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

10 In the Matter of the Accusation Against:

Case No. 4537

11 **VI PHARMACY, INC.; MARYA KHALIL;**
12 **HARRY P. WONG**
13 **1558 10th Street, Ste. B**
Santa Monica, CA 90401

ACCUSATION

14 **Permit No. PHY 50560,**

15 **and**

16 **HARRY WONG**

17 **7624 Vicky Ave.,**
18 **Canoga Park, CA 91304**

19 **Pharmacist-In-Charge No. RPH 42747**

20 Respondents.

21
22 Complainant alleges:

23 **PARTIES**

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

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

1 3. On or about August 8, 1989, the Board issued Pharmacist-In-Charge Number RPH
2 42747 to Harry Wong (Respondent Wong). The Permit was in full force and effect at all times
3 relevant to the charges brought herein and will expire on September 30, 2014, unless renewed.

4 JURISDICTION

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

8 STATUTORY PROVISIONS

9 5. Section 118 states:

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

15 "(b) The suspension, expiration, or forfeiture by operation of law of a license issued by a
16 board in the department, or its suspension, forfeiture, or cancellation by order of the board or by
17 order of a court of law, or its surrender without the written consent of the board, shall not, during
18 any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its
19 authority to institute or continue a disciplinary proceeding against the licensee upon any ground
20 provided by law or to enter an order suspending or revoking the license or otherwise taking
21 disciplinary action against the licensee on any such ground.

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

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

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

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

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

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

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

12 “The pharmacist-in-charge shall be responsible for a pharmacy’s compliance with all
13 state and federal laws and regulations pertaining to the practice of pharmacy.”

14 9. Section 4300 of the Code states:

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

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

19 “(1) Suspending judgment.

20 “(2) Placing him or her upon probation.

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

22 “(4) Revoking his or her license.

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

25 “. . . .”

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1 10. Section 4300.1 of the Code states:

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

7 11. Section 4301 of the Code states:

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

11 "...."

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

16 "...."

17 12. Section 4116 of the Code provides:

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

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

3”

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

5 “(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section
6 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's
7 compliance with federal and state pharmacy law. The assessment shall be performed before July 1
8 of every odd-numbered year. The primary purpose of the self-assessment is to promote
9 compliance through self-examination and education.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 “....

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

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

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

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

1 11 of this Chapter, and shall maintain, for at least three years from the time of making, records
2 adequate to establish compliance with these sections and written policies and procedures.”

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

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

8 **COST RECOVERY**

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

15 **DRUGS**

16 27. The following drugs are referenced herein:

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18 BRAND NAME	19 GENERIC NAME	20 DANGERO US DRUG PER Code Section 4022	21 CONTROLLED SUBSTANCE PER Health and Safety Code (HSC)	22 INDICATION FOR USE
23 Vi Peel	24 Trichloroacetic acid, 25 salicylic acid, reinoic 26 acid, phenol, asorbic 27 acid	28 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

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1 **FIRST CAUSE FOR DISCIPLINE**

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

4 28. Respondents Pharmacy and Wong are subject to disciplinary action under section
5 4301, subdivision (o), for violating California Code of Regulations section 1714.1, subsection (e),
6 in that the pharmacist was absent for more than thirty (30) minutes from the pharmacy. The
7 circumstances are as follows:

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

12 **SECOND CAUSE FOR DISCIPLINE**

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

14 29. Respondents Pharmacy and Wong are subject to disciplinary action under section
15 4301, subdivision (o), for violating California Code of Regulations section 1711, subsection (a),
16 in that they failed to establish a quality assurance program, which documents and assesses
17 medication errors. The circumstances are as follows:

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

21 **THIRD CAUSE FOR DISCIPLINE**

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

23 30. Respondents Pharmacy and Wong are subject to disciplinary action under section
24 4301, subdivision (o), for violating Business and Professions Code section 4342, subsection (a),
25 in that there were unlabeled compounded drugs in stock. The circumstances are as follows:

26 a. On or about May 17, 2012, Respondent Wong was in charge of Respondent
27 Pharmacy located at 1558 10th Street # B, in Santa Monica, when an investigation found
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1 unlabeled (no drug name, strength, lot number, or expiration date) compounded amber colored
2 liquids in the refrigerator and on the prescription counter.

3 **FOURTH CAUSE FOR DISCIPLINE**

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

5 31. Respondents Pharmacy and Wong are subject to disciplinary action under section
6 4301, subdivision (o), for violating California Code of Regulations section 1735.2, subsection (h),
7 in that the pharmacy had compounded drug products that had been there longer than the allowable
8 180 days from preparation of the drug or the shortest expiration date of any of the components
9 used to compound the drug. The circumstances are as follows:

10 a. On or about May 17, 2012, Respondent Wong was in charge of Respondent
11 Pharmacy located at 1558 10th Street # B, in Santa Monica, when the pharmacy had in stock Vi
12 Peel Lot #E0412A compounded on May 4, 2012 with a given final expiration date of May 2013
13 (one (1) year) when the ingredients in the drug - Trichloroacetic acid expired on February 28,
14 2013, and ingredient Ethyl alcohol expired on May 31, 2013 (before the labeled expiration date).

15 **FIFTH CAUSE FOR DISCIPLINE**

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

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

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

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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).

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1 **EIGHTH CAUSE FOR DISCIPLINE**

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

3 35. Respondents Pharmacy and Wong are subject to disciplinary action under section
4 4301, subdivision (o), for violating California Code of Regulations section 1735.4, subsection (b),
5 in that there was no statement on the container or receipt that the product was compounded by the
6 pharmacy. The circumstances are as follows:

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

11 **DISCIPLINARY CONSIDERATIONS**

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

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

25 a. Failure to Maintain Proper Records for Compounded Medication. On
26 February 2, 2009, while working at Drugtown Pharmacy, located at 802 7th Street, in Santa
27 Monica, Respondent Wong did not have compounding records for multiple compounded
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1 medications stored in his pharmacy nor did he have any acquisition records for them from Regent
2 Square Pharmacy in violation of Business and Professions Code section 4081, subsection (a).

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

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

12 d. Lack of Policy and Procedures for Employee Theft or Impairment. On February
13 2, 2009, while working at Drugtown Pharmacy, located at 802 7th Street, in Santa Monica,
14 Respondent Wong could not produce a policy or procedure for theft or impaired employee in
15 violation of Business and Professions Code section 4104, subsection (b).

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

21 f. Failure to Complete a Biennial Controlled Substances Inventory. On February,
22 2, 2009, while working at Drugtown Pharmacy, located at 802 7th Street, in Santa Monica,
23 Respondent Wong could not produce any controlled substances inventory in violation of Federal
24 Regulations Section 1304.11, subsection (c).

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

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

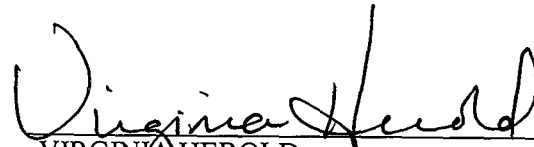
7 **PRAYER**

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

- 10 1. Revoking or suspending Permit Number PHY 50560, issued to Vi Pharmacy, Inc.;
- 11 Marya Khalil;
- 12 2. Revoking or suspending Pharmacist-In-Charge Number RPH 42747, issued to Harry
- 13 Wong.;
- 14 3. Ordering Marya Khalil and Harry Wong to pay the Board of Pharmacy the reasonable
- 15 costs of the investigation and enforcement of this case, pursuant to Business and Professions
- 16 Code section 125.3;
- 17 4. Taking such other and further action as deemed necessary and proper.

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19
20 DATED: _____

11/4/13



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

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