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

In the Matter of the First Amended Accusation Against**:** **SAYBIAN ENTERPRISES INC. DBA WARNER WEST PHARMACY & SUPPLY, CAMILL SAYADEH** **22030 Sherman Way, #100** **Canoga Park, CA 91303** **Pharmacy Permit No. PHY 49208** **ASKAR NADJAVOF** **4601 Willis Ave., Apt. 208** **Sherman Oaks, CA 91403** **Pharmacist License No. RPH 71122** **AYOUB MERHI** **20921 Community St., Unit 9** **Canoga Park, CA 91304** **Pharmacist License No. RPH 72499** and **HARSHAD H. GAJJAR** **20608 Vercelli Way** **Porter Ranch, CA 91326** **Pharmacist License No. RPH 41722** Respondents.	Case No. 5866 **FIRST AMENDED 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.

Warner West Pharmacy & Supplies

2. On or about April 17, 2009, the Board of Pharmacy (Board) issued Original Pharmacy Permit Number PHY 49208 to Saybian Enterprises Inc. dba Warner West Pharmacy & Supply, Camill Sayadeh (Respondent Warner). The Original Pharmacy Permit expired on September 8, 2015, and has not been renewed.

Askar Nadjavof

3. On or about August 26, 2014, the Board issued Pharmacy License No. RPH 71122 to Askar Nadjavof (Respondent Nadjavof). RPH No. 71122 was in full force and effect at all times relevant to the Accusation and will expire on April 30, 2018, unless renewed. During the time period between March 1, 2015 to May 1, 2015, Respondent Nadjavof was employed as the Pharmacist-in-Charge at Warner West Pharmacy & Supplies.

Ayoub Merhi

4. On or about March 25, 2015, the Board issued Pharmacy License No. RPH 72499 to Ayoub Merhi (Respondent Merhi). RPH No. 72499 was in full force and effect at all times relevant to the Accusation and will expire on October 31, 2018, unless renewed. During the time period between May 1, 2015 to May 20, 2015, Respondent Merhi was employed as the Pharmacist-in-Charge at Warner West Pharmacy & Supplies.

Harshad H. Gajjar

5. On or about April 23, 1988, the Board issued Pharmacy License No. RPH 41722 to Harshad H. Gajjar (Respondent Gajjar). RPH No. 41722 was in full force and effect at all times relevant to the Accusation and will expire on December 31, 2017, unless renewed. During the time period between May 20, 2015 to October 14, 2015, Respondent Gajjar was employed as the Pharmacist-in-Charge at Warner West Pharmacy & Supplies.

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JURISDICTION

6. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

7. Section 118, subdivision (b), provides in pertinent part that the suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.

8. Section 4300 states, in pertinent part:

"(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper."

9. Section 4307 subdivision (a) states, in pertinent part:

Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, or partner or any partnership, corporation, firm, or association whose application for a license has been denied or

revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manger, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

10. Section 4342 subdivision (a) states that "[t]he board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

STATUTORY PROVISIONS

11. Section 4076 subdivision (a)(8) states in pertinent part:

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

(8) The quantity of the drug or drugs dispensed."

12. Section 4081 subdivision (a) states:

"(a) All records of manufacture and of sale, acquisition, receipt, shipment, 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, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, 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."

13. Section 4105 subdivision (a) states in pertinent part that "[a]ll records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form."

14. Section 4301 subdivision (f) states in pertinent part:

"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:

…

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

REGULATORY PROVISIONS

15. Cal. Code of Regs. title 16 section 1716 states that "[p]harmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code. Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription."

16. Cal. Code of Regs. title 16 section 1717 states in pertinent part:

"(b) In addition to the requirements of Business and Professions Code Section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

…

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

…

(f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years."

17. Cal. Code of Regs. title 16 section 1717.3 subdivision (a) states that "no person shall dispense a controlled substance pursuant to a preprinted multiple check-off prescription blank."

18. Cal. Code of Regs. title 16 section 1735.2 states in pertinent part:

"(f) Where a pharmacy does not routinely compound a particular drug preparation, the master formula record for that preparation may be recorded on the prescription document itself.

…

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(i) Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding."

19. Cal. Code of Regs. title 16 section 1735.3 states in pertinent part:

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

…

(2) A compounding log consisting of a single document containing all of the following:

…

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply."

20. Cal. Code of Regs. title 16 section 1735.7 states:

"(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.

(b) The pharmacy shall develop and maintain an ongoing 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.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation."

21. Cal. Code of Regs. title 16 section 1735.8 states in pertinent part:

"(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 preparations.

…

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

22. Cal. Code of Regs. title 16 section 1761 subdivision (a) states:

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

HEALTH AND SAFETY CODE SECTIONS

23. Health and Safety Code section 111330 states that any drug or device is misbranded if its labeling is false or misleading in any particular.

24. Health and Safety Code section 111340 subdivision (b) states in pertinent part that any drug or device is misbranded unless it bears a label containing an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

FIRST CAUSE FOR DISCIPLINE

(Unlawfully Dispensing Prescription Medication)

25. Respondent Warner and Respondent Nadjavof are subject to disciplinary action pursuant to Bus. & Prof. Code § 4076(a)(8) in conjunction with Health and Safety Code sections 111330 and 111340(b) in that Respondents dispensed inadequately labeled prescriptions. Specifically, Respondents failed to accurately identify the quantity of the drug dispensed.

26. On or around March 26, 2015, while Respondent Nadjavof was employed as Pharmacist-in-Charge for Respondent Warner, an unidentified pharmacist verified Rx# 636526 for consumer CS[1] for Resveratrol 21gm, however, pharmacy records showed the quantity dispensed was Resveratrol 121gm.

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SECOND CAUSE FOR DISCIPLINE

[1] Initials are used here and throughout to protect consumer confidentiality.

(Unlawfully Deviating From Prescription Requirements)

27. Respondent Warner and Respondent Gajjar are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1716 in that Respondents deviated from the requirements of a prescription.

28. On or around July 24, 2015 while employed for Respondent Warner, Respondent Gajjar incorrectly dispensed Rx# 658026 (VC3 Stress Metabolic Capusle) to consumer DP. Rx# 658026 was a compounded product which contained magnesium glycinate 60mg and lipoic acid 200mg instead of the prescribed amount of magnesium glycinate 100mg and lipoic acid 150mg, respectively. Rx# 658026 also failed to contain vitamin A .65mg, as ordered.

THIRD CAUSE FOR DISCIPLINE

(Failure to Create a New Prescription for Drug Changes)

29. Respondent Warner, Respondent Merhi and Respondent Nadjavof are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1717(b)(4) in that Respondents failed to create a new prescription pursuant to a change in drug used, strength, prescriber or directions for use.

Respondent Warner

30. On or around May 1, 2015, unidentified pharmacist(s) dispensed Rx# 641735 to consumer CE, labeled as "Resveratrol 700mg powder, mix ½ tsp (=700mg) of powder, three times daily" and "Resveratrol 350mg/cap, empty contents of two capsules three times daily". However, computerized pharmacy records obtained on August 11, 2015 showed that the directions for Rx# 641735 was "mix ¼ tsp (=350mg) of powder in 8 oz. of water twice daily". Accordingly, there was a change in direction for consumer CE's use of Rx# 641735 however a new prescription was not created.

Respondent Merhi

31. During the time period between May 1, 2015 and May 20, 2015, while Respondent Merhi was employed as Pharmacist-in-Charge for Respondent Warner, an unidentified pharmacist(s) compounded Rx# 636940 for consumer JD. However, there was a discrepancy in

the documentation of the product dispensed. The April 2, 2015 compounding log linked to Rx# 636940 showed that the product compounded was Resveratrol 175mg capsule. However, the May 4, 2015 compounding log linked to Rx# 636940 showed that the product compounded was Resveratrol 350mg capsule. Accordingly, there was a change in the strength of the drug dispensed however a new prescription was not created.

Respondent Nadjavof

32. During the time period between March 1, 2015 and May 1, 2015 while Respondent was employed as Pharmacist-in-Charge for Respondent Warner, an unidentified pharmacist(s) dispensed Rx# 636914, labeled as Resveratrol 175mg POW to consumer AA. On April 6, 2015, Rx# 636914 was labeled as Resveratrol 350mg capsules. Accordingly, there was a change in the strength of the drug dispensed however a new prescription was not created.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Possess Prescription Filling Procedures)

33. Respondent Warner, Respondent Nadjavof, Respondent Merhi and Respondent Gajjar are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1717(f) in that Respondents failed to have written procedures that identify the pharmacist(s) responsible for filling prescriptions and a corresponding entry of information into an automated data processing system, or a manual record system.

34. Specifically, during the time period between March 26, 2015 and June 8, 2015, Respondents failed to maintain procedures identifying each individual pharmacist responsible for compounding the following prescriptions:

Respondent Nadjavof

- Rx# 636526, 3/26/15;
- Rx# 636914, 4/1/15 (Resveratrol 175mg capsule);
- Rx# 636914, 4/6/15 (Resveratrol 350mg capsule);
- Rx# 636940, compounded 4/2/15 (Resveratrol 175mg capsule);

- Rx# 640553, 4/24/15 (Resveratrol 350mg capsule; date made was 4/28/15 per compounding log.

Respondent Merhi

- Rx# 636940, compounded 5/4/15 (Resveratrol 350mg capsule);
- VITAC 5 BCCFMPV-RESV Caps, Lot# 05112015@2, compounded on 5/11/15.

Respondent Gajjar

- PAIN BGAN Cream, Lot# 06022015@10, compounded on 6/2/15;
- PAIN BGAN Cream, Lot# 06082015@1, compounded on 6/8/2015.

FIFTH CAUSE FOR DISCIPLINE

(Unlawfully Dispensing a Controlled Substance)

35. Respondent Warner is subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1717.3(a) in that Respondents dispensed a controlled substance pursuant to a preprinted multiple check-off prescription blank.

SIXTH CAUSE FOR DISCIPLINE

(Misbranded Drugs)

36. Respondents Warner, Respondent Merhi and Respondent Gajjar are subject to disciplinary action pursuant to Bus. & Prof. Code §4342(a) and Cal. Code of Regs. title 16 § 1735.2(f) in conjunction with Health and Safety Code §§ 111330 and 111340(b) in that Respondent failed to properly record the master formula.

Respondent Merhi

37. On or around May 11, 2015 while employed as Pharmacist-in-Charge for Respondent Warner, an unidentified staff pharmacist compounded VITAC 5 BCCFMPV-RESV CAPS (Lot# 05112015@2) containing Resveratrol and other active ingredients, including biotin 2mg. However, the container fro compounded product PCCFMPV-RESV CAPS (Lot# 05112015@2) was labeled as containing Resveratrol and other active ingredients, including biotin 1.5mg. The

pharmacist did not ensure the compounded product contained the accurate content and quantity of biotin as labeled.

Respondent Gajjar

38. On or around July 29, 2015 while Respondent Gajjar was employed as Pharmacist-in-Charge for Respondent Warner, a laboratory report from Eagle Analytical Services revealed that BGAN Cream (Lot# 06082015) was subpotent. Compounding logs revealed that the pharmacy dispensed Rx# 649149, consisting of subpotent BGAN Cream (Lot# 06082015) to consumer LJ on June 2, 2015. The compounded product dispensed did not contain an accurate amount of baclofen 2%, gabapentin 6%, amitriptyline 3%, and nifedipine 2% as ordered.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Properly Store Components of Compounded Drugs)

39. Respondent Warner, Respondent Merhi, and Respondent Gajjar are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1735.2(h) in that Respondents failed to properly store chemicals, bulk drug substances, drug products and other components used for drug compounding according to requirements provided to maintain their integrity, potency, quality and labeled strength as follows:

Respondent Merhi

40. On or around May 11, 2015 while Respondent Merhi was employed as Pharmacist-in-Charge for Respondent Warner, unidentified pharmacist(s) compounded VITAC 5 BCCFMPV-RESV CAPS (Lot# 05112015@2). The beyond use date on the container label was November 14, 2015, a date exceeding 180 days from the compounding date of May 11, 2015.

Respondent Gajjar

41. On or around June 8, 2015, while Respondent Gajjar was employed as Pharmacist-in-Charge for Respondent Warner, an unidentified pharmacist(s) compounded Multivita-Resv capsule (Lot# 06082015@12). The beyond use date identified on the container label was "15/5/2015", an invalid date.

42. On or around June 15, 2015, an unidentified pharmacist(s) compounded Resveratrol 350mg capsule (Lot# 06152015@7). The beyond use date on the label exceeded the beyond use date identified on the compounding log.

EIGHTH CAUSE FOR DISCIPLINE

(Inadequate "Beyond Use" Date Labeling)

43. Respondent Warner and Respondent Nadjavof are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1735.2(i) in that Respondents failed to properly provide a "beyond use" date representing the date and/or time beyond which the compounded drug should not be used, stored, transported or administered based on the professional judgment of the pharmacist performing or supervising the compounding as follows:

Respondent Warner, Respondent Nadjavof

44. On or around March 26, 2015, while Respondent Nadjavof was employed as Pharmacist-in-Charge for Respondent Warner, an unidentified pharmacist(s) verified consumer CS' Rx# 636526, however, there was a discrepancy in the documentation of the product. Specifically, the stickered label on the back of the prescription document identified the dispensed product as "CVIT1 RESVERATROL 175mg POW" however, the Rx Linked to a Log document identified the product as "Resveratrol 175mg capsule".

45. The Drug Utilization Report (DUR) document for RX# 636914 was "Resveratrol 350mg*POW". The label reprint indicated the product was "VITAP2 Resveratrol POW".

46. On or around April 24, 2015, unidentified pharmacist(s) verified consumer ML's Rx# 640553, however, there was a discrepancy in the documentation of the product. Specifically, the stickered label on the back of the prescription document identified the dispensed product as "CVIT1 RESVERATROL 175mg POW" however, the Rx Log document identified the product as "Resveratrol 175mg capsule". In addition, the April 28, 2015 compounding log indicated the product dispensed was "Resveratrol 350mg capsule, however, the Drug Utilization Report (DUR) document for RX# 640533 was "Resveratrol 350mg*POW".

NINTH CAUSE FOR DISCIPLINE

(Inadequate Compounded Drug Logs)

47. Respondent Warner, Respondent Nadjavof and Respondent Gajjar are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1735.3(a)(2)(F) in that Respondents failed to properly maintain records of compounded drug logs providing the name of the manufacturer (or supplier), expiration date and lot number of each compounded drug component.

Respondent Nadjavof

48. On or around April 2, 2015, while Respondent Nadjavof was employed as Pharmacist-in-Charge for Respondent Warner, an unidentified pharmacist(s) compounded Resveratrol 175mg capsule (Lot# 04022015) and dispensed Rx# 636940 to consumer JD. However, the compound log showed there was no lot number and expiration date for microcrystalline used in compounding the dispensed product.

Respondent Gajjar

49. On or around June 2, 2015, while Respondent Gajjar was employed as Pharmacist-in-Charge for Respondent Warner, an unidentified pharmacist(s) compounded BGAN Cream (Lot# 06022015@10) and dispensed Rx# 643177 to consumer RB. However, the compound log showed there was no lot number or expiration date for the propylene glycol used to compound the dispensed product.

50. On or around June 15, 2015, an unidentified pharmacist(s) compounded Resveratrol 350mg capules (Lot# 06152015@7). However, the compound log showed there was no expiration date for the Resveratrol used to compound the product.

TENTH CAUSE FOR DISCIPLINE

(Failure to Document Compounded Drug Personnel Skills and Training)

51. Respondent Gajjar is subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1735.7(a)-(c) in that Respondent failed to properly demonstrate the skills and training possessed by compounded drug personnel.

52. On or around August 11, 2015 while Respondent Gajjar was employed as Pharmacist-in-Charge for Respondent Warner, an inspection revealed that Respondent Warner did not have written documentation indicating the technicians had the skills and training required to properly and accurately perform their assigned tasks related to compounding. In addition, Respondent Gajjar failed to develop or maintain an ongoing competency evaluation process for pharmacy personnel and staff involved in compounding prior to August 11, 2015.

ELEVENTH CAUSE FOR DISCIPLINE

(Inadequate Quality Assurance Plan)

53. Respondent Warner and Respondent Gajjar are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1735.8(a) and (d) in that Respondents failed to maintain a written quality assurance plan designed to monitor and ensure the integrity, potency, quality and strength of compounded drugs.

54. On or around July 29, 2015 while Respondent Gajjar was employed as Pharmacist-in-Charge for Respondent Warner, a laboratory report from Eagle Analytical Services revealed that BGAN Cream (Lot# 06082015) was subpotent. Compounding logs revealed that the pharmacy dispensed Rx# 649149, consisting of subpotent BGAN Cream (Lot# 06082015) to consumer LJ on June 2, 2015. The Respondents' subpotent/superpotent compounded policy stated that in the event a laboratory test result indicated a deviation of 10 percent or more from the labeled potency, the pharmacy shall institute a recall of the products dispensed. Respondents did not follow written quality assurance and institute a recall for prescriptions dispensed to LJ, per its policy.

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TWELFTH CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

55. Respondent Warner and Respondent Nadjavof are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1761(a) in conjunction with Health and Safety Code sections 111330 and 111340(b) that Respondents dispensed prescriptions containing errors, omissions or irregularities and failed to contact the prescriber to validate them.

56. Specifically, on or around April 1, 2015 and April 6, 2015 Respondents dispensed Rx# 636914 to AA dated 4/1/15 (Resveratrol 175mg Pow) and 4/6/15 (Resveratrol 350mg Pow), two different products, with different directions and dosages pursuant to an incomplete, uncertain and ambiguous prescription document. The prescription document did not specify a quantity and the dosage was for two (2) scoops twice daily. The directions on the prescription labels were for capsules. There was no indication or a reference to connect the capsules (as dispensed) to scoops (as ordered). Respondents did not contact the prescriber to obtain the information needed to verify the prescription prior to dispensing to AA.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Dangerous Drugs)

57. Respondent Warner is subject to disciplinary action pursuant to Bus. & Prof. Code § 4105(a) in that it failed to retain records of dangerous drugs on licensed premises. Specifically, during the time period between 9/8/15 and 8/26/16, Respondent stored records of acquisition and disposition of dangerous drugs (Resveratrol) at an unlicensed location "where [Respondent Warner] used to conduct business."

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Keep Records of Dangerous Drugs Open for Inspection)

58. Respondent Warner is subject to disciplinary action pursuant to Bus. & Prof. Code § 4081(a) in that it failed to keep open for inspection, all records of manufacture, sale, acquisition and disposition of dangerous drugs, by authorized officers of the law. Specifically, on 9/9/16 and

12/19/17, Respondent Warner did not produce, vis-à-vis The Pharmacy Depot[2], all records of acquisition and disposition for the following prescriptions for inspection:

Prescription Number	Date Filled	NDC Label Name	Name of Prescriber
637383	3/24/15	Resveratrol Pow	K.S.
638562	4/13/15	Resveratrol Pow	A.E.
639132	4/16/15	Compound	N.G.
640249	4/23/15	Compound	K.S.
646069	5/15/15	Compound	N.G.

FIFTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

59. Respondent Merhi and Respondent Nadjafov are subject to disciplinary action pursuant to Bus. & Prof. Code § 4301(f) in that Respondents committed acts constituting unprofessional conduct.

Respondent Merhi

60. Specifically, on 5/17/15, while Respondent Merhi was the Pharmacist-in-Charge of Respondent Warner from 3/1/15 until 5/20/15, Respondent Warner processed and dispensed Resveratrol prescription Rx#636624 for patient P.Y. Investigation revealed that Rx#636624 was not prescribed by T.L, the listed physician. P.Y's insurer paid $14,862.06 for the unlawful prescription.

Respondent Nadjavof

61. Specifically, on 3/27/15 and 4/23/15, while Respondent Nadjafov was the Pharmacist-in-Charge of Respondent Warner, from 3/1/15 until 5/1/15, Respondent Warner processed and dispensed Resveratrol prescription Rx#636624 for patient P.Y. Investigation revealed that Rx#636624 was not prescribed by T.L., the listed physician. P.Y.'s insurer paid $14,862.06 per each unlawful prescription processed on each day.

[2] The Pharmacy Depot, located at 4948B Pico Blvd., Los Angeles, CA 90019

62. Specifically, on 4/22/15, while Respondent Nadjafov was the Pharmacist-in-Charge of Respondent Warner, from 3/1/15 until 5/1/15, Respondent Warner processed and dispensed Resveratrol prescription Rx#648271 for patient A.K. Investigation revealed that Rx#636624 was not prescribed by T.L., the listed physician. A.K.'s insurer paid $44,824.61 for the prescription.

DISCIPLINARY CONSIDERATIONS

63. On or around August 26, 2011 during an inspection of Santa Anita Prescription Compound Respondent Gajjar was found to be in violation of the following:

- Bus. and Prof. Code § 4081 – Failure to Maintain Records of Dangerous Drugs
- Bus. and Prof. Code § 4342 – Drugs Lacking Quality and Strength
- Bus. and Prof. Code § 4169(a)(3) – Misbranded Drugs
- Cal. Code of Regs. title 16 § 1735.3(a) – Improper Records of Compounded Drug Products
- Cal. Code of Regs. title 16 § 1735.5(a) – Failure to Maintain Compounding Policies and Procedures

64. On or around January 26, 2012, Respondent Gajjar was issued an Order of Abatement and Citation and Fine in Case No. CI 2011 50910. The citation amount of $4,250 was paid in full.

OTHER MATTERS

65. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 49208 issued to Saybian Enterprises Inc. dba Warner West Pharmacy & Supply, then Saybian Enterprises Inc. dba Warner West Pharmacy & Supply shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49208 is placed on probation or until Pharmacy Permit Number PHY 49208 is reinstated if it is revoked.

66. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 49208 issued to Saybian Enterprises Inc. dba Warner West Pharmacy & Supply, Pharmacy while Camill Sayadeh was an officer and owner and had knowledge of or knowingly

participated in any conduct for which the licensee was disciplined, Camill Sayadah shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49208 is placed on probation or until Pharmacy Permit Number PHY 49208 is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Original Pharmacy Permit Number PHY 49208, issued to Saybian Enterprises Inc. dba Warner West Pharmacy & Supply, Camill Sayadeh;

2. Revoking or suspending Pharmacy License No. RPH 71122, issued to Askar Nadjavof;

3. Revoking or suspending Pharmacy License No. RPH 72499, issued to Ayoub Merhi;

4. Revoking or suspending Pharmacy License No. RPH 41722, issued to Harshad H. Gajjar;

5. Prohibiting Saybian Enterprises Inc. dba Warner West Pharmacy & Supply from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49208 is placed on probation or until Pharmacy Permit Number PHY 49208 is reinstated if Pharmacy Permit Number PHY 49208 issued to Saybian Enterprises Inc. dba Warner West Pharmacy & Supply is revoked;

6. Prohibiting Camill Sayadeh from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49208 is placed on probation or until Pharmacy Permit Number PHY 49208 is reinstated if Pharmacy Permit Number 49208 issued to Saybian Enterprises Inc. dba Warner West Pharmacy & Supply is revoked;

7. Ordering Saybian Enterprises Inc. dba Warner West Pharmacy & Supply, Askar Nadjavof, Ayoub Merhi, and Harshad H. Gajjar to pay the Board of Pharmacy the reasonable

costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: April 12, 2018

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

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

In the Matter of the Accusation Against: **SAYBIAN ENTERPRISES INC. DBA WARNER WEST PHARMACY & SUPPLY, CAMILL SAYADEH** **22030 Sherman Way, #100** **Canoga Park, CA 91303** **Pharmacy Permit No. PHY 49208** **ASKAR NADJAVOF** **4601 Willis Ave., Apt. 208** **Sherman Oaks, CA 91403** **Pharmacist License No. RPH 71122** **AYOUB MERHI** **20921 Community St., Unit 9** **Canoga Park, CA 91304** **Pharmacist License No. RPH 72499** and **HARSHAD H. GAJJAR** **20608 Vercelli Way** **Porter Ranch, CA 91326** **Pharmacist License No. RPH 41722** Respondents.	Case No. 5866 **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.

Warner West Pharmacy & Supplies

2. On or about April 17, 2009, the Board of Pharmacy (Board) issued Original Pharmacy Permit Number PHY 49208 to Saybian Enterprises Inc. dba Warner West Pharmacy & Supply, Camill Sayadeh (Respondent Warner). The Original Pharmacy Permit expired on October 14, 2015, and has not been renewed.

Askar Nadjavof

3. On or about August 26, 2014, the Board issued Pharmacy License No. RPH 71122 to Askar Nadjavof (Respondent Nadjavof). RPH No. 71122 was in full force and effect at all times relevant to the Accusation and will expire on April 30, 2018, unless renewed. During the time period between March 1, 2015 to May 1, 2015, Respondent Nadjavof was employed as the Pharmacist-in-Charge at Warner West Pharmacy & Supplies.

Ayoub Merhi

4. On or about March 25, 2015, the Board issued Pharmacy License No. RPH 72499 to Ayoub Merhi (Respondent Merhi). RPH No. 72499 was in full force and effect at all times relevant to the Accusation and will expire on October 31, 2018, unless renewed. During the time period between May 1, 2015 to May 20, 2015, Respondent Merhi was employed as the Pharmacist-in-Charge at Warner West Pharmacy & Supplies.

Harshad H. Gajjar

5. On or about April 23, 1988, the Board issued Pharmacy License No. RPH 41722 to Harshad H. Gajjar (Respondent Gajjar). RPH No. 41722 was in full force and effect at all times relevant to the Accusation and will expire on December 31, 2017, unless renewed. During the time period between May 20, 2015 to October 14, 2015, Respondent Gajjar was employed as the Pharmacist-in-Charge at Warner West Pharmacy & Supplies.

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JURISDICTION

6. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

7. Section 118, subdivision (b), provides in pertinent part that the suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.

8. Section 4300 states, in pertinent part:

"(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper."

9. Section 4307 subdivision (a) states, in pertinent part:

Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, or partner or any partnership, corporation, firm, or association whose application for a license has been denied or

revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manger, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

10. Section 4342 subdivision (a) states that "[t]he board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

STATUTORY AND REGULATORY PROVISIONS

11. Section 4076 subdivision (a)(8) states in pertinent part:

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

(8) The quantity of the drug or drugs dispensed."

12. Cal. Code of Regs. title 16 section 1716 states that "[p]harmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code. Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription."

13. Cal. Code of Regs. title 16 section 1717 states in pertinent part:

"(b) In addition to the requirements of Business and Professions Code Section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

...

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

...

(f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years."

14. Cal. Code of Regs. title 16 section 1717.3 subdivision (a) states that "no person shall dispense a controlled substance pursuant to a preprinted multiple check-off prescription blank."

15. Cal. Code of Regs. title 16 section 1735.2 states in pertinent part:

"(f) Where a pharmacy does not routinely compound a particular drug preparation, the master formula record for that preparation may be recorded on the prescription document itself.

...

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(i) Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

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16. Cal. Code of Regs. title 16 section 1735.3 states in pertinent part:

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

...

(2) A compounding log consisting of a single document containing all of the following:

...

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply."

17. Cal. Code of Regs. title 16 section 1735.7 states:

"(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.

(b) The pharmacy shall develop and maintain an ongoing 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.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation."

18. Cal. Code of Regs. title 16 section 1735.8 states in pertinent part:

"(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 preparations.

...

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

19. Cal. Code of Regs. title 16 section 1761 subdivision (a) states:

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

HEALTH AND SAFETY CODE SECTIONS

20. Health and Safety Code section 111330 states that any drug or device is misbranded if its labeling is false or misleading in any particular.

21. Health and Safety Code section 111340 subdivision (b) states in pertinent part that any drug or device is misbranded unless it bears a label containing an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

FIRST CAUSE FOR DISCIPLINE

(Unlawfully Dispensing Prescription Medication)

22. Respondent Warner and Respondent Nadjavof are subject to disciplinary action pursuant to Bus. & Prof. Code § 4076(a)(8) in conjunction with Health and Safety Code sections 111330 and 111340(b) in that Respondents dispensed inadequately labeled prescriptions. Specifically, Respondents failed to accurately identify the quantity of the drug dispensed.

23. On or around March 26, 2015, while Respondent Nadjavof was employed as Pharmacist-in-Charge for Respondent Warner, an unidentified pharmacist verified Rx# 636526

for consumer CS[1] for Resveratrol 21gm, however, pharmacy records showed the quantity dispensed was Resveratrol 121gm.

SECOND CAUSE FOR DISCIPLINE

(Unlawfully Deviating From Prescription Requirements)

24. Respondent Warner and Respondent Gajjar are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1716 in that Respondents deviated from the requirements of a prescription.

25. On or around July 24, 2015 while employed for Respondent Warner, Respondent Gajjar incorrectly dispensed Rx# 658026 (VC3 Stress Metabolic Capusle) to consumer DP. Rx# 658026 was a compounded product which contained magnesium glycinate 60mg and lipoic acid 200mg instead of the prescribed amount of magnesium glycinate 100mg and lipoic acid 150mg, respectively. Rx# 658026 also failed to contain vitamin A .65mg, as ordered.

THIRD CAUSE FOR DISCIPLINE

(Failure to Create a New Prescription for Drug Changes)

26. Respondent Warner, Respondent Merhi and Respondent Nadjavof are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1717(b)(4) in that Respondents failed to create a new prescription pursuant to a change in drug used, strength, prescriber or directions for use.

Respondent Warner

27. On or around May 1, 2015, unidentified pharmacist(s) dispensed Rx# 641735 to consumer CE, labeled as "Resveratrol 700mg powder, mix ½ tsp (=700mg) of powder, three times daily" and "Resveratrol 350mg/cap, empty contents of two capsules three times daily". However, computerized pharmacy records obtained on August 11, 2015 showed that the directions for Rx# 641735 was "mix ¼ tsp (=350mg) of powder in 8 oz. of water twice daily".

[1] Initials are used here and throughout to protect consumer confidentiality.

Accordingly, there was a change in direction for consumer CE's use of Rx# 641735 however a new prescription was not created.

Respondent Merhi

28. During the time period between May 1, 2015 and May 20, 2015, while Respondent Merhi was employed as Pharmacist-in-Charge for Respondent Warner, an unidentified pharmacist(s) compounded Rx# 636940 for consumer JD. However, there was a discrepancy in the documentation of the product dispensed. The April 2, 2015 compounding log linked to Rx# 636940 showed that the product compounded was Resveratrol 175mg capsule. However, the May 4, 2015 compounding log linked to Rx# 636940 showed that the product compounded was Resveratrol 350mg capsule. Accordingly, there was a change in the strength of the drug dispensed however a new prescription was not created.

Respondent Nadjavof

29. During the time period between March 1, 2015 and May 1, 2015 while Respondent was employed as Pharmacist-in-Charge for Respondent Warner, an unidentified pharmacist(s) dispensed Rx# 636914, labeled as Resveratrol 175mg POW to consumer AA. On April 6, 2015, Rx# 636914 was labeled as Resveratrol 350mg capsules. Accordingly, there was a change in the strength of the drug dispensed however a new prescription was not created.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Possess Prescription Filling Procedures)

30. Respondent Warner, Respondent Nadjavof, Respondent Merhi and Respondent Gajjar are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1717(f) in that Respondents failed to have written procedures that identify the pharmacist(s) responsible for filling prescriptions and a corresponding entry of information into an automated data processing system, or a manual record system.

31. Specifically, during the time period between March 26, 2015 and June 8, 2015, Respondents failed to maintain procedures identifying each individual pharmacist responsible for compounding the following prescriptions:

Respondent Nadjavof

- Rx# 636526, 3/26/15;
- Rx# 636914, 4/1/15 (Resveratrol 175mg capsule);
- Rx# 636914, 4/6/15 (Resveratrol 350mg capsule);
- Rx# 636940, compounded 4/2/15 (Resveratrol 175mg capsule);
- Rx# 640553, 4/24/15 (Resveratrol 350mg capsule; date made was 4/28/15 per compounding log.

Respondent Merhi

- Rx# 636940, compounded 5/4/15 (Resveratrol 350mg capsule);
- VITAC 5 BCCFMPV-RESV Caps, Lot# 05112015@2, compounded on 5/11/15.

Respondent Gajjar

- PAIN BGAN Cream, Lot# 06022015@10, compounded on 6/2/15;
- PAIN BGAN Cream, Lot# 06082015@1, compounded on 6/8/2015.

FIFTH CAUSE FOR DISCIPLINE

(Unlawfully Dispensing a Controlled Substance)

32. Respondent Warner is subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1717.3(a) in that Respondents dispensed a controlled substance pursuant to a preprinted multiple check-off prescription blank.

SIXTH CAUSE FOR DISCIPLINE

(Misbranded Drugs)

33. Respondents Warner, Respondent Merhi and Respondent Gajjar are subject to disciplinary action pursuant to Bus. & Prof. Code §4342(a) and Cal. Code of Regs. title 16 § 1735.2(f) in conjunction with Health and Safety Code §§ 111330 and 111340(b) in that Respondent failed to properly record the master formula.

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Respondent Merhi

34. On or around May 11, 2015 while employed as Pharmacist-in-Charge for Respondent Warner, an unidentified staff pharmacist compounded VITAC 5 BCCFMPV-RESV CAPS (Lot# 05112015@2) containing Resveratrol and other active ingredients, including biotin 2mg. However, the container fro compounded product PCCFMPV-RESV CAPS (Lot# 05112015@2) was labeled as containing Resveratrol and other active ingredients, including biotin 1.5mg. The pharmacist did not ensure the compounded product contained the accurate content and quantity of biotin as labeled.

Respondent Gajjar

35. On or around July 29, 2015 while Respondent Gajjar was employed as Pharmacist-in-Charge for Respondent Warner, a laboratory report from Eagle Analytical Services revealed that BGAN Cream (Lot# 06082015) was subpotent. Compounding logs revealed that the pharmacy dispensed Rx# 649149, consisting of subpotent BGAN Cream (Lot# 06082015) to consumer LJ on June 2, 2015. The compounded product dispensed did not contain an accurate amount of baclofen 2%, gabapentin 6%, amitriptyline 3%, and nifedipine 2% as ordered.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Properly Store Components of Compounded Drugs)

36. Respondent Warner, Respondent Merhi, and Respondent Gajjar are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1735.2(h) in that Respondents failed to properly store chemicals, bulk drug substances, drug products and other components used for drug compounding according to requirements provided to maintain their integrity, potency, quality and labeled strength as follows:

Respondent Merhi

37. On or around May 11, 2015 while Respondent Merhi was employed as Pharmacist-in-Charge for Respondent Warner, unidentified pharmacist(s) compounded VITAC 5 BCCFMPV-RESV CAPS (Lot# 05112015@2). The beyond use date on the container label was November 14, 2015, a date exceeding 180 days from the compounding date of May 11, 2015.

Respondent Gajjar

38. On or around June 8, 2015, while Respondent Gajjar was employed as Pharmacist-in-Charge for Respondent Warner, an unidentified pharmacist(s) compounded Multivita-Resv capsule (Lot# 06082015@12). The beyond use date identified on the container label was "15/5/2015", an invalid date.

39. On or around June 15, 2015, an unidentified pharmacist(s) compounded Resveratrol 350mg capsule (Lot# 06152015@7). The beyond use date on the label exceeded the beyond use date identified on the compounding log.

EIGHTH CAUSE FOR DISCIPLINE

(Inadequate "Beyond Use" Date Labeling)

40. Respondent Warner and Respondent Nadjavof are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1735.2(i) in that Respondents failed to properly provide a "beyond use" date representing the date and/or time beyond which the compounded drug should not be used, stored, transported or administered based on the professional judgment of the pharmacist performing or supervising the compounding as follows:

Respondent Warner, Respondent Nadjavof

41. On or around March 26, 2015, while Respondent Nadjavof was employed as Pharmacist-in-Charge for Respondent Warner, an unidentified pharmacist(s) verified consumer CS' Rx# 636526, however, there was a discrepancy in the documentation of the product. Specifically, the stickered label on the back of the prescription document identified the dispensed product as "CVIT1 RESVERATROL 175mg POW" however, the Rx Linked to a Log document identified the product as "Resveratrol 175mg capsule".

42. The Drug Utilization Report (DUR) document for RX# 636914 was "Resveratrol 350mg*POW". The label reprint indicated the product was "VITAP2 Resveratrol POW".

43. On or around April 24, 2015, unidentified pharmacist(s) verified consumer ML's Rx# 640553, however, there was a discrepancy in the documentation of the product. Specifically, the stickered label on the back of the prescription document identified the dispensed product as

"CVIT1 RESVERATROL 175mg POW" however, the Rx Log document identified the product as "Resveratrol 175mg capsule". In addition, the April 28, 2015 compounding log indicated the product dispensed was "Resveratrol 350mg capsule, however, the Drug Utilization Report (DUR) document for RX# 640533 was "Resveratrol 350mg*POW".

NINTH CAUSE FOR DISCIPLINE

(Inadequate Compounded Drug Logs)

44. Respondent Warner, Respondent Nadjavof and Respondent Gajjar are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1735.3(a)(2)(F) in that Respondents failed to properly maintain records of compounded drug logs providing the name of the manufacturer (or supplier), expiration date and lot number of each compounded drug component.

Respondent Nadjavof

45. On or around April 2, 2015, while Respondent Nadjavof was employed as Pharmacist-in-Charge for Respondent Warner, an unidentified pharmacist(s) compounded Resveratrol 175mg capsule (Lot# 04022015) and dispensed Rx# 636940 to consumer JD. However, the compound log showed there was no lot number and expiration date for microcrystalline used in compounding the dispensed product.

Respondent Gajjar

46. On or around June 2, 2015, while Respondent Gajjar was employed as Pharmacist-in-Charge for Respondent Warner, an unidentified pharmacist(s) compounded BGAN Cream (Lot# 06022015@10) and dispensed Rx# 643177 to consumer RB. However, the compound log showed there was no lot number or expiration date for the propylene glycol used to compound the dispensed product.

47. On or around June 15, 2015, an unidentified pharmacist(s) compounded Resveratrol 350mg capules (Lot# 06152015@7). However, the compound log showed there was no expiration date for the Resveratrol used to compound the product.

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TENTH CAUSE FOR DISCIPLINE

(Failure to Document Compounded Drug Personnel Skills and Training)

48. Respondent Gajjar is subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1735.7(a)-(c) in that Respondent failed to properly demonstrate the skills and training possessed by compounded drug personnel.

49. On or around August 11, 2015 while Respondent Gajjar was employed as Pharmacist-in-Charge for Respondent Warner, an inspection revealed that Respondent Warner did not have written documentation indicating the technicians had the skills and training required to properly and accurately perform their assigned tasks related to compounding. In addition, Respondent Gajjar failed to develop or maintain an ongoing competency evaluation process for pharmacy personnel and staff involved in compounding prior to August 11, 2015.

ELEVENTH CAUSE FOR DISCIPLINE

(Inadequate Quality Assurance Plan)

50. Respondent Warner and Respondent Gajjar are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1735.8(a) and (d) in that Respondents failed to maintain a written quality assurance plan designed to monitor and ensure the integrity, potency, quality and strength of compounded drugs.

51. On or around July 29, 2015 while Respondent Gajjar was employed as Pharmacist-in-Charge for Respondent Warner, a laboratory report from Eagle Analytical Services revealed that BGAN Cream (Lot# 06082015) was subpotent. Compounding logs revealed that the pharmacy dispensed Rx# 649149, consisting of subpotent BGAN Cream (Lot# 06082015) to consumer LJ on June 2, 2015. The Respondents' subpotent/superpotent compounded policy stated that in the event a laboratory test result indicated a deviation of 10 percent or more from the labeled potency, the pharmacy shall institute a recall of the products dispensed. Respondents did not follow written quality assurance and institute a recall for prescriptions dispensed to LJ, per its policy.

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TWELFTH CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

52. Respondent Warner and Respondent Nadjavof are subject to disciplinary action pursuant to Cal. Code of Regs. title 16 § 1761(a) in conjunction with Health and Safety Code sections 111330 and 111340(b) that Respondents dispensed prescriptions containing errors, omissions or irregularities and failed to contact the prescriber to validate them.

53. Specifically, on or around April 1, 2015 and April 6, 2015 Respondents dispensed Rx# 636914 to AA dated 4/1/15 (Resveratrol 175mg Pow) and 4/6/15 (Resveratrol 350mg Pow), two different products, with different directions and dosages pursuant to an incomplete, uncertain and ambiguous prescription document. The prescription document did not specify a quantity and the dosage was for two (2) scoops twice daily. The directions on the prescription labels were for capsules. There was no indication or a reference to connect the capsules (as dispensed) to scoops (as ordered). Respondents did not contact the prescriber to obtain the information needed to verify the prescription prior to dispensing to AA.

DISCIPLINARY CONSIDERATIONS

54. On or around August 26, 2011 during an inspection of Santa Anita Prescription Compound Respondent Gajjar was found to be in violation of the following:

- Bus. and Prof. Code § 4081 – Failure to Maintain Records of Dangerous Drugs
- Bus. and Prof. Code § 4342 – Drugs Lacking Quality and Strength
- Bus. and Prof. Code § 4169(a)(3) – Misbranded Drugs
- Cal. Code of Regs. title 16 § 1735.3(a) – Improper Records of Compounded Drug Products
- Cal. Code of Regs. title 16 § 1735.5(a) – Failure to Maintain Compounding Policies and Procedures

55. On or around January 26, 2012, Respondent Gajjar was issued an Order of Abatement and Citation and Fine in Case No. CI 2011 50910. The citation amount of $4,250 was paid in full.

OTHER MATTERS

56. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 49208 issued to Saybian Enterprises Inc. dba Warner West Pharmacy & Supply, then Saybian Enterprises Inc. dba Warner West Pharmacy & Supply shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49208 is placed on probation or until Pharmacy Permit Number PHY 49208 is reinstated if it is revoked.

57. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 49208 issued to Saybian Enterprises Inc. dba Warner West Pharmacy & Supply, Pharmacy while Camill Sayadeh was an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Camill Sayadah shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49208 is placed on probation or until Pharmacy Permit Number PHY 49208 is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Original Pharmacy Permit Number PHY 49208, issued to Saybian Enterprises Inc. dba Warner West Pharmacy & Supply, Camill Sayadeh;

2. Revoking or suspending Pharmacy License No. RPH 71122, issued to Askar Nadjavof;

3. Revoking or suspending Pharmacy License No. RPH 72499, issued to Ayoub Merhi;

4. Revoking or suspending Pharmacy License No. RPH 41722, issued to Harshad H. Gajjar;

5. Prohibiting Saybian Enterprises Inc. dba Warner West Pharmacy & Supply from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49208 is placed on probation or until

Pharmacy Permit Number PHY 49208 is reinstated if Pharmacy Permit Number PHY 49208 issued to Saybian Enterprises Inc. dba Warner West Pharmacy & Supply is revoked;

6. Prohibiting Camill Sayadeh from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49208 is placed on probation or until Pharmacy Permit Number PHY 49208 is reinstated if Pharmacy Permit Number 49208 issued to Saybian Enterprises Inc. dba Warner West Pharmacy & Supply is revoked;

7. Ordering Saybian Enterprises Inc. dba Warner West Pharmacy & Supply, Askar Nadjavof, Ayoub Merhi, and Harshad H. Gajjar to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 7/10/17

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

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