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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:

Case No. 5866

OAH No. 2017100704

DEFAULT DECISION AND ORDER

**SAYBIAN ENTERPRISES INC. DBA
WARNER WEST PHARMACY &
SUPPLY, CAMILL SAYADEH
22030 Sherman Way, #100
Canoga Park, CA 91303**

[Gov. Code, §11520]

Original Pharmacy Permit No. PHY 49208

Respondents.

FINDINGS OF FACT

1. On or about July 10, 2017, Complainant Virginia Herold, in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs, filed Accusation No. 5866 against Saybian Enterprises Inc. dba Warner West Pharmacy & Supply, Camill Sayadeh (Respondent) before the Board of Pharmacy. (Accusation attached as Exhibit A.)

1 2. On or about April 17, 2009, the Board of Pharmacy (Board) issued Original
2 Pharmacy Permit No. PHY 49208 to Respondent. The Original Pharmacy Permit expired on
3 September 8, 2015, and has not been renewed.

4 3. On or about August 1, 2017, Respondent was served by Certified and First Class Mail
5 copies of the Accusation No. 5866, Statement to Respondent, Notice of Defense, Request for
6 Discovery, Discovery Statutes (Government Code sections 11507.5, 11507.6, and 11507.7), and
7 Notice of Hearing at Respondent's address of record which, pursuant to Business and Professions
8 Code section 4100, is required to be reported and maintained with the Board. Respondent's
9 address of record was and is: 22030 Sherman Way, #100, Canoga Park, CA 91303.

10 4. On or about April 12, 2018, Complainant Virginia Herold, in her official capacity as
11 the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs, filed First
12 Amended Accusation No. 5866 against Saybian Enterprises Inc. dba Warner West Pharmacy &
13 Supply, Camill Sayadeh (Respondent) before the Board of Pharmacy. (First Amended
14 Accusation attached as Exhibit B.)

15 5. On or about April 13, 2018, Respondent was served by Certified and First Class Mail
16 copies of the First Amended Accusation No. 5866, Supplemental Statement to Respondent,
17 Notice of Defense, Request for Discovery, Discovery Statutes (Government Code sections
18 11507.5, 11507.6, and 11507.7), and Notice of Hearing at Respondent's address of record which,
19 pursuant to Business and Professions Code section 4100, is required to be reported and
20 maintained with the Board. Respondent's address of record was and is: 22030 Sherman Way,
21 #100, Canoga Park, CA 91303.

22 6. Government Code section 11506(c) states, in pertinent part:

23 (c) The respondent shall be entitled to a hearing on the merits if the respondent
24 files a notice of defense . . . and the notice shall be deemed a specific denial of all
25 parts of the accusation . . . not expressly admitted. Failure to file a notice of defense
26 . . . shall constitute a waiver of respondent's right to a hearing, but the agency in its
27 discretion may nevertheless grant a hearing.

28 7. The Board takes official notice of its records and the fact that Respondent failed to
file a Notice of Defense within 15 days after service upon them of the Accusation and First

1 Amended, and therefore waived their right to a hearing on the merits of Accusation and First
2 Amended Accusation No. 5866.

3 8. California Government Code section 11520(a) states, in pertinent part:

4 (a) If the respondent either fails to file a notice of defense . . . or to appear at
5 the hearing, the agency may take action based upon the respondent's express
6 admissions or upon other evidence and affidavits may be used as evidence without
any notice to respondent

7 9. Pursuant to its authority under Government Code section 11520, the Board finds
8 Respondent is in default. The Board will take action without further hearing and, based on the
9 relevant evidence contained in the Default Decision Evidence Packet in this matter, as well as
10 taking official notice of all the investigatory reports, exhibits and statements contained therein on
11 file at the Board's offices regarding the allegations contained in Accusation and First Amended
12 Accusation No. 5866, finds that the charges and allegations in Accusation and First Amended
13 Accusation No. 5866, are separately and severally, found to be true and correct by clear and
14 convincing evidence.

15
16 **DETERMINATION OF ISSUES**

17 1. Based on the foregoing findings of fact, Respondent Saybian Enterprises Inc. dba
18 Warner West Pharmacy & Supply, Camill Sayadeh has subjected its Original Pharmacy Permit
19 No. PHY 49208 to discipline.

20 2. The agency has jurisdiction to adjudicate this case by default.

21 3. The Board of Pharmacy is authorized to revoke Respondent's Original Pharmacy
22 Permit based upon the following violations alleged in the Accusation which are supported by the
23 evidence contained in the Default Decision Evidence Packet in this case:

24 a. Unlawfully Dispensing Prescription Medication [Bus. & Prof. Code § 4076(a)(8)];

25 b. Unlawfully Deviating From Prescription Requirements [Cal. Code of Regs. title 16 §
26 1716];

27 c. Failure to Create a New Prescription for Drug Changes [Cal. Code of Regs. title 16 §
28 1717(b)(4)];

- 1 d. Failure to Possess Prescription Filling Procedures [Cal. Code of Regs. title 16 §
2 1717(f)];
- 3 e. Unlawfully Dispensing a Controlled Substance [Cal. Code of Regs. title 16 §
4 1717.3(a)];
- 5 f. Misbranded Drugs [Bus. & Prof. Code §4342(a) and Cal. Code of Regs. title 16 §
6 1735.2(f) in conjunction with Health and Safety Code §§ 111330 and 111340(b)];
- 7 g. Failure to Properly Store Components of Compounded Drugs [Cal. Code of Regs.
8 title 16 § 1735.2(h)];
- 9 h. Inadequate “Beyond Use” Date Labeling [Cal. Code of Regs. title 16 § 1735.2(i)];
- 10 i. Inadequate Compounded Drug Logs [Cal. Code of Regs. title 16 § 1735.3(a)(2)(F)];
- 11 j. Inadequate Quality Assurance Plan [Cal. Code of Regs. title 16 § 1735.8(a) and (d)];
- 12 k. Erroneous or Uncertain Prescriptions [Cal. Code of Regs. title 16 § 1761(a) in
13 conjunction with Health and Safety Code sections 111330 and 111340(b)];
- 14 l. Failure to Maintain Records of Dangerous Drugs [Bus. & Prof. Code § 4105(a)]; and
- 15 m. Failure to Keep Records of Dangerous Drugs Open for Inspection [Bus. & Prof. Code
16 § 4081(a)];

17

18 **ORDER**

19 IT IS SO ORDERED that Original Pharmacy Permit No. PHY 49208, heretofore issued to
20 Respondent Saybian Enterprises Inc. dba Warner West Pharmacy & Supply, Camill Sayadeh, is
21 revoked.

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1 Pursuant to Government Code section 11520, subdivision (c), Respondent may serve a
2 written motion requesting that the Decision be vacated and stating the grounds relied on within
3 seven (7) days after service of the Decision on Respondent. The agency in its discretion may
4 vacate the Decision and grant a hearing on a showing of good cause, as defined in the statute.

5 This Decision shall become effective at 5:00 p.m. on July 10, 2018.

6 It is so ORDERED on June 11, 2018.

7 BOARD OF PHARMACY
8 DEPARTMENT OF CONSUMER AFFAIRS
9 STATE OF CALIFORNIA

10 

11 By _____
12 Victor Law, R.Ph.
13 Board President
14

15 62798443.DOCX
16 DOJ Matter ID:LA2016601721

17 Attachment:
18 Exhibit A: Accusation
19 Exhibit B: First Amended Accusation
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Exhibit A

Accusation

1 XAVIER BECERRA
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2 ARMANDO ZAMBRANO
Supervising Deputy Attorney General
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6 Facsimile: (213) 897-2804
Attorneys for Complainant

7
8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

10
11 In the Matter of the First Amended Accusation
Against:

Case No. 5866

12 **SAYBIAN ENTERPRISES INC. DBA**
13 **WARNER WEST PHARMACY &**
14 **SUPPLY, CAMILL SAYADEH**
22030 Sherman Way, #100
15 **Canoga Park, CA 91303**

FIRST AMENDED ACCUSATION

16 **Pharmacy Permit No. PHY 49208**

17 **ASKAR NADJAVOF**
4601 Willis Ave., Apt. 208
18 **Sherman Oaks, CA 91403**

19 **Pharmacist License No. RPH 71122**

20 **AYOUB MERHI**
20921 Community St., Unit 9
21 **Canoga Park, CA 91304**

22 **Pharmacist License No. RPH 72499**

23 and

24 **HARSHAD H. GAJJAR**
20608 Vercelli Way
25 **Porter Ranch, CA 91326**

26 **Pharmacist License No. RPH 41722**

27 Respondents.
28

1 Complainant alleges:

2 **PARTIES**

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

5 Warner West Pharmacy & Supplies

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

10 Askar Nadjavof

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

16 Ayoub Merhi

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

22 Harshad H. Gajjar

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

28 //

1 **JURISDICTION**

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

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

13 8. Section 4300 states, in pertinent part:

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

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

18 (1) Suspending judgment.

19 (2) Placing him or her upon probation.

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

21 (4) Revoking his or her license.

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

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

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

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

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

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

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

16 17 **STATUTORY PROVISIONS**

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

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

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

22 12. Section 4081 subdivision (a) states:

23 “(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition
24 of dangerous drugs or dangerous devices shall be at all times during business hours open to
25 inspection by authorized officers of the law, and shall be preserved for at least three years from
26 the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-
27 party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility,
28 physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment

1 holding a currently valid and unrevoked certificate, license, permit, registration, or exemption
2 under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4
3 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who
4 maintains a stock of dangerous drugs or dangerous devices.”

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

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

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

13 ...

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

17
18 **REGULATORY PROVISIONS**

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

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

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

28 ...

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

4 ...

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

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

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

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

16 ...

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

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

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

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

26 ...

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

28 ...

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

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

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

14 (b) The pharmacy shall develop and maintain an ongoing competency evaluation process
15 for pharmacy personnel involved in compounding, and shall maintain documentation of any and
16 all training related to compounding undertaken by pharmacy personnel.

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

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

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

24 ...

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

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

(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 Capsule) 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

1 the documentation of the product dispensed. The April 2, 2015 compounding log linked to Rx#
2 636940 showed that the product compounded was Resveratrol 175mg capsule. However, the May
3 4, 2015 compounding log linked to Rx# 636940 showed that the product compounded was
4 Resveratrol 350mg capsule. Accordingly, there was a change in the strength of the drug
5 dispensed however a new prescription was not created.

6 Respondent Nadjavof

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

12
13 **FOURTH CAUSE FOR DISCIPLINE**

14 (Failure to Possess Prescription Filling Procedures)

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

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

23 Respondent Nadjavof

- 24 • Rx# 636526, 3/26/15;
25 • Rx# 636914, 4/1/15 (Resveratrol 175mg capsule);
26 • Rx# 636914, 4/6/15 (Resveratrol 350mg capsule);
27 • Rx# 636940, compounded 4/2/15 (Resveratrol 175mg capsule);
28

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

3 Respondent Merhi

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

6 Respondent Gajjar

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

9
10 **FIFTH CAUSE FOR DISCIPLINE**

11 (Unlawfully Dispensing a Controlled Substance)

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

15
16 **SIXTH CAUSE FOR DISCIPLINE**

17 (Misbranded Drugs)

18 36. Respondents Warner, Respondent Merhi and Respondent Gajjar are subject to
19 disciplinary action pursuant to Bus. & Prof. Code §4342(a) and Cal. Code of Regs. title 16 §
20 1735.2(f) in conjunction with Health and Safety Code §§ 111330 and 111340(b) in that
21 Respondent failed to properly record the master formula.

22 Respondent Merhi

23 37. On or around May 11, 2015 while employed as Pharmacist-in-Charge for Respondent
24 Warner, an unidentified staff pharmacist compounded VITAC 5 BCCFMPV-RESV CAPS (Lot#
25 05112015@2) containing Resveratrol and other active ingredients, including biotin 2mg.
26 However, the container fro compounded product PCCFMPV-RESV CAPS (Lot# 05112015@2)
27 was labeled as containing Resveratrol and other active ingredients, including biotin 1.5mg. The
28

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

3 Respondent Gajjar

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

10
11 **SEVENTH CAUSE FOR DISCIPLINE**

12 (Failure to Properly Store Components of Compounded Drugs)

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

18 Respondent Merhi

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

23 Respondent Gajjar

24 41. On or around June 8, 2015, while Respondent Gajjar was employed as Pharmacist-in-
25 Charge for Respondent Warner, an unidentified pharmacist(s) compounded Multivita-Resv
26 capsule (Lot# 06082015@12). The beyond use date identified on the container label was
27 "15/5/2015", an invalid date.

1 42. On or around June 15, 2015, an unidentified pharmacist(s) compounded Resveratrol
2 350mg capsule (Lot# 06152015@7). The beyond use date on the label exceeded the beyond use
3 date identified on the compounding log.

4
5 **EIGHTH CAUSE FOR DISCIPLINE**

6 (Inadequate “Beyond Use” Date Labeling)

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

12 Respondent Warner, Respondent Nadjavof

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

19 45. The Drug Utilization Report (DUR) document for RX# 636914 was “Resveratrol
20 350mg*POW”. The label reprint indicated the product was “VITAP2 Resveratrol POW”.

21 46. On or around April 24, 2015, unidentified pharmacist(s) verified consumer ML’s Rx#
22 640553, however, there was a discrepancy in the documentation of the product. Specifically, the
23 stickered label on the back of the prescription document identified the dispensed product as
24 “CVIT1 RESVERATROL 175mg POW” however, the Rx Log document identified the product
25 as “Resveratrol 175mg capsule”. In addition, the April 28, 2015 compounding log indicated the
26 product dispensed was “Resveratrol 350mg capsule, however, the Drug Utilization Report (DUR)
27 document for RX# 640533 was “Resveratrol 350mg*POW”.

1 **NINTH CAUSE FOR DISCIPLINE**

2 (Inadequate Compounded Drug Logs)

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

7 **Respondent Nadjavof**

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

13 **Respondent Gajjar**

14 49. On or around June 2, 2015, while Respondent Gajjar was employed as Pharmacist-in-
15 Charge for Respondent Warner, an unidentified pharmacist(s) compounded BGAN Cream (Lot#
16 06022015@10) and dispensed Rx# 643177 to consumer RB. However, the compound log
17 showed there was no lot number or expiration date for the propylene glycol used to compound the
18 dispensed product.

19 50. On or around June 15, 2015, an unidentified pharmacist(s) compounded Resveratrol
20 350mg capules (Lot# 06152015@7). However, the compound log showed there was no
21 expiration date for the Resveratrol used to compound the product.

22
23 **TENTH CAUSE FOR DISCIPLINE**

24 (Failure to Document Compounded Drug Personnel Skills and Training)

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

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

7
8 **ELEVENTH CAUSE FOR DISCIPLINE**

9 (Inadequate Quality Assurance Plan)

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

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

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1 **TWELFTH CAUSE FOR DISCIPLINE**

2 (Erroneous or Uncertain Prescriptions)

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

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

15
16 **THIRTEENTH CAUSE FOR DISCIPLINE**

17 (Failure to Maintain Records of Dangerous Drugs)

18 57. Respondent Warner is subject to disciplinary action pursuant to Bus. & Prof. Code §
19 4105(a) in that it failed to retain records of dangerous drugs on licensed premises. Specifically,
20 during the time period between 9/8/15 and 8/26/16, Respondent stored records of acquisition and
21 disposition of dangerous drugs (Resveratrol) at an unlicensed location “where [Respondent
22 Warner] used to conduct business.”

23
24 **FOURTEENTH CAUSE FOR DISCIPLINE**

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

26 58. Respondent Warner is subject to disciplinary action pursuant to Bus. & Prof. Code §
27 4081(a) in that it failed to keep open for inspection, all records of manufacture, sale, acquisition
28 and disposition of dangerous drugs, by authorized officers of the law. Specifically, on 9/9/16 and

1 12/19/17, Respondent Warner did not produce, vis-à-vis The Pharmacy Depot², all records of
2 acquisition and disposition for the following prescriptions for inspection:

3 Prescription	Date Filled	NDC Label Name	Name of Prescriber
4 Number			
5 637383	3/24/15	Resveratrol Pow	K.S.
6 638562	4/13/15	Resveratrol Pow	A.E.
7 639132	4/16/15	Compound	N.G.
8 640249	4/23/15	Compound	K.S.
9 646069	5/15/15	Compound	N.G.

10
11 **FIFTEENTH CAUSE FOR DISCIPLINE**

12 (Unprofessional Conduct)

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

16 **Respondent Merhi**

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

22 **Respondent Nadjavov**

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

28 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

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

5
6 **PRAYER**

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


- 9 1. Revoking or suspending Original Pharmacy Permit Number PHY 49208, issued to
10 Saybian Enterprises Inc. dba Warner West Pharmacy & Supply, Camill Sayadeh;
- 11 2. Revoking or suspending Pharmacy License No. RPH 71122, issued to Askar
12 Nadjavof;
- 13 3. Revoking or suspending Pharmacy License No. RPH 72499, issued to Ayoub Merhi;
- 14 4. Revoking or suspending Pharmacy License No. RPH 41722, issued to Harshad H.
15 Gajjar;
- 16 5. Prohibiting Saybian Enterprises Inc. dba Warner West Pharmacy & Supply from
17 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
18 licensee for five years if Pharmacy Permit Number PHY 49208 is placed on probation or until
19 Pharmacy Permit Number PHY 49208 is reinstated if Pharmacy Permit Number PHY 49208
20 issued to Saybian Enterprises Inc. dba Warner West Pharmacy & Supply is revoked;
- 21 6. Prohibiting Camill Sayadeh from serving as a manager, administrator, owner, member,
22 officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number
23 PHY 49208 is placed on probation or until Pharmacy Permit Number PHY 49208 is reinstated if
24 Pharmacy Permit Number 49208 issued to Saybian Enterprises Inc. dba Warner West Pharmacy
25 & Supply is revoked;
- 26 7. Ordering Saybian Enterprises Inc. dba Warner West Pharmacy & Supply, Askar
27 Nadjavof, Ayoub Merhi, and Harshad H. Gajjar to pay the Board of Pharmacy the reasonable
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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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7
8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

10
11 In the Matter of the Accusation Against:

Case No. 5866

12 **SAYBIAN ENTERPRISES INC. DBA**
13 **WARNER WEST PHARMACY &**
SUPPLY, CAMILL SAYADEH
14 **22030 Sherman Way, #100**
Canoga Park, CA 91303

A C C U S A T I O N

15 **Pharmacy Permit No. PHY 49208**

16 **ASKAR NADJAVOF**
17 **4601 Willis Ave., Apt. 208**
Sherman Oaks, CA 91403

18 **Pharmacist License No. RPH 71122**

19 **AYOUB MERHI**
20 **20921 Community St., Unit 9**
Canoga Park, CA 91304

21 **Pharmacist License No. RPH 72499**

22 and

23 **HARSHAD H. GAJJAR**
24 **20608 Vercelli Way**
Porter Ranch, CA 91326

25 **Pharmacist License No. RPH 41722**

26
27 Respondents.
28

1 Complainant alleges:

2 **PARTIES**

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

5 Warner West Pharmacy & Supplies

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

10 Askar Nadjavof

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

16 Ayoub Merhi

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

22 Harshad H. Gajjar

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

28 //

1 JURISDICTION

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

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

13 8. Section 4300 states, in pertinent part:

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

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

18 (1) Suspending judgment.

19 (2) Placing him or her upon probation.

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

21 (4) Revoking his or her license.

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

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

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

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

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

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

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

16
17 **STATUTORY AND REGULATORY PROVISIONS**

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

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

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

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

27 13. Cal. Code of Regs. title 16 section 1717 states in pertinent part:
28

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

4 ...

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

8 ...

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

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

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

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

20 ...

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

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

28 //

1 16. Cal. Code of Regs. title 16 section 1735.3 states in pertinent part:
2 “(a) For each compounded drug preparation, pharmacy records shall include:
3 ...
4 (2) A compounding log consisting of a single document containing all of the following:
5 ...
6 (F) The manufacturer, expiration date and lot number of each component. If the
7 manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If
8 the manufacturer does not supply an expiration date for any component, the records shall include
9 the date of receipt of the component in the pharmacy, and the limitations of section 1735.2,
10 subdivision (l) shall apply.”

11 17. Cal. Code of Regs. title 16 section 1735.7 states:
12 “(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that
13 personnel involved in compounding have the skills and training required to properly and
14 accurately perform their assigned responsibilities and documentation demonstrating that all
15 personnel involved in compounding are trained in all aspects of policies and procedures. This
16 training shall include but is not limited to support personnel (e.g. institutional environmental
17 services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are
18 related to the compounding process.

19 (b) The pharmacy shall develop and maintain an ongoing competency evaluation process
20 for pharmacy personnel involved in compounding, and shall maintain documentation of any and
21 all training related to compounding undertaken by pharmacy personnel.

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

25 18. Cal. Code of Regs. title 16 section 1735.8 states in pertinent part:
26 “(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies
27 and procedures, a written quality assurance plan designed to monitor and ensure the integrity,
28 potency, quality, and labeled strength of compounded drug preparations.

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(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

1 for consumer CS¹ for Resveratrol 21gm, however, pharmacy records showed the quantity
2 dispensed was Resveratrol 121gm.

3
4 **SECOND CAUSE FOR DISCIPLINE**

5 (Unlawfully Deviating From Prescription Requirements)

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

9 25. On or around July 24, 2015 while employed for Respondent Warner, Respondent
10 Gajjar incorrectly dispensed Rx# 658026 (VC3 Stress Metabolic Capusle) to consumer DP. Rx#
11 658026 was a compounded product which contained magnesium glycinate 60mg and lipoic acid
12 200mg instead of the prescribed amount of magnesium glycinate 100mg and lipoic acid 150mg,
13 respectively. Rx# 658026 also failed to contain vitamin A .65mg, as ordered.

14
15 **THIRD CAUSE FOR DISCIPLINE**

16 (Failure to Create a New Prescription for Drug Changes)

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

21 Respondent Warner

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

27
28 ¹ Initials are used here and throughout to protect consumer confidentiality.

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

3 Respondent Merhi

4 28. During the time period between May 1, 2015 and May 20, 2015, while Respondent
5 Merhi was employed as Pharmacist-in-Charge for Respondent Warner, an unidentified
6 pharmacist(s) compounded Rx# 636940 for consumer JD. However, there was a discrepancy in
7 the documentation of the product dispensed. The April 2, 2015 compounding log linked to Rx#
8 636940 showed that the product compounded was Resveratrol 175mg capsule. However, the May
9 4, 2015 compounding log linked to Rx# 636940 showed that the product compounded was
10 Resveratrol 350mg capsule. Accordingly, there was a change in the strength of the drug
11 dispensed however a new prescription was not created.

12 Respondent Nadjavof

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

18
19 **FOURTH CAUSE FOR DISCIPLINE**

20 (Failure to Possess Prescription Filling Procedures)

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

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

1 Respondent Merhi

2 34. On or around May 11, 2015 while employed as Pharmacist-in-Charge for Respondent
3 Warner, an unidentified staff pharmacist compounded VITAC 5 BCCFMPV-RESV CAPS (Lot#
4 05112015@2) containing Resveratrol and other active ingredients, including biotin 2mg.
5 However, the container fro compounded product PCCFMPV-RESV CAPS (Lot# 05112015@2)
6 was labeled as containing Resveratrol and other active ingredients, including biotin 1.5mg. The
7 pharmacist did not ensure the compounded product contained the accurate content and quantity of
8 biotin as labeled.

9 Respondent Gajjar

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

16
17 **SEVENTH CAUSE FOR DISCIPLINE**

18 (Failure to Properly Store Components of Compounded Drugs)

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

24 Respondent Merhi

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

1 Respondent Gajjar

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

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

9
10 **EIGHTH CAUSE FOR DISCIPLINE**

11 (Inadequate “Beyond Use” Date Labeling)

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

17 Respondent Warner, Respondent Nadjavof

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

24 42. The Drug Utilization Report (DUR) document for RX# 636914 was “Resveratrol
25 350mg*POW”. The label reprint indicated the product was “VITAP2 Resveratrol POW”.

26 43. On or around April 24, 2015, unidentified pharmacist(s) verified consumer ML’s Rx#
27 640553, however, there was a discrepancy in the documentation of the product. Specifically, the
28 stickered label on the back of the prescription document identified the dispensed product as

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

5
6 **NINTH CAUSE FOR DISCIPLINE**

7 (Inadequate Compounded Drug Logs)

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

12 Respondent Nadjavof

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

18 Respondent Gajjar

19 46. On or around June 2, 2015, while Respondent Gajjar was employed as Pharmacist-in-
20 Charge for Respondent Warner, an unidentified pharmacist(s) compounded BGAN Cream (Lot#
21 06022015@10) and dispensed Rx# 643177 to consumer RB. However, the compound log
22 showed there was no lot number or expiration date for the propylene glycol used to compound the
23 dispensed product.

24 47. On or around June 15, 2015, an unidentified pharmacist(s) compounded Resveratrol
25 350mg capules (Lot# 06152015@7). However, the compound log showed there was no
26 expiration date for the Resveratrol used to compound the product.

27 //

28 //

1 **TENTH CAUSE FOR DISCIPLINE**

2 (Failure to Document Compounded Drug Personnel Skills and Training)

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

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

12
13 **ELEVENTH CAUSE FOR DISCIPLINE**

14 (Inadequate Quality Assurance Plan)

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

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

28 //

1 **TWELFTH CAUSE FOR DISCIPLINE**

2 (Erroneous or Uncertain Prescriptions)

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

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

15
16 **DISCIPLINARY CONSIDERATIONS**

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

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

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

1 OTHER MATTERS

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

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

15
16 PRAYER

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

- 19 1. Revoking or suspending Original Pharmacy Permit Number PHY 49208, issued to
20 Saybian Enterprises Inc. dba Warner West Pharmacy & Supply, Camill Sayadeh;
- 21 2. Revoking or suspending Pharmacy License No. RPH 71122, issued to Askar
22 Nadjavof;
- 23 3. Revoking or suspending Pharmacy License No. RPH 72499, issued to Ayoub Merhi;
- 24 4. Revoking or suspending Pharmacy License No. RPH 41722, issued to Harshad H.
25 Gajjar;
- 26 5. Prohibiting Saybian Enterprises Inc. dba Warner West Pharmacy & Supply from
27 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
28 licensee for five years if Pharmacy Permit Number PHY 49208 is placed on probation or until


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

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

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

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

13
14 DATED: 7/10/17



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

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