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

In the Matter of the Accusation Against: **HS PHARMACY D.B.A. HIGH STREET PHARMACY** **4248 Macarthur Blvd.** **Oakland, CA 94619** **Original Permit Number PHY 48720** **GAREEN AVAKIAN** **1 Lakeside Dr., #506** **Oakland, CA 94612-** **Original Pharmacist License No. RPH 44906** and, **KENNETH PAUL MARINAI** **1180 Monticello Rd.** **Lafayette, CA 94549** **Original Pharmacist License No. RPH 28204** Respondents.	Case No. 4667 **ORDER WITHDRAWING ACCUSATION SOLELY AS TO RESPONDENT KENNETH PAUL MARINAI**

TO ALL INTERESTED PARTIES:

PARTIES

1. On or about April 13, 2017, Complainant Virginia Herold (Complainant) filed Accusation No. 4667 in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

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2. Upon further review of the evidence and issues presented by this case, Complainant believes that the interests of justice would be best served by withdrawing Accusation No. 4667 solely as to Respondent Kenneth Paul Marinai.

3. WHEREFORE, IN THE INTEREST OF JUSTICE, Accusation No. 4667 is hereby withdrawn, without prejudice, solely as to Respondent Kenneth Paul Marinai.

DATED: 12/1/17

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

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In the Matter of the Accusation Against: **HS PHARMACY D.B.A. HIGH STREET PHARMACY** **4248 Macarthur Blvd.** **Oakland, CA 94619** **Original Permit Number PHY 48720** **GAREEN AVAKIAN** **1 Lakeside Dr., #506** **Oakland, CA 94612-** **Original Pharmacist License No. RPH 44906** and, **KENNETH PAUL MARINAI** **1180 Monticello Rd.** **Lafayette, CA 94549** **Original Pharmacist License No. RPH 28204** Respondents.	Case No. 4667 **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 October 9, 2007, the Board of Pharmacy (Board) issued Pharmacy License Number PHY 48720 to HS Pharmacy Inc. d.b.a. High Street Pharmacy, at 4248

Macarthur Blvd., Oakland, CA 94619 (Respondent High Street). Respondent High Street's Pharmacy License was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2016, unless renewed.

3. On or about October 7, 1991, the Board issued Pharmacist License Number RPH 44906 to Gareen Avakian (Respondent Avakian). The Pharmacist License has been in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2017, unless renewed. Respondent Avakian has been the Pharmacist-in-Charge (PIC) of Respondent High Street since May 1, 2012; has been the Vice President of Respondent High Street since October 9, 2007; and has been the Chief Executive Officer, President, Secretary, Treasurer, and Chief Financial Officer of Respondent High Street since April 12, 2012. In addition, Respondent Avakian became a partial owner of Respondent High Street in 2007, and became the sole owner of Respondent High Street in April 2012.

4. On or about April 24, 1973, the Board issued Pharmacist License Number RPH 28204 to Kenneth Paul Marinai (Respondent Marinai). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2017, unless renewed.

JURISDICTION

5. This Accusation is brought before the 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.

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

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8. Section 4307(a) of the Code provides:

"Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

"(1) 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."

9. 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 AND REGULATORY PROVISIONS

10. Section 4036.5 of the Code provides:

"'Pharmacist-in-charge' means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

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11. Section 4081 of the Code states:

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

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

"(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate."

12. 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."

13. Section 4156 of the Code provides:

"A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter."

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14. 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 issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

". . . .

"(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.

. . . ."

15. Section 4302 of the Code provides:

"The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee."

16. Code section 4306.5 provides:

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

". . . .

"(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.

. . . ."

17. Section 4332 of the Code provides:

"Any person who fails, neglects, or refuses to maintain the records required by section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time . . . is guilty of a misdemeanor."

18. California Code of Regulations, title 16, section 1714(c) provides:

"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."

19. California Code of Regulations, title 16, section 1707.2 provides:

"(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

"(1) upon request; or

"(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

"(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

"(A) whenever the prescription drug has not previously been dispensed to a patient; or

"(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

"(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:

"(A) of his or her right to request consultation; and

"(B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

". . . .

"(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation."

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20. California Code of Regulations, title 16, section 1715(a) provides:

"The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education."

21. California Code of Regulations, title 16, section 1716 provides, in pertinent part, that 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 Code (pertaining to substitution of generic for brand name).

22. California Code of Regulations, title 16, section 1718 states:

"'Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

"The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory."

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

"(a) . . . .

". . . .

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

"(1) Active ingredients to be used.

"(2) Equipment to be used.

"(3) Expiration dating requirements.

"(4) Inactive ingredients to be used.

"(5) Process and/or procedure used to prepare the drug.

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

"(7) Post-compounding process or procedures required, if any.

". . . .

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

". . . .

"(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education."

24. California Code of Regulations, title 16, section 1735.3 states, in pertinent part:

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

"(1) The master formula record.

". . . .

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

25. California Code of Regulations, title 16, section 1735.4(b) states:

"A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient."

26. California Code of Regulations, title 16, section 1735.5 states, in pertinent part:

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

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

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

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

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

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

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

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

27. California Code of Regulations, title 16, section 1735.7 provides, in pertinent part:

"(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

"(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

. . . ."

28. California Code of Regulations, title 16, section 1735.8 provides"

"(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

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

"(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

"(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength."

29. California Code of Regulations, title 16, section 1761 states:

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

"(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose."

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30. Health and Safety Code section 11153(a) provides:

"A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized in this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use."

31. Health and Safety Code section 11162.1 provides, in pertinent part, that prescription forms shall contain specified security features and be sequentially numbered.

32. Health and Safety Code section 11164 provides, in pertinent part, that no person shall fill, compound, or dispense a prescription unless it contains specified information and is made on a controlled substance prescription form as specified in Health and Safety Code section 11162.1.

33. Health and Safety Code section 11165(d) requires pharmacies that dispense a schedule II, III, or IV controlled substance (as determined by federal law) to report the quantity of controlled substance, specified information about the prescriber and ultimate user of the controlled substance, and other detailed information to the Department of Justice no later than seven days after dispensing the substance.

34. Code of Federal Regulations, title 21, section 1301.75(b) provides:

"Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances."

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35. Code of Federal Regulations, title 21, section 1304.11 provides, in pertinent part:

"(a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

". . . .

"(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

. . . ."

COSTS

36. 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 the reasonable costs of investigation and enforcement.

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DRUGS

37. HC/APAP, which refers to hydrocodone mixed with acetaminophen, is available in various dosages (e.g., 10/325mg or 5/500mg), is a Schedule III controlled substance as designated by Health and Safety Code section 11056(e)(4), is a Schedule II controlled substance under federal law, and is a dangerous drug as designated by Code section 4022. It is often referenced by the brand names Lortab, Norco, or Vicodin.

38. Oxycodone, sometimes referred to by the brand name Oxycontin, is a Schedule II controlled substance as designated by Health and Safety Code section 11055(b)(1)(M), and a dangerous drug pursuant to Code section 4022.

39. Promethazine with codeine is an antihistamine/antitussive, narcotic analgesic, and sleep aid containing codeine, a Schedule V controlled substance as designated by Health and Safety Code section 11058(c)(1), and a dangerous drug as designated by Code section 4022.

40. Diazepam, first marketed as Valium, is a Schedule IV controlled substance as designated by Health and Safety Code section 11057(d)(9), and a dangerous drug as designated by Code section 4022.

41. Carisoprodol, often referenced by the brand name Soma, has been a Schedule IV controlled substance under federal law since January 11, 2012, and is a dangerous drug as designated by Code section 4022.

42. Hydroxyzine is an antihistamine with anxiolytic properties. It is a dangerous drug pursuant to Code section 4022.

43. Hydralazine is a vasodilator used to treat hypertension. It is a dangerous drug pursuant to Code section 4022.

44. Glipizide is an anti-diabetic drug. It is a dangerous drug pursuant to Code section 4022.

45. Opana ER is a brand name for the opioid oxymorphone, a Schedule II controlled substance as designated by Health and Safety Code section 11055(b)(1)(N), and a dangerous drug pursuant to Code section 4022.

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46. Clonazepam (Klonopin) is a Schedule IV controlled substance as designated by Health and Safety Code section 11057(d)(7), and is a dangerous drug as designated by Code section 4022.

47. Zolpidem tartrate, often referred to by the brand name Ambien, is a Schedule IV controlled substance as designated by Health and Safety Code section 11057(d)(32), and is a dangerous drug as designated by Code section 4022.

I. INVESTIGATION 59086 BACKGROUND

48. On or about October 15, 2013, Respondent High Street refilled a prescription for SJ.[1] Respondent Avakian dispensed and/or approved the dispensed prescription. The prescription was for hydroxyzine 25mg tablets. The refill medication bottle depicted this information.

49. A few days after taking the medication, SJ began feeling dizzy and experiencing diarrhea and nausea. SJ also felt itchy and suffered from congestion and some difficulty breathing. SJ had previously taken the medication without these effects. SJ's mother took SJ to the emergency room.

50. The medication inside the bottle, in fact, was not hydroxyzine 25mg, but hydralazine 25mg.

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[1] Full consumer names will be provided in discovery.

FIRST CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Deviation from Prescription)

51. Respondent Avakian is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1716, in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as the Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 59086 Background," Respondent Avakian dispensed or was indirectly responsible for the dispensing of medication that deviated from the requirements of a prescription.

SECOND CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Deviation from Prescription)

52. Respondent High Street is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1716, in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 59086 Background," Respondent High Street dispensed or was responsible for the dispensing of medication that deviated from the requirements of a prescription.

II. INVESTIGATION 59245 BACKGROUND

53. On or about October 24, 2013, Respondent High Street filled a prescription for MC. Respondent Avakian dispensed and/or approved the dispensed medication. The prescription was for glipizide 5mg. The medication bottle depicted this information.

54. The medication inside the bottle, in fact, was not glipizide 5mg, but glipizide 10mg.

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THIRD CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Deviation from Prescription)

55. Respondent Avakian is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1716, in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 59245 Background," Respondent Avakian dispensed or was indirectly responsible for the dispensing of medication that deviated from the requirements of a prescription.

FOURTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Deviation from Prescription)

56. Respondent High Street is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1716, in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 59245 Background," Respondent High Street dispensed or was responsible for the dispensing of medication that deviated from the requirements of a prescription.

III. INVESTIGATION 56653 BACKGROUND

57. In or around April 2013, the Board received a complaint from a wholesaler that Respondent High Street was purchasing excessive amounts of hydrocodone/ acetaminophen products. Over the course of the subsequent investigation, the Board received similar reports and information from other wholesalers.

58. The Board performed two inspections at Respondent High Street, during which it discovered a problem with controlled substance security. At the time of the first inspection, on July 2, 2013, all of Respondent High Street's Schedule II controlled substances were being stored

in an unlocked cabinet. Although the issue was discussed with Respondent Avakian at that time, during a subsequent inspection on July 7, 2013, the cabinet containing the Schedule II controlled substances was again unlocked. When the Board investigators reexamined it later in the day on July 7, it was still unlocked.

59. The Board audited Respondent High Street's inventories of selected controlled substances for the period from April 1, 2012, through September 25, 2013. Respondent High Street was unable to account for overages or shortages of the following controlled substances in its September 25, 2013 inventory:

a) 188 tablets of diazepam 5mg (overage);

b) 1,602 tablets of diazepam 10mg (overage);

c) 6,013 tablets of HC/APAP 10/325mg (shortage);

d) 15 tablets of oxycodone 30mg (shortage);

e) 600 tablets of HC/APAP 5/500mg (overage);

f) 398 tablets of HC/APAP 7.5/750mg (overage);

g) 12,986 units (approximately 27.5 pints) of promethazine with codeine (overage); and

h) 160 tablets of carisoprodol 350mg (overage).

60. Respondent Avakian searched for additional records to reconcile the numbers, but she was unsuccessful. With regard to HC/APAP 10/325mg, for example, Respondent Avakian reported that Respondent High Street had actually received 7,900 less tablets than the invoices indicated, such that Respondent High Street actually had an overage of 1,887 tablets compared to its records. Thereafter, Respondent Avakian informed the Board that she had found another invoice for 1,000, reducing the overage to 887 tablets. Ultimately, however, Respondent Avakian corrected the earlier reports, stating that, having taken additional time to work through the documents, it appeared that Respondent High Street was indeed short 2,613 tablets of HC/APAP 10/325mg.

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61. Respondent Avakian admitted to the Board that Respondent High Street was not in possession of all of the records of its acquisitions and could not be certain whether Respondent High Street had received all of its controlled substances orders.

62. The Board reviewed data provided to the CURES/ Prescription Drug Monitoring Program (PDMP) by other pharmacies to assess Respondent High Street's comparative dispensing practices. The data indicated that out of a sample of 6 pharmacies within 3 miles of Respondent High Street, Respondent High Street filled the highest number of 5 of 6 different controlled substances reviewed, including 1.5 times as many prescriptions for HC/APAP 10/325mg as the second-highest dispensing pharmacy, more than 3 times the number of diazepam 10mg prescriptions of the second-highest dispensing pharmacy, nearly 2.5 times the number of prescriptions for carisoprodol 350mg of the second-highest dispensing pharmacy, nearly 2.5 times the number of prescriptions for HC/APAP 7.5/750mg of the second-highest dispensing pharmacy, and nearly 5 times the number of oxycodone 30mg of the second-highest dispensing pharmacy.

63. The Board performed a review of selected prescriptions Respondent High Street had filled between January 1, 2012, and November 2013, as well as related data from PDMP. PDMP data are made available to pharmacists to assist them in making determinations about the legitimacy of controlled substance prescriptions. Respondent Avakian admitted that Respondent High Street had not been using PDMP to make such determinations. Respondent Avakian further admitted that she did not feel it was her job to evaluate diagnoses so only sometimes inquired in that regard, and that she did not assess patients for pain.

64. In reviewing the prescriptions, the Board found that many prescriptions for controlled substances had not been reported by Respondent High Street to CURES within the required time frame.

65. The Board discovered multiple specific prescriptions for controlled substances that were of questionable legitimacy and/or were clearly illegitimate. Various circumstances (apart from the background circumstances described above) surrounding such prescriptions should have raised red flags for Respondent High Street's pharmacists, such as: the long distance from the customer's residence to Respondent High Street; the long distance the customer had travelled for

the visit with the prescriber; the customer's utilization of private payment (cash); the customer's history of pharmacy and/or prescriber shopping; the early timing of the fill request in relation to prior fills at the same or other pharmacies; a customer's use of the pharmacy for only controlled substances; the prescriber's high volume of controlled substance prescriptions, particularly when not a pain specialist or other type of specialist that would explain the volume; inconsistency between the diagnosis and the patient's prescriptions; and/or the combination of medications prescribed.

66. Respondent High Street had nonetheless failed to inquire with prescribers regarding the prescriptions, and Respondent High Street filled prescriptions that Respondent High Street had objective reason to know were not issued for a legitimate medical purpose. Of a sample of 35 customers' controlled substance prescriptions, the following were the most troubling in this regard, broken down by customer, along with a description of some of the most significant red flags indicating that prescriptions may not have been issued (and/or were not issued) for legitimate medical purposes:

Customer WP

67. During 2012, Respondent High Street dispensed HC/APAP 10/325mg to WP on 10/30, 11/26, and 12/24.

68. The distances WP travelled raised red flags. WP had travelled 13.9 miles from WP's residence to come to Respondent High Street, and WP had travelled 81.2 miles to see the prescriber of the controlled substances, Dr. C.L. Nate Pettinger (Dr. Pettinger). The distance between the prescriber and Respondent High Street was roughly 92.9 miles.

69. Respondent Avakian admitted that she did not know Dr. Pettinger. The Medical Board's website did not identify Dr. Pettinger as a pain specialist. Yet according to data reported by Respondent High Street, Respondent High Street filled 379 controlled substance prescriptions written by Dr. Pettinger during 2012, making Dr. Pettinger Respondent High Street's 5th highest prescriber of controlled substances.

70. Available PDMP data suggested that WP was engaged in doctor-shopping and pharmacy-shopping. Specifically:

A. By the time Respondent High Street filled the 10/30/12 prescription, WP had already obtained HC/APAP 10/325mg prescriptions from 9 different prescribers during 2012. WP had filled these prescriptions at 9 different pharmacies, making Respondent High Street the 10th pharmacy that dispensed HC/APAP 10/325mg to WP during calendar year 2012.

B. By the time Respondent High Street dispensed the 11/26/12 refill, the number of different prescribers providing HC/APAP 10/325mg prescriptions to WP during 2012 had increased to 11. Respondent High Street remained one of 10 different pharmacies used by WP in 2012 to fill such prescriptions.

C. As of the 11/26/12 refill, WP had filled, in the preceding 30 days, HC/APAP 10/325mg prescriptions at four different pharmacies. WP had obtained during that 30-day period a total of 146 days worth of HC/APAP 10/325mg. WP had obtained a 20-day supply at Respondent High Street on 10/30/12, a 33-day supply at Safeway on 11/13/12, a 46-day supply at Target on 11/14/12, and a 47-day supply at Wal-Mart on 11/21/12. Yet Respondent High Street provided another 20-day supply five days later, on 11/26/12.

71. According to Respondent High Street's records, WP filled only controlled substance prescriptions (6 total during the year) when WP came to Respondent High Street. WP private-paid (cash) for all of them.

Customer RW

72. During 2012, RW obtained carisoprodol 350mg from Respondent High Street on 8/23, 11/5, and 12/1.

73. The distances RW travelled raised red flags. RW travelled 7 miles from RW's residence to come to Respondent High Street and 87.5 miles to visit the prescriber, Dr. Pettinger. The distance between Respondent High Street and the prescriber was 92.9 miles.

74. The 8/23/12 carisoprodol prescription was accompanied by prescriptions, filled the same day at Respondent High Street, for HC/APAP 10/325mg and diazepam 10mg. In combination, these drugs form a version of what is known illicitly as the "trinity" or "holy

trinity."[2] The combination of such drugs, which have overlapping effects, is of dubious medical legitimacy and a significant red flag to a pharmacist. Furthermore, seven days later, on 8/30/12, RW returned to Respondent High Street and filled a prescription for another opioid, Opana ER.

75. Available PDMP data showed that by the time Respondent High Street dispensed the 8/23/12 carisoprodol prescription, RW had obtained carisoprodol prescriptions from four different prescribers during 2012.

76. On September 28, 2012, RW filled prescriptions for HC/APAP 10/325mg and diazepam 10mg at Respondent High Street. Data available on PDMP showed that RW had obtained the third component of the holy trinity elsewhere that month: RW had filled a carisoprodol prescription at Walgreens 7 days earlier.

77. On November 5, 2012, RW filled prescriptions for HC/APAP 10/325mg and carisoprodol 350mg at Respondent High Street. PDMP data show that RW had just obtained, four days prior, a prescription for 30 days of Oxycontin, written by a different prescriber and filled at a different pharmacy. Even if that information were not yet available on PDMP at that time, Respondent High Street filled identical prescriptions one month later, on December 1, 2012, and again, RW had just refilled the Oxycontin at another pharmacy.

78. By the time Respondent High Street dispensed the 12/1/12 refill, RW had filled 10 prescriptions at Respondent High Street, all from Dr. Pettinger, private-paying (cash) $1,198.95 for one of them. All were for controlled substances.

Customer KO

79. During 2012, KO filled prescriptions for oxycodone 30mg at Respondent High Street on 7/2[3] and 8/24. The prescriptions were written by Dr. Tariq Mirza and Dr. Robert Gentile, both of whom worked at Ariba Healthcare Group, Inc., in Fremont.

80. The distances KO travelled with regard to these two prescriptions raised red flags. KO travelled 11.6 miles from KO's residence to come to Respondent High Street and 11.8 miles

[2] "The Holy Trinity" or "trinity" is a drug regimen that includes at least one opioid, a benzodiazepine, and carisoprodol.

[3] This prescription was not reported to CURES.

in the other direction to visit the prescribers. (The distance from the prescribers to Respondent High Street was roughly 24 miles.)

81. Available PDMP data suggested that KO was engaged in doctor-shopping and pharmacy-shopping. Specifically:

A. As of the time Respondent High Street filled the 7/2/12 prescription, KO had obtained prescriptions for oxycodone 30mg from three different prescribers during 2012, filling the prescriptions at three different pharmacies other than Respondent High Street. Moreover, KO had obtained a 30-day supply of oxycodone 30mg just 7 days prior, on 6/25/12, at Haller's Pharmacy, along with a 30-day supply of HC/APAP 10/325mg, both of which were written by a different prescriber than the prescription filled by Respondent High Street.

B. As of the time Respondent High Street filled the 8/24/12 prescription, KO had obtained prescriptions for oxycodone 30mg from four different prescribers during 2012, filling them at 5 different pharmacies other than Respondent High Street. Moreover, KO had obtained, within the previous 30 days, a 30-day supply at Safeway (on 7/27/12), and another 45-day supply at Walgreens (on 8/3/12). Respondent High Street nevertheless dispensed another 30-day supply on 8/24/12.

82. KO private-paid (cash) for both of the oxycodone 30mg prescriptions filled at Respondent High Street. KO paid $209.95 for the 7/2/12 prescription and $214.95 for the 8/24/12 prescription.

83. Additionally, KO filled prescriptions at Respondent High Street for HC/APAP 10/325mg and diazepam 10mg, together, on 10/29/12, 11/24/12, and 12/24/12. The distances travelled with respect to these prescriptions, too, raised red flags. KO travelled 11.6 miles to come to Respondent High Street and 104 miles to visit the prescriber, Dr. Pettinger, who was located 92.9 miles from Respondent High Street.

84. KO obtained a total of 13 prescriptions from Respondent High Street during 2012, 12 of which were for controlled substances.

Customer NJ

85. NJ obtained prescriptions for HC/APAP 10/325mg from Respondent High Street on 7/24/2012, 8/2/2012, 9/14/2012, 1/11/2013, 2/7/2013, 3/6/2013[4], and 6/5/2013. NJ further obtained oxycodone 30mg prescriptions from Respondent High Street on 6/23/2012, 7/24/2012, 8/2/2012, 8/29/2012, 9/14/2012, 1/11/2013, and 4/17/2013[5].

86. Several of these prescriptions were written by Dr. Pettinger. For those prescriptions, the distances NJ travelled raised red flags. NJ travelled 96 miles to visit the prescriber, who was 92.9 miles from Respondent High Street.

87. Some of the prescriptions were written by Dr. Pacita Aducayen. For those prescriptions, too, the distances NJ travelled raised red flags. NJ travelled 7.3 miles to get to Respondent High Street and 39.4 miles to get to the prescriber (who was 34.5 miles from Respondent High Street).

88. Available PDMP data suggested that NJ was engaged in doctor-shopping and pharmacy-shopping. By way of illustration, on 9/14/2012, NJ filled prescriptions for oxycodone 30mg, HC/APAP 10/325mg, and carisoprodol at Respondent High Street. By that time, NJ had filled prescriptions for oxycodone 30mg at 4 different pharmacies during 2012, and had filled prescriptions for HC/APAP 10/325mg at 6 different pharmacies during 2012. Additionally, as of that date, NJ had filled prescriptions for oxycodone 30mg from 5 different prescribers, and had filled prescriptions for HC/APAP 10/325mg from 5 different prescribers, during 2012.

89. NJ presented early and duplicative prescriptions for overlapping short-term opioids.

A. By way of illustration, on July 24, 2012, NJ filled a prescription for 160 tablets of oxycodone 30mg (a 20-day supply) and a prescription for 180 tablets of HC/APAP 10/325mg (a 22-day supply) at Respondent High Street.[6] Nine days later, on August 2, 2012, NJ again returned to Respondent High Street and

[4] This prescription was not reported to CURES.
[5] This prescription was not reported to CURES.
[6] HC/APAP and oxycodone are both short-acting opioids, overlapping in their effects.

filled additional prescriptions for 180 tablets of oxycodone 30mg (a 60-day supply) and 180 tablets of HC/APAP 10/325mg (a 45-day supply).

B. PDMP records show that NJ then obtained another 60-day supply of oxycodone 30mg, thirteen days later (on August 15, 2012), at a different pharmacy, as well as a another prescription for HC/APAP 325/10mg. NJ thereafter returned to Respondent High Street on August 29, 2012, and filled another prescription for a 30-day supply of oxycodone 30mg. Even ignoring the parallel HC/APAP prescriptions, as of the time Respondent High Street filled the oxycodone 30mg prescription on August 29, NJ had already obtained 140 days worth of oxycodone 30mg during the preceding 36 days. Of that, 80 days worth (of the 140) were provided by Respondent High Street itself. Respondent High Street nevertheless provided another 30 days worth, on 8/29/12.

90. NJ was not an elderly patient, suggesting long-term, heavy opioid treatment was less likely appropriate from a medical perspective.

91. NJ private-paid (cash) for all of NJ's prescriptions filled at Respondent High Street during 2012, despite the fact that available PDMP data showed that NJ had commercial insurance.

92. Thirteen of fifteen prescriptions filled by NP at Respondent High Street during 2012 were for controlled substances.

Customer SH

93. During 2012, SH obtained prescriptions from Respondent High Street for HC/APAP 10/325mg, oxycodone 30mg, and promethazine with codeine. SH filled prescriptions for all three drugs together on 6/22/2012 and 12/5/2012. The cocktail of drugs was a red flag, as was the overlapping nature of the opioid prescriptions.

94. The distances SH travelled with respect to these prescriptions were also cause for inquiry. SH travelled 14.2 miles to get to Respondent High Street and 108 miles to get to the prescriber, Dr. Pettinger.

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95. Available PDMP data showed that SH filled early prescriptions at Respondent High Street:

A. Before filling the 6/22/2012 prescription for HC/APAP 10/325mg at Respondent High Street, SH filled HC/APAP 10/325mg prescriptions at other pharmacies on 6/12/2012 (a 12-day supply) and 6/15/2012 (a 30-day supply). Thus, in the ten days prior, SH had obtained 42 days worth of HC/APAP 10/325mg from other pharmacies. SH had also, within the same time frame, obtained 30 days worth of oxycodone 30mg from other pharmacies. Respondent High Street nevertheless provided SH an additional 19 days worth of HC/APAP 10/325mg and an additional 30 days worth of oxycodone 30mg, on 6/22/12.

B. Respondent High Street filled the 12/5/12 HC/APAP 10/325mg prescription ten days early.

96. PDMP data further showed that SH was engaged in pharmacy and prescriber shopping. By the time Respondent High Street filled the 12/5/2012 prescriptions, SH had obtained HC/APAP 10/325mg from 7 different pharmacies and 3 different prescribers during 2012, and had obtained oxycodone 30mg from 5 different pharmacies and 4 different prescribers during 2012.

97. SH private-paid (cash) for all of the prescriptions filled at Respondent High Street, even though available PDMP data showed that SH had commercial insurance.

98. SH obtained only controlled substances from Respondent High Street.

Customer MSJ

99. In 2012 and 2013, Respondent High Street filled multiple prescriptions for MSJ for HC/APAP, diazepam, and carisoprodol. Over the course of 2012 and 2013, MSJ filled enough of these three prescriptions at Respondent High Street to remain consistently, for all intents and purposes, medicated on the holy trinity. Between January 1, 2012, and October 23, 2013, MSJ obtained from Respondent High Street 444 days worth of diazepam, 660 days worth of carisoprodol, and 579 days worth of HC/APAP. Incorporating prescriptions filled by MSJ at

other pharmacies, as shown on PDMP, more than enough of these medications were provided to MSJ to remain constantly on the holy trinity.

100. MSJ further obtained many of the prescriptions early. By way of illustration:

A. On April 5, 2012, MSJ filled an original prescription for diazepam 10mg at Respondent High Street (15-day supply), and then filled the refill prescription at Respondent High Street on the same day (15-day supply). MSJ used insurance to pay for the first and then private-paid (cash) for the refill.

B. On August 8, 2012, MSJ filled a prescription for diazepam 10mg at Respondent High Street (15-day supply). MSJ then obtained from Respondent High Street a refill of that prescription on August 14, 2012 (15-day supply). MSJ used insurance to pay for the original prescription and then private-paid (cash) for the refill. Two days later, on August 16, 2012, MSJ filled another new prescription for diazepam 10mg at Respondent High Street (30-day supply). The prescription was from the same doctor as the first, and MSJ again private-paid (cash). Thus, over a period of eight days, MSJ filled three separate prescription orders for the same controlled substance, all at Respondent High Street.

C. On May 16, 2012 and May 31, 2012, MSJ filled prescriptions at Respondent High Street for carisoprodol 350mg, each of which were for a 30-day supply.

D. On August 8, 2012 and August 16, 2012, MSJ filled prescriptions at Respondent High Street for carisoprodol 350mg, each of which were for a 30-day supply.

E. On March 8, 2013, and March 27, 2013, MSJ filled prescriptions at Respondent High Street for carisoprodol 350mg, each of which were for a 30-day supply. Information on PDMP shows that MSJ then obtained another 30-day supply at a different pharmacy 14 days later, on 4/10/2013, after which MSJ obtained 30-day supplies from Respondent High Street on 5/6/2013, 5/13/2013, 6/6/2013, 6/14/2013, 7/2/2013, and 7/27/2013. By the time Respondent High Street filled the 7/27/2013 prescription, MSJ had obtained 210 days worth of carisprodol

350mg over the preceding 141 days (and of that 210, Respondent High Street had itself provided 180). Respondent High Street then provided yet another 30-day supply, on 7/27/2013.

F. Respondent High Street filled HC/APAP 10/325mg prescriptions for MSJ on 5/16/2012 (30-day supply), followed by a separate prescription from the same prescriber 9 days later, on 5/25/2012 (30-day supply).

G. Respondent High Street filled separate HC/APAP 10/325mg prescriptions for MSJ on 8/8/2012 (30-day supply) and 8/16/2012 (30-day supply).

H. Respondent High Street filled prescriptions for HC/APAP 10/325mg for MSJ on 3/22/2013 (22-day supply), and then another (30-day supply) 4 days later, on 3/27/2013, from a different prescriber. Respondent High Street continued filling HC/APAP 10/325mg prescriptions for MSJ from these two prescribers, providing a 30-day supply on 4/24/2013, a 22-day supply on 5/13/2013, a 22-day supply on 6/6/2013, a 30-day supply on 6/14/2013, a 22-day supply on 7/2/2013, and a 22-day supply on 7/26/2013. By the time Respondent High Street filled the 7/26/2013 prescription, MSJ had obtained (from Respondent High Street alone) 178 days worth of HC/APAP 10/325mg over the preceding 126 days. Respondent High Street then provided yet another 22-day supply, on 7/26/13.

101. MSJ obtained 26 controlled prescriptions from Respondent High Street in 2012, and another 25 controlled substance prescriptions from Respondent High Street in 2013.

Customer AP

102. In 2012 and 2013, Respondent High Street filled multiple prescriptions for AP for drugs that together constitute the holy trinity. Respondent High Street filled prescriptions for HC/APAP 10/325mg, carisoprodol 350mg, and diazepam 10mg, together, on 1/10/2012, 2/14/2012, 3/15/2012, 4/17/2012, 5/15/2012, 6/13/2012, 7/18/2012, 8/15/2012[7], 9/13/2012,

[7] Respondent High Street filled the HC/APAP and carisoprodol prescriptions on 8/15/2012 and filled the diazepam prescription the next day.

10/10/2012[8], 11/8/2012, 12/11/2012, 1/10/2013, 2/7/2013, 3/6/2013, 4/3/2013, 5/1/2013, 6/5/2013, and 8/7/2013. In July of 2013, Respondent High Street filled prescriptions for drugs together constituting the holy trinity for AP, with clonazepam in place of diazepam.

103. During 2012 and 2013, Respondent High Street also provided AP with sufficient oxycontin to permit continual usage.

104. Available PDMP data showed that, during some of this time, AP was also obtaining additional benzodiazepines and HC/APAP at other pharmacies.

105. Although AP paid for most of the medication with commercial insurance, AP private paid (cash) for virtually all of the diazepam.

FIFTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Physical Security for Controlled Substances)

106. Respondent Avakian is subject to disciplinary action under Code section 4301(o) and Code of Federal Regulations, title 21, section 1301.75(b), in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As described above in "Investigation 56653 Background," Respondent Avakian either failed to store or was indirectly responsible for failing to store controlled substances listed in Schedules II, III, IV, or V in a securely locked, substantially constructed cabinet or in a dispersed manner so as to obstruct theft or diversion.

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[8] Respondent High Street filled the carisoprodol and diazepam prescriptions on 10/10/2012, and filled the HC/APAP prescription the next day.

SIXTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Physical Security for Controlled Substances)

107. Respondent High Street is subject to disciplinary action under Code section 4301(o) and Code of Federal Regulations, title 21, section 1301.75(b), in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 56653 Background," Respondent High Street failed to store or was indirectly responsible for failing to store controlled substances listed in Schedules II, III, IV, or V in a securely locked, substantially constructed cabinet or in a dispersed manner so as to obstruct theft or diversion.

SEVENTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Inability to Account for Current Inventory)

108. Respondent Avakian is subject to disciplinary action under Code section 4301(o), in conjunction with sections 4081(a) and/or 4332 of the Code and/or California Code of Regulations, title 16, section 1718, in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 56653 Background," Respondent Avakian failed to keep or was indirectly responsible for failing to keep a current inventory for Respondent High Street, including complete accountability for all dangerous drugs.

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EIGHTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Inability to Account for Current Inventory)

109. Respondent High Street is subject to disciplinary action under Code section 4301(o), in conjunction with sections 4081(a) and/or 4332 of the Code and/or California Code of Regulations, title 16, section 1718, and pursuant to sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 56653 Background," Respondent High Street failed to keep or was indirectly responsible for failing to keep a current inventory, including complete accountability for all dangerous drugs.

NINTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Maintenance of Records Available for Inspection)

110. Respondent Avakian is subject to disciplinary action under Code section 4301(o), in conjunction with sections 4081(a) and/or 4332 of the Code, in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 56653 Background," Respondent Avakian failed to maintain or was indirectly responsible for failing to maintain all records of the acquisition and/or disposition of dangerous drugs available for inspection during business hours and/or to preserve those records for three years from the date they were made.

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TENTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Maintenance of Records Available for Inspection)

111. Respondent High Street is subject to disciplinary action under Code section 4301(o), in conjunction with sections 4081(a) and/or 4332 of the Code, and pursuant to sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 56653 Background," Respondent High Street failed to maintain or was indirectly responsible for failing to maintain all records of the acquisition and/or disposition of dangerous drugs available for inspection during business hours and/or to preserve those records for three years from the date they were made.

ELEVENTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Corresponding Responsibility)

112. Respondent Avakian is subject to disciplinary action under Code section 4301(o) in conjunction with Health and Safety Code section 11153(a) and/or California Code of Regulations, title 16, section 1761, in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations governing the practice of pharmacy.

113. As discussed above in "Investigation 56653 Background," with regard to customers WP, RW, KO, NJ, SH, MSJ, and AP, Respondent Avakian and/or employees of Respondent High Street failed to appropriately exercise the corresponding responsibility to ensure that Respondent High Street only filled prescriptions issued for legitimate medical purposes. Respondent Avakian and/or employees of Respondent High Street failed to contact the prescribers to obtain information to verify the customers' prescriptions. Moreover, in multiple instances, Respondent Avakian and/or employees of Respondent High Street filled prescriptions despite having objective reason to know that said prescriptions were not issued for legitimate medical purposes.

114. More specifically, Respondent Avakian and/or employees of Respondent High Street failed to contact the prescriber to verify the customer's prescription and/or filled prescriptions with objective reason to know those prescriptions were not issued for legitimate medical purposes in each of the following cases:

A. Customer WP: Prescriptions dispensed 10/30/12, 11/26/12, and 12/24/12.

B. Customer RW: Prescriptions dispensed 8/23/12, 9/28/12, 11/5/12, and 12/1/12.

C. Customer KO: Prescriptions dispensed 7/2/12, 8/24/12, 10/29/12, 11/24/12, and 12/24/12.

D. Customer NJ: Prescriptions dispensed 6/23/12, 7/24/12, 8/2/12, 8/29/12, 9/14/12, 1/11/13, 2/7/13, 3/6/13, 4/17/13, and 6/5/13.

E. Customer SH: Prescriptions dispensed 6/22/12 and 12/5/12.

F. Customer MSJ: Prescriptions dispensed 4/5/12, 5/16/12, 5/25/12, 5/31/12, 8/8/12, 8/14/12, 8/16/12, 3/8/13, 3/22/13, 3/27/13, 4/24/13, 5/6/13, 5/13/13, 6/6/13, 6/14/13, 7/2/13, 7/26/13, and 7/27/13.

G. Customer AP: Prescriptions dispensed 1/10/12, 2/14/12, 3/15/12, 4/17/12, 5/15/12, 6/13/12, 7/18/12, 8/15/12, 9/13/12, 10/10/12, 11/8/12, 12/11/12, 1/10/13, 2/7/13, 3/6/13, 4/3/13, 5/1/13, 6/5/13, 7/10/13, 7/23/13, and 8/7/13.

TWELFTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Corresponding Responsibility)

115. Respondent High Street is subject to disciplinary action under Code section 4301(o), in conjunction with Health and Safety Code section 11153(a) and/or California Code of Regulations, title 16, section 1761, and pursuant to sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy.

116. As discussed above in "Investigation 56653 Background," with regard to the prescriptions specified above in the Eleventh Cause for Discipline for customers WP, RW, KO, NJ, SH, MSJ, and AP, Respondent Avakian and/or employees of Respondent High Street failed to

appropriately exercise the corresponding responsibility to ensure that Respondent High Street only filled prescriptions issued for legitimate medical purposes. Respondent Avakian and/or employees of Respondent High Street failed to contact the prescribers to obtain information to verify the customers' prescriptions. Moreover, in multiple instances, Respondent Avakian and/or employees of Respondent High Street filled prescriptions despite having objective reason to know that said prescriptions were not issued for legitimate medical purposes.

THIRTEENTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Unprofessional Conduct - Corresponding Responsibility)

117. Respondent Avakian is subject to disciplinary action under Code sections 4301 and 4306.5(b) in that Respondent Avakian engaged in unprofessional conduct. The circumstances are described above in the Eleventh Cause for Discipline and "Investigation 56653 Background."

FOURTEENTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Unprofessional Conduct - Corresponding Responsibility)

118. Respondent High Street is subject to disciplinary action under Code sections 4301 and 4306.5, pursuant to sections 4302 and/or 4156 of the Code, in that Respondent High Street engaged in unprofessional conduct. The circumstances are described above in the Eleventh Cause for Discipline, Twelfth Cause for Discipline, and "Investigation 56653 Background."

FIFTEENTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(CURES Reporting)

119. Respondent Avakian is subject to disciplinary action under Code section 4301(o), in conjunction with Health and Safety Code section 11165(d), in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy.

120. Respondent Avakian and/or employees of Respondent High Street failed to report the following controlled substance prescriptions to the Department of Justice (CURES system) within seven days after dispensing the medication:

a) Customer LE, RX# 827293, filled 7/12/2012, for carisoprodol 350mg.

b) Customer DE, RX# 828599, filled 7/24/2012, for carisoprodol 350mg.

c) Customer NG, RX# 824495, filled 6/21/2012, for carisoprodol 350mg.

d) Customer NG, RX# 829818, filled 8/2/2012, for carisoprodol 350mg.

e) Customer NJ, RX# 828621, filled 7/24/2012, for carisoprodol 350mg.

f) Customer NJ, RX# 829811, filled 8/2/2012, for carisoprodol 350mg.

g) Customer NJ, RX# C847619, filled 3/6/2013, for HC/APAP 10/325mg.

h) Customer EJ, RX# C823540, filled 7/6/2012, for HC/APAP 10/325mg.

i) Customer EJ, RX# 823514, filled 6/14/2012, for carisoprodol 350mg.

j) Customer EJ, RX# 823514, filled 7/10/2012, for carisoprodol 350mg.

k) Customer EJ, RX# 823514, filled 8/8/2012, for carisoprodol 350mg.

l) Customer DM, RX# C826387, filled 7/6/2012, for HC/APAP 10/325mg.

m) Customer DM, RX# 826388, filled 7/6/2012, for carisoprodol 350mg.

n) Customer DM, RX# 826388, filled 7/17/2012, for carisprodol 350mg.

o) Customer DM, RX# 826388, filled 7/31/2012, for carisoprodol 350mg.

p) Customer DM, RX# C841834, filled 12/11/2012, for HC/APAP 10/325mg.

q) Customer DM, RX# C841835, filled 1/16/2013, for carisoprodol 350mg.

r) Customer KO, RX# N825863, filled 7/2/2012, for oxycodone 30mg.

s) Customer KO, RX# 825865, filled 7/2/2012, for carisoprodol 350mg.

t) Customer KO, RX# C853886, filled 3/6/2013, for zolpidem 10mg.

u) Customer RP, RX# C822701, filled 7/2/2012, for diazepam 10mg.

v) Customer BP, RX# 826865, filled 7/10/2012, for carisoprodol 350mg.

w) Customer BP, RX# C842613, filled 12/13/2012, for HC/APAP 10/325mg.

x) Customer BP, RX# C842613, filled 1/15/2013, for HC/APAP 10/325mg.

y) Customer KS, RX# N844719, filled 12/13/2012, for oxycodone 30mg.

z) Customer ET, RX# C826211, filled 7/5/2012, for HC/APAP 10/325mg.

aa) Customer ET, RX# 826212, filled 7/5/2012, for carisoprodol 350mg.

bb) Customer ET, RX# 830129, filled 8/4/2012, for carisoprodol 350mg.

cc) Customer AV, RX# C826541, filled 7/6/2012, for HC/APAP 10/325mg.

dd) Customer AV, RX# C826542, filled 7/6/2012, for diazepam 10mg.

ee) Customer BW, RX# C854312, filled 3/9/2013, for HC/APAP 10/325mg.

ff) Customer BW, RX# C854313, filled 3/9/2013, for alprazolam 2mg.

gg) Customer AW, RX# 830141, filled 8/4/2012, for carisoprodol 350mg.

hh) Customer AW, RX# 830141, filled 8/14/2012, for carisoprodol 350mg.

SIXTEENTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(CURES Reporting)

121. Respondent High Street is subject to disciplinary action under Code section 4301(o) and Health and Safety Code section 11165(d), in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. Respondent High Street, Respondent Avakian, and/or employees of Respondent High Street failed to report the controlled substance prescriptions listed above in the Fifteenth Cause for Discipline to the Department of Justice (CURES system) within seven days after dispensing the medication.

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SEVENTEENTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Duty to Consult)

122. Respondent Avakian is subject to disciplinary action under Code section 4301(o), in conjunction with California Code of Regulations, title 16, section 1707.2, in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy.

123. Specifically, on or about July 2, 2013, as witnessed during the Board's inspection, Respondent High Street delivered prescriptions to patients that were not present in the pharmacy without including written notice to the patients of their right to consultation. Moreover, pharmacy staff of Respondent High Street were observed screening for consultations at the pharmacy counter.

EIGHTEENTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Duty to Consult)

124. Respondent High Street is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1707.2, in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy.

125. Specifically, on or about July 2, 2013, as witnessed during the Board's inspection, Respondent High Street delivered prescriptions to patients that were not present in the pharmacy without including written notice to the patients of their right to consultation. Moreover, pharmacy staff of Respondent High Street were observed screening for consultations at the pharmacy counter.

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IV. INVESTIGATION 48413 BACKGROUND

126. On or about May 11, 2011, Respondent Marinai, while working as a pharmacist at High Street, dispensed two prescriptions for controlled substances (RX# 781216 and RX# 781217) that were written on a prescription form lacking required security elements. Specifically, the prescription form lacked a description of the security features, quantity check-off boxes with spaces for unit designation, notice that the prescription is void if the number of drugs prescribed is not noted, sequential numbering, refill check-boxes, and check-boxes for orders not to substitute.

127. Despite the lacking security elements, Respondent Marinai did not call the prescriber to verify the validity of the prescriptions. The prescriptions were not, in fact, valid.

NINETEENTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT MARINAI

(Erroneous Prescription)

128. Respondent Marinai is subject to disciplinary action under Code section 4301(o) and Health and Safety Code sections 11164 and 11162.1, in that Respondent Marinai directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 48413 Background," Respondent Marinai dispensed controlled substances based on a prescription lacking required security elements.

TWENTIETH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Erroneous Prescription)

129. Respondent High Street is subject to disciplinary action under Code section 4301(o) and Health and Safety Code sections 11164 and 11162.1, in conjunction with section 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 48413 Background," Respondent High Street dispensed controlled substances based on a prescription lacking required security elements.

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TWENTY-FIRST CAUSE FOR DISCIPLINE

AS TO RESPONDENT MARINAI

(Corresponding Responsibility)

130. Respondent Marinai is subject to disciplinary action under Code section 4301(o), in conjunction with Health and Safety Code section 11153(a) and/or California Code of Regulations, title 16, section 1761(a), in that Respondent Marinai directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations governing the practice of pharmacy. As discussed above in "Investigation 48413 Background," Respondent Marinai failed to exercise the pharmacist's corresponding responsibility to ensure controlled substances are dispensed only for a legitimate medical purpose. Respondent Marinai failed to contact the prescriber of controlled substance prescriptions RX# 781216 and RX# 781217, despite the prescription form's significant omission and/or irregularity.

TWENTY-SECOND CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Corresponding Responsibility)

131. Respondent High Street is subject to disciplinary action under Code section 4301(o), in conjunction with Health and Safety Code section 11153(a) and/or California Code of Regulations, title 16, section 1761(a), and pursuant to section 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 48413 Background," Respondent High Street and/or its pharmacist failed to exercise the corresponding responsibility to ensure controlled substances are dispensed only for a legitimate medical purpose. Respondent High Street and/or its pharmacist failed to contact the prescriber of controlled substance prescriptions RX# 781216 and RX# 781217, despite the prescription form's significant omission and/or irregularity.

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TWENTY-THIRD CAUSE FOR DISCIPLINE

AS TO RESPONDENT MARINAI

(Unprofessional Conduct - Corresponding Responsibility)

132. Respondent Marinai is subject to disciplinary action under Code sections 4301 and 4306.5(b) in that Respondent Marinai engaged in unprofessional conduct. The circumstances are described above in the Nineteenth Cause for Discipline and "Investigation 48413 Background."

TWENTY-FOURTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Unprofessional Conduct - Corresponding Responsibility)

133. Respondent High Street is subject to disciplinary action under Code sections 4301 and 4306.5(b), and pursuant to section 4156 of the Code, in that Respondent High Street engaged in unprofessional conduct. The circumstances are described above in the Twentieth Cause for Discipline and "Investigation 48413 Background."

IV. INVESTIGATION 66051 BACKGROUND

134. On September 14, 2015, the Board inspected Respondent High Street. The inspector found the pharmacy to be dusty, cluttered, and unclean. There were spiders hanging from the wall, a dog bowl at the sink, and ice cream and other food in the pharmacy freezer. No hot water was available.

135. The controlled substances were stored in a locked cabinet. However, the key to the locked cabinet was in an unlocked drawer accessible to non-pharmacist, ancillary staff.

136. The most recent Drug Enforcement Agency Biennial Controlled Substance Inventory performed by Respondent High Street was on November 14, 2013. However, no count had been recorded for HC/APAP 10/325mg or various other controlled substances.

137. The most recent Community Pharmacy Self-Assessment that was completed for Respondent High Street was performed on November 14, 2013. It had not been signed or dated. No subsequent Community Pharmacy Self-Assessment had been performed.

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138. Respondent High Street performed some compounding. A Compounding Self-Assessment had been performed and signed on November 14, 2013. No subsequent Compounding Self-Assessment had been performed.

139. Respondent High Street had no master formulas for the drug products it compounded. Nor did Respondent High Street have policies and procedures for compounding, a quality assurance plan for compounding, or a training plan or competency evaluation process for personnel engaged in compounding. Furthermore, records revealed that Respondent High Street had given "beyond use dates" to drug products that were in excess of 180 days from the date of compounding. For example, compound serial numbers 915871, 923110, and 938310 contained such excessively late "beyond use dates." Additionally, Respondent High Street had failed to include on the container or receipt of compounded drug products that were provided to customers a statement that the drug product had been compounded by the pharmacy.

140. The Board performed an audit of Respondent High Street's HC/APAP 10/325mg inventory for the period between September 26, 2013 and September 14, 2015. The audit discovered that Respondent High Street could not account for the absence of 870 tablets.

TWENTY-FIFTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Physical Security for Controlled Substances)

141. Respondent Avakian is subject to disciplinary action under Code section 4301(o) and Code of Federal Regulations, title 21, section 1301.75(b), in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes and regulations regulating the practice of pharmacy. As described above in "Investigation 66051 Background," Respondent Avakian either failed to store or was indirectly responsible for failing to store controlled substances listed in Schedules II, III, IV, or V in a securely locked, substantially constructed cabinet or in a dispersed manner so as to obstruct theft or diversion.

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TWENTY-SIXTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Physical Security for Controlled Substances)

142. Respondent High Street is subject to disciplinary action under Code section 4301(o) and Code of Federal Regulations, title 21, section 1301.75(b), in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent High Street failed to store or was indirectly responsible for failing to store controlled substances listed in Schedules II, III, IV, or V in a securely locked, substantially constructed cabinet or in a dispersed manner so as to obstruct theft or diversion.

TWENTY-SEVENTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Inability to Account for Current Inventory)

143. Respondent Avakian is subject to disciplinary action under Code section 4301(o), in conjunction with sections 4081(a) and/or 4332 of the Code and/or California Code of Regulations, title 16, section 1718, in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent Avakian failed to keep or was indirectly responsible for failing to keep a current inventory for Respondent High Street, including complete accountability for all dangerous drugs.

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TWENTY-EIGHTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Inability to Account for Current Inventory)

144. Respondent High Street is subject to disciplinary action under Code section 4301(o), in conjunction with sections 4081(a) and/or 4332 of the Code and/or California Code of Regulations, title 16, section 1718, and pursuant to sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent High Street failed to keep or was indirectly responsible for failing to keep a current inventory, including complete accountability for all dangerous drugs.

TWENTY-NINTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Operational Standards)

145. Respondent Avakian is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1714(c), in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," upon inspection Respondent High Street was unclean, was not free from insects, and was not equipped with hot water.

THIRTIETH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Operational Standards)

146. Respondent High Street is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1714(c), in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or

attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," upon inspection Respondent High Street was unclean, was not free from insects, and was not equipped with hot water.

THIRTY-FIRST CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Pharmacy Self-Assessment)

147. Respondent Avakian is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1715(a), in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent Avakian failed to complete a self-assessment of Respondent High Street's compliance with federal and state pharmacy law before July 1 of every odd-numbered year.

THIRTY-SECOND CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Pharmacy Self-Assessment)

148. Respondent High Street is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1715(a), in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent Avakian, as PIC, an officer, and an owner of Respondent High Street, failed to complete a self-assessment of Respondent High Street's compliance with federal and state pharmacy law before July 1 of every odd-numbered year.

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THIRTY-THIRD CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Compounding Without Written Master Formula Record)

149. Respondent Avakian is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1735.2(d) and/or 1735.3, in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent Avakian failed to ensure that a master formula record was prepared, including all of the required elements, prior to Respondent High Street compounding drug products. Furthermore, Respondent Avakian failed to ensure that Respondent High Street's pharmacy records included, for at least three years from the date of record creation, those master formula records.

THIRTY-FOURTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Compounding Without Written Master Formula Record)

150. Respondent High Street is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1735.2(d) and/or 1735.3, in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent High Street compounded drug products without first preparing a master formula record for each such drug product. Furthermore, Respondent High Street failed to retain, for at least three years from the date of record creation, those master formula records.

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THIRTY-FIFTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Improper Compounding "Beyond Use Dates")

151. Respondent Avakian is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1735.2(h), in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent Avakian failed to ensure that Respondent High Street gave "beyond use dates" not exceeding 180 days from preparation of compounded drug products.

THIRTY-SIXTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Improper Compounding "Beyond Use Dates")

152. Respondent High Street is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1735.2(h), in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent High Street gave "beyond use dates" exceeding 180 days from preparation of compounded drug products.

THIRTY-SEVENTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Compounding Self-Assessment)

153. Respondent Avakian is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1735.2(j), in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or

attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent Avakian failed to complete a self-assessment for compounding pharmacies prior to allowing a drug product to be compounded in the pharmacy.

THIRTY-EIGHTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Compounding Self-Assessment)

154. Respondent High Street is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1735.2(j), in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent Avakian, as PIC, an officer, and an owner of Respondent High Street, failed to complete a self-assessment for compounding pharmacies prior to allowing a drug product to be compounded in the pharmacy.

THIRTY-NINTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Failure to Provide Required Compounding Notice)

155. Respondent Avakian is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1735.4(b), in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent Avakian failed to ensure that a statement that the drug product was compounded by the pharmacy was included on either the container or receipt provided to the patient for each compounded drug product.

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FORTIETH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Failure to Provide Required Compounding Notice)

156. Respondent High Street is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1735.4(b), in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent High Street failed to provide a statement that the drug product was compounded by the pharmacy on either the container or receipt provided to the patient for each compounded drug product.

FORTY-FIRST CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Failure to Maintain Compounding Policy/Procedure Manual)

157. Respondent Avakian is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1735.5, in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent Avakian failed to ensure that Respondent High Street maintained a written policy and procedure manual for compounding containing the required information. Furthermore, Respondent Avakian failed to review any such manual on an annual basis.

FORTY-SECOND CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Failure to Maintain Compounding Policy/Procedure Manual)

158. Respondent High Street is subject to disciplinary action under Code section 4301(o) and California Code of Regulations, title 16, section 1735.5, in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or

attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent High Street failed to maintain a written policy and procedure manual for compounding containing the required information. Furthermore, Respondent Avakian, as PIC, an officer, and owner of Respondent High Street, failed to review any such manual on an annual basis.

FORTY-THIRD CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Failure to Maintain Compounding Training Documentation and Evaluation Process)

159. Respondent Avakian is subject to disciplinary action under Code section 4301(o) in conjunction with California Code of Regulations, title 16, section 1735.7(a) and/or (b), in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent Avakian failed to ensure that Respondent High Street maintained written documentation, including documentation of trainings, demonstrating that pharmacy personnel have the skills and training to accurately perform their assigned responsibilities relating to compounding. Respondent Avakian further failed to ensure that Respondent High Street developed and maintained an on-going competency evaluation process for pharmacy personnel involved in compounding, including documentation of trainings.

FORTY-FORTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Failure to Maintain Compounding Training Documentation and Evaluation Process)

160. Respondent High Street is subject to disciplinary action under Code section 4301(o) in conjunction with California Code of Regulations, title 16, section 1735.7(a) and/or (b), in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051

Background," Respondent High Street failed to maintain written documentation, including documentation of trainings, demonstrating that pharmacy personnel have the skills and training to accurately perform their assigned responsibilities relating to compounding. Respondent High Street further failed to develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding.

FORTY-FIFTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Failure to Maintain Compounding Quality Assurance Plan)

161. Respondent Avakian is subject to disciplinary action under Code section 4301(o) in conjunction with California Code of Regulations, title 16, section 1735.8, in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent Avakian failed to ensure that Respondent High Street maintained a quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products. Respondent Avakian further failed to ensure that any such plan required all of the required standards and procedures.

FORTY-SIXTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Failure to Maintain Compounding Quality Assurance Plan)

162. Respondent High Street is subject to disciplinary action under Code section 4301(o) in conjunction with California Code of Regulations, title 16, section 1735.8, in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent High Street did not maintain a quality assurance plan designed to monitor and ensure

the integrity, potency, quality, and labeled strength of compounded drug products. Respondent High Street further did not include in any such plan all of the required standards and procedures.

FORTY-SEVENTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT AVAKIAN

(Failure to Perform Complete Biennial Controlled Substance Inventory)

163. Respondent Avakian is subject to disciplinary action under Code section 4301(o) and Code of Federal Regulations, title 21, section 1304.11(a) and/or (c), in that, either through her own conduct or inaction, or derivatively as an owner of Respondent High Street or as a Pharmacist-in-Charge under Code section 4113(c) and/or 4036.5, Respondent Avakian directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent Avakian failed to ensure that Respondent High Street performed a biennial controlled substance inventory containing a complete and accurate record of all controlled substances on hand.

FORTY-EIGHTH CAUSE FOR DISCIPLINE

AS TO RESPONDENT HIGH STREET

(Failure to Perform Complete Biennial Controlled Substance Inventory)

164. Respondent High Street is subject to disciplinary action under Code section 4301(o) and Code of Federal Regulations, title 21, section 1304.11(a) and/or (c), in conjunction with sections 4302 and/or 4156 of the Code, in that Respondent High Street directly or indirectly violated, or attempted to violate, or assisted in or abetted a violation of, the statutes or regulations regulating the practice of pharmacy. As discussed above in "Investigation 66051 Background," Respondent High Street failed to perform a biennial controlled substance inventory containing a complete and accurate record of all controlled substances on hand.

OTHER MATTERS

165. Pursuant to Code section 4307, if discipline is imposed on Pharmacy License No. PHY 48720 issued to Respondent High Street, HS Pharmacy Inc. 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 No. PHY 48720 is placed on probation, or until Pharmacy License No. PHY 48720 is reinstated if it is revoked.

166. Pursuant to Code section 4307, if discipline is imposed on Pharmacy License No. PHY 48720 issued to Respondent High Street, and Gareen Avakian had knowledge of or knowingly participated in any of the conduct for which Pharmacy License No. PHY 48720 was disciplined, Gareen Avakian 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 No. PHY 48720 is placed on probation, or until Pharmacy License No. PHY 48720 is reinstated if it is revoked.

DISCIPLINE CONSIDERATIONS

167. In order to determine the degree of discipline, if any, to be imposed, Complainant alleges that on or around May 26, 2009, the Board issued Respondent High Street Citation No. CI 2008 38187. That citation is now final and is incorporated herein as if fully set forth.

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 Pharmacist License No. RPH 44906, issued to Gareen Avakian;

2. Revoking or suspending Pharmacy License No. PHY 48720, issued to HS Pharmacy Inc. d.b.a. High Street Pharmacy, at Macarthur Blvd., Oakland, CA 94619;

3. Revoking or suspending Pharmacist License No. RPH 28204, issued to Kenneth Paul Marinai;

4. Prohibiting HS Pharmacy Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy License PHY 48720 is placed on probation, or until Pharmacy License PHY 48720 is reinstated if Pharmacy License PHY 48720 is revoked;

5. Prohibiting Gareen Avakian from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy License

PHY 48720 is placed on probation, or until Pharmacy License PHY 48720 is reinstated if Pharmacy License PHY 48720 is revoked;

6. Ordering Gareen Avakian and HS Pharmacy Inc. d.b.a. High Street Pharmacy, at Macarthur Blvd., Oakland, CA 94619, 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;

7. Ordering Kenneth Paul Marinai 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;

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

DATED: 4/13/17

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

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