted there were grounds for disciplinary action. Respondent’s Pharmacist License No. RPH 21273 was revoked, with revocation stayed in favor of a period of probation of three (3) years, with specified terms and conditions. Pursuant to the agreement, the Accusation against Barron Park Pharmacy was dismissed. That decision is now final and is incorporated by reference as if fully set forth herein.

b. On or about March 27, 2008, Citation No. CI 200734727 with a fine of $5,000.00 was issued to Respondent Santa Clara for violations including failure to maintain a quality assurance program for sterile compounded drugs, maintenance of outdated drugs and chemicals in the pharmacy’s inventory, and failure to keep adequate preparation records for compounded
products (including the master worksheet, the preparation worksheet, and end-product evaluation results). That citation is now final and is incorporated by reference as if fully set forth herein.

c. On or about March 27, 2008, Citation No. CI 2007 35712 with a fine of $5,000.00 was issued to Respondent Jara for violations including failure to maintain a quality assurance program for sterile compounded drugs, maintenance of outdated drugs and chemicals in the pharmacy’s inventory, and failure to keep adequate preparation records for compounded products (including the master worksheet, the preparation worksheet, and end-product evaluation results). 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 Pharmacy License No. PHY 39079, issued to Santa Clara Drug Pharmacy Inc. dba Santa Clara Drug “The Compounding Shop” (Respondent Santa Clara);

2. Revoking or suspending Sterile Compounding License No. LSC 99114, issued to Respondent Santa Clara.

3. Revoking or suspending Pharmacist License No. RPH 21273, issued to Lionel Francis Jara (Respondent Jara)

4. Ordering Respondent Santa Clara and Respondent Jara to jointly and severally be responsible 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;

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

DATED: 3/19/12

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