KAMALA D. HARRIS
Attorney General of California
ARMANDO ZAMBRANO
Supervising Deputy Attorney General
KRITHTHIKA VASUDEVAN
Deputy Attorney General
State Bar No. 247590
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-2540
Facsimile: (213) 897-2804
*Attorneys for Complainant*

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

| | |
|---|---|
| In the Matter of the Accusation Against:<br><br>**VI PHARMACY, INC.; MARYA KHALIL; HARRY P. WONG**<br>**1558 10th Street, Ste. B**<br>**Santa Monica, CA 90401**<br><br>**Permit No. PHY 50560,**<br><br>**and**<br><br>**HARRY WONG**<br><br>**7624 Vicky Ave.,**<br>**Canoga Park, CA 91304**<br><br>**Pharmacist-In-Charge No. RPH 42747**<br><br>Respondents. | Case No. 4537<br><br>**ACCUSATION** |

Complainant alleges:

## PARTIES

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

2. On or about April 4, 2011, the Board issued Permit Number PHY 50560 to Vi Pharmacy, Inc.; Marya Khalil (Respondent Pharmacy). The Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2014, unless renewed.

3. On or about August 8, 1989, the Board issued Pharmacist-In-Charge Number RPH 42747 to Harry Wong (Respondent Wong). The Permit was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2014, unless renewed.

## JURISDICTION

4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

## STATUTORY PROVISIONS

5. Section 118 states:

"(a) The withdrawal of an application for a license after it has been filed with a board in the department shall not, unless the board has consented in writing to such withdrawal, deprive the board of its authority to institute or continue a proceeding against the applicant for the denial of the license upon any ground provided by law or to enter an order denying the license upon any such ground.

"(b) 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.

"(c) As used in this section, >board= includes an individual who is authorized by any provision of this code to issue, suspend, or revoke a license, and 'license' includes 'certificate,' 'registration,' and 'permit.'"

6. Section 4081, subsection (a), states:

" All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of

making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices."

7. Section 4104, subsection (b), states:

"Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy."

8. Section 4113, subsection (b), states:

"The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

9. Section 4300 of the Code states:

"(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.

". . . ."

//

//

//

10. Section 4300.1 of the Code states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

11. Section 4301 of the Code states:

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

". . . ."

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

". . . ."

12. Section 4116 of the Code provides:

"(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present."

//

//

13. Section 4342 of the Code, subsection (a), states:

"The 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 ...."

14. Section 4402(a) of the Code states that any license that is not renewed within three years following its expiration may not be renewed, restored, or reinstated and shall be canceled by operation of law at the end of the three-year period.

**REGULATORY PROVISIONS**

15. California Code of Regulations, title 16, section 1711, subsection (a), states:

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

16. California Code of Regulations, title 16, section 1714, subsection (d), states: "Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist."

17. California Code of Regulations, title 16, section 1714.1, states:

"This section is to ensure that pharmacists are able to have duty free breaks and meal periods to which they are entitled under Section 512 of the Labor Code and the orders of the Industrial Welfare Commission, without unreasonably impairing the ability of a pharmacy to remain open.

....

(e) The temporary absence authorized by this section shall be limited to the minimum period authorized for pharmacists by section 512 of Labor Code or orders of the Industrial

Welfare Commission, and any meal shall be limited to 30 minutes. The pharmacist who is on break shall not be required to remain in the pharmacy area during the break period.

...."

18. California Code of Regulations, title 16, section 1715, states:

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

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(3) There is a change in the licensed location of a pharmacy to a new address.

(c) The components of this assessment shall be on Form 17M-13 (Rev. 01/11) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment" and on Form 17M-14 (Rev. 01/11) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed."

19. California Code of Regulations, title 16, section 1716, states:

"Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code .

Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription."

//

20. California Code of Regulations, title 16, section 1735.2, subsection (h), states:

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

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

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

22. California Code of Regulations, title 16, section 1735.6, subsection (a), states:

"Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment."

23. California Code of Regulations, title 16, section 1735.8, states:

"....

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

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

24. California Code of Regulations, title 16, section 1793.7, subsection (d), states:

"Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article

11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures."

25. Code of Federal Regulations, title 21, section 1304.11, subsection (c), states:

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

## COST RECOVERY

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

## DRUGS

27. The following drugs are referenced herein:

| BRAND NAME | GENERIC NAME | DANGEROUS DRUG PER Code Section 4022 | CONTROLLED SUBSTANCE PER Health and Safety Code (HSC) | INDICATION FOR USE |
|---|---|---|---|---|
| Vi Peel | Trichloroacetic acid, salicylic acid, reinoic acid, phenol, asorbic acid | Yes | No | Topical Skin Peel |
| Vi Peel Acne | Trichloroacetic acid, salicylic acid, retinoic acid, phenol, ascorbic acid, benzyl peroxide, H hydrocortisone, kojic Acid | Yes | No | Topical Skin Peel |
| Ultra A | Retinoic acid, ascorbic acid, vitamin e | Yes | No | Topical Skin Peel |

//

//

## FIRST CAUSE FOR DISCIPLINE

**(Respondents Pharmacy and Wong: Pharmacist Absent for More Than Thirty (30) Minutes)**

28. Respondents Pharmacy and Wong are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations section 1714.1, subsection (e), in that the pharmacist was absent for more than thirty (30) minutes from the pharmacy. The circumstances are as follows:

a. On or about May 17, 2012, Respondent Wong was in charge of Respondent Pharmacy located at 1558 10th Street # B, in Santa Monica, when a Board inspector found that the pharmacy was operating without a pharmacist from at least 11:45 am till 12:30 p.m., when Respondent Wong arrived.

## SECOND CAUSE FOR DISCIPLINE

**(Respondents Pharmacy and Wong: Failure to Develop Quality Assurance Policies)**

29. Respondents Pharmacy and Wong are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations section 1711, subsection (a), in that they failed to establish a quality assurance program, which documents and assesses medication errors. The circumstances are as follows:

a. On or about May 17, 2012, Respondent Wong was in charge of Respondent Pharmacy located at 1558 10th Street # B, in Santa Monica, and did not have a quality assurance program to document and assess medication errors.

## THIRD CAUSE FOR DISCIPLINE

**(Respondents Pharmacy and Wong: Unlabeled Compounded Drugs in Stock)**

30. Respondents Pharmacy and Wong are subject to disciplinary action under section 4301, subdivision (o), for violating Business and Professions Code section 4342, subsection (a), in that there were unlabeled compounded drugs in stock. The circumstances are as follows:

a. On or about May 17, 2012, Respondent Wong was in charge of Respondent Pharmacy located at 1558 10th Street # B, in Santa Monica, when an investigation found

unlabeled (no drug name, strength, lot number, or expiration date) compounded amber colored liquids in the refrigerator and on the prescription counter.

## FOURTH CAUSE FOR DISCIPLINE

**(Respondents Pharmacy and Wong: Compounded Drug Expiration Dating)**

31. Respondents Pharmacy and Wong are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations section 1735.2, subsection (h), in that the pharmacy had compounded drug products that had been there longer than the allowable 180 days from preparation of the drug or the shortest expiration date of any of the components used to compound the drug. The circumstances are as follows:

a. On or about May 17, 2012, Respondent Wong was in charge of Respondent Pharmacy located at 1558 10th Street # B, in Santa Monica, when the pharmacy had in stock Vi Peel Lot #E0412A compounded on May 4, 2012 with a given final expiration date of May 2013 (one (1) year) when the ingredients in the drug - Trichloroacetic acid expired on February 28, 2013, and ingredient Ethyl alcohol expired on May 31, 2013 (before the labeled expiration date).

## FIFTH CAUSE FOR DISCIPLINE

**(Respondents Pharmacy and Wong: Failure to Maintain Security of Dangerous Drugs)**

32. Respondent Pharmacy and Respondent Wong are subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4116, subdivision (a), in conjunction with California Code of Regulations section 1714, subdivision (d), in that Respondents failed to ensure that the area where dangerous drugs was stored, possessed, prepared, manufactured, derived, compounded, disposed or repackaged was restricted to a pharmacist, and that a pharmacist remained present when other individuals were present. The circumstances are as follows:

a. On or about May 17, 2012, Respondent Wong was in charge of Respondent Pharmacy located at 1558 10th Street # B, in Santa Monica, when compounded drug Ultra A cream and prescription chemical Ascorbyl Palmitate were found stored in refrigerators outside the pharmacy.

//

//

## SIXTH CAUSE FOR DISCIPLINE

**(Respondents Pharmacy and Wong: End Product Analysis on Compounded Drug and Recall Action Plan)**

33. Respondents Pharmacy and Wong are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations section 1735.8, subsection (c) and (d), in that the pharmacy failed to analyze the compounded drug products for integrity, potency, quality and strength as labeled on the product. There was no written procedure for action in the event any compounded drug was discovered to not meet the minimum standards of integrity, potency, quality, or strength of the compounded product. . The circumstances are as follows:

a. On or about October 17, 2012, Respondent Wong was in charge of Respondent Pharmacy located at 1558 10th Street # B, in Santa Monica, when the pharmacy did not have any end product analysis for its compounded products and did not have a written action plan for recalling products that did not meet the integrity, potency, quality or strength standards as on the labeled product.

## SEVENTH CAUSE FOR DISCIPLINE

**(Respondents Pharmacy and Wong: Failure to Document Calibration and Maintenance of Compounding Equipment)**

34. Respondents Pharmacy and Wong are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations section 1735.6, subsection (a), in that there was no documentation in regards to the maintenance, calibration, and certification of all the compounding equipment. The circumstances are as follows:

a. On or about October 17, 2012, Respondent Wong was in charge of Respondent Pharmacy located at 1558 10th Street # B, in Santa Monica, when he failed to document the cleaning, calibration, tube changing, and maintenance of the pharmacy's compounding equipment. Specifically, the certification for the Unidirectional Flow Device (powder hood) expired about two (2) months prior to the inspection (expired on August 31, 2012).

//

## EIGHTH CAUSE FOR DISCIPLINE

**(Respondents Pharmacy and Wong: Incomplete Labeling of Compounded Drugs)**

35. Respondents Pharmacy and Wong are subject to disciplinary action under section 4301, subdivision (o), for violating California Code of Regulations section 1735.4, subsection (b), in that there was no statement on the container or receipt that the product was compounded by the pharmacy. The circumstances are as follows:

a. On or about October 17, 2012, when Respondent Wong was in charge of Respondent Pharmacy located at 1558 10th Street # B, in Santa Monica, an investigation found that the pharmacy did not label the drugs or advise on its receipts that their drugs were compounded by this particular pharmacy.

## DISCIPLINARY CONSIDERATIONS

36. To determine the degree of discipline, if any, to be imposed on Respondent Wong, Complainant alleges that on or about January 14, 2005, in a prior action, the Board issued Citation Number CI 2004 28884 and ordered Respondent Wong to pay $1,000. The circumstances surrounding this citation are that on or about June 28, 2004, at Drugtown Pharmacy, located at 802 7th Street, in Santa Monica, Respondent Wong dispensed prescription number 6411570 filled with Warfarin 5 mg when Warfarin 1 mg had been prescribed in violation of California Code of Regulations, title 16, section 1716. Respondent Wong paid the fine. This Citation is now final and is incorporated by reference as if fully set forth.

37. To determine the degree of discipline, if any, to be imposed on Respondent Wong, Complainant alleges that on or about August 30, 2010, in a prior action, the Board issued Citation Number CI 2010 45511 and ordered Respondent to pay $3, 000. Respondent Wong paid the fine. This Citation is now final and is incorporated by reference as if fully set forth. The circumstances surrounding this citation are as follows:

a. Failure to Maintain Proper Records for Compounded Medication. On February 2, 2009, while working at Drugtown Pharmacy, located at 802 7th Street, in Santa Monica, Respondent Wong did not have compounding records for multiple compounded

medications stored in his pharmacy nor did he have any acquisition records for them from Regent Square Pharmacy in violation of Business and Professions Code section 4081, subsection (a).

b. Stocking Dangerous Drugs Lacking Quality or Strength. On February 2, 2009, while working at Drugtown Pharmacy, located at 802 7th Street, in Santa Monica, Respondent Wong, stored compounded medications without any information on lot numbers, expiration dates, dates compounded, or raw ingredients in violation of Business and Professions Code section 4342.

c. Failure to Complete a Pharmacy Self-Assessment. On February 2, 2009, while working at Drugtown Pharmacy, located at 802 7th Street, in Santa Monica, Respondent Wong had not completed a self-assessment since his last one in 2003 in violation of California Code of Regulations Section 1715, subsection (c).

d. Lack of Policy and Procedures for Employee Theft or Impairment. On February 2, 2009, while working at Drugtown Pharmacy, located at 802 7th Street, in Santa Monica, Respondent Wong could not produce a policy or procedure for theft or impaired employee in violation of Business and Professions Code section 4104, subsection (b).

e. Lack of Written Policy and Procedure for Hiring Technicians and Defining Their Job Duties. On February 2, 2009, while working at Drugtown Pharmacy, located at 802 7th Street, in Santa Monica, Respondent Wong could not produce a policy and procedure for hiring technicians and their job duties in violation of California Code of Regulations section 1793.7, subsection (d).

f. Failure to Complete a Biennial Controlled Substances Inventory. On February, 2, 2009, while working at Drugtown Pharmacy, located at 802 7th Street, in Santa Monica, Respondent Wong could not produce any controlled substances inventory in violation of Federal Regulations Section 1304.11, subsection (c).

38. To determine the degree of discipline, if any, to be imposed on Respondent Wong, Complainant alleges that on or about July 23, 2013, in a prior action, the Board issued Citation Number CI 2013 57617 and ordered Respondent Wong to pay $500.00. The circumstances surrounding this citation are that on or about October 25, 2012, at Regent Square Pharmacy,

located at 17609 Ventura Blvd. No. LL07, in Encino, a Board inspector observed the manager open the pharmacy, without the pharmacist, Respondent Wong, present. The security of the prescription department was not maintained since the manager was in possession of the pharmacy and the prescription drug room key(s). The key(s) were not in a tamper evident container in violation of California Code of Regulations, title 16, section 1714, subdivisions (d) and (e). Respondent Wong has not paid the fine.

**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 Permit Number PHY 50560, issued to Vi Pharmacy, Inc.; Marya Khalil;

2. Revoking or suspending Pharmacist-In-Charge Number RPH 42747, issued to Harry Wong.;

3. Ordering Marya Khalil and Harry Wong 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;

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

DATED: 11/4/13

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

LA2013508663
51392144.doc
10.24.13