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

In the Matter of the Accusation Against: **VIERAN CORP.,** **DBA DRUG CO. PHARMACY;** **HASHEM HEIATI, PRESIDENT;** **PHUONG DUNG NGUYEN, VICE PRESIDENT** **307 North Ash Street** **Escondido, CA 92027** **Pharmacy Permit No. PHY 48533** **PHUONG DUNG NGUYEN** **13596 Penfield Point** **San Diego, CA 92130** **Pharmacist License No. RPH 50748** **ROHINEE AGARWAL** **13227 Jacarte Court** **San Diego, CA 92130** **Pharmacist License No. RPH 66992** **and** **HOWARD STANLEY WRIGHT** **620 Dorinda Drive** **Oceanside, CA 92057** **Pharmacist License No. RPH 32151** Respondents.	Case No. 5739 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about April 26, 2007, the Board issued Pharmacy Permit Number PHY 48533 to Vieran Corp., to do business as Drug Co. Pharmacy (Respondent Pharmacy), with Hashem Heiati as President and Phuong Dung Nguyen as Vice President. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein, and will expire on April 1, 2016, unless renewed.

3. On or about March 29, 1999, the Board issued Pharmacist License No. RPH 50748 to Phuong Dung Nguyen (Respondent Nguyen). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein, and will expire on July 31, 2016, unless renewed.

4. On or about March 14, 2012, the Board issued Pharmacist License No. RPH 66992 to Rohinee Agarwal (Respondent Agarwal). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein, and will expire on May 31, 2017, unless renewed.

5. On or about August 3, 1978, the Board issued Pharmacist License No. RPH 32151 to Howard Stanley Wright (Respondent Wright). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein, and will expire on March 31, 2018, unless renewed.

JURISDICTION

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

7. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

8. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

9. 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.

10. Section 4307(a) of the Code states:

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

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

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

STATUTORY PROVISIONS

11. Section 4013(a) of the Code states:

Any facility licensed by the board shall join the board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal.

12. Section 4059(b) of the Code states:

A pharmacist may furnish a dangerous drug authorized for use pursuant to Section 2620.3 to a physical therapist. A record containing the date, name and address of the buyer, and name and quantity of the drug shall be maintained. This subdivision shall not be construed to authorize the furnishing of a controlled substance.

13. Section 4059.5(e) of the Code states:

A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the

transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

14. Section 4081 of the Code states:

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

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

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

15. Section 4113, subdivision (c) of the Code provides that 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.

16. Section 4126.5(a)(4) of the Code states:

(a) A pharmacy may furnish dangerous drugs only to the following:

. . . .

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

17. Section 4169 of the Code states:

(a) A person or entity shall not do any of the following:

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health.

18. Section 4301 of the Code states in pertinent part:

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

. . . .

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

. . . .

(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.

. . . .

19. Health and Safety Code section 111335 provides that any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290.)

20. Health and Safety Code section 111400 provides that any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

21. Health and Safety Code section 111440 provides that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

22. Health and Safety Code section 111450 provides that it is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

23. Title 21 United States Code section 352 states:

A Drug or device shall be deemed to be misbranded—

...

(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

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REGULATORY PROVISIONS

24. California Code of Regulations, title 16, section 1735, subdivision (a): states in pertinent part:

> "Compounding" means any of the following activates occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
>
> (1) Altering the dosage form or delivery system of a drug
>
> (2) Altering the strength of a drug
>
> (3) Combining components or active ingredients
>
> (4) Preparing a drug product from chemicals or bulk drug substances
>
> ...

25. California Code of Regulations, title 16, section 1735 states:

> (a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
>
> (1) Altering the dosage form or delivery system of a drug
>
> (2) Altering the strength of a drug
>
> (3) Combining components or active ingredients
>
> (4) Preparing a drug product from chemicals or bulk drug substances
>
> (b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.
>
> (c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.
>
> (d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.).

26. California Code of Regulations, title 16, section 1735.2 states:

. . . .

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

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

(4) Inactive ingredients to be used.

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

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

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

. . . .

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

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

. . . .

COST RECOVERY

27. 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.

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DRUG

28. Domperidone is a drug not approved for use in humans in the United States by the Food and Drug Administration. Drug products compounded using domperiodone are subject to the approval requirements of the Federal Food, Drug and Cosmetic Act.

FACTUAL ALLEGATIONS

29. Since April 26, 2007, and at all times mentioned herein, Respondent Nguyen has been the Pharmacist-in-Charge (PIC) of Respondent Pharmacy. Respondent Agarwal and Respondent Wright are staff pharmacists at Respondent Pharmacy.

30. On June 7, 2004, the FDA issued a talk paper titled, "FDA Warns Against Women Using Unapproved Drug, Domperidone, to Increase Milk Production." The paper stated in pertinent part that domperidone is an "unapproved drug," and that it is "not approved in the U.S. for any indication." It also warned breast-feeding women not to use the product because of safety concerns, and that FDA field personnel were alerted to be on the lookout for attempts to import domperidone so it could be detained. The talk paper indicated that the FDA issued six letters to pharmacies that compound products containing domperidone and firms that supply domperidone for use in compounding. The paper stated, "[t]he letters issued by FDA today stated that all drug products containing domperidone (whether compounded or not) violate the Federal Food, Drug, and Cosmetic Act (the Act) because they are unapproved new drugs and misbranded. In addition, distribution within the U.S., or importation of domperidone-containing products, violates the law."

31. On March 18, 2011, the FDA issued an import alert for domperidone indicating the agency learned domperidone was being imported as a bulk active pharmaceutical ingredient for pharmacy compounding, and presented a public health risk and violated the Act.

32. On March 12, 2012, the FDA issued a revised import alert for domperidone. This revised import alert stated that ". . . domperidone is not appropriate for pharmacy compounding use because this bulk active ingredient is not a component of an FDA approved drug, or is a component of a drug that was withdrawn or removed from the market for safety reasons."

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33. On or about April 14, 2015, the Board issued a "subscriber alert" to pharmacies and pharmacists stating, "Domperidone is not FDA-approved for any use in humans in the United States. Drug products compounded using domperidone are subject to the approval requirements of the Federal Food, Drug, and Cosmetic Act."

34. Respondents did not possess a FDA-approved Investigational New Drug application, allowing them expanded access for domperiodone.

35. Between April 21, 2015 and June 5, 2015, Respondents compounded and dispensed fourteen prescriptions for domperidone. Of the fourteen prescriptions dispensed for domperidone, ten prescriptions for domperidone were compounded without first preparing the required written master formula, and eleven prescriptions for domperidone were assigned a beyond-use-date (BUD) that was greater than 180 days from the compounded date, as follows:

Date	Lot/RX #	Strength	Amount compounded	BUD	Verifying RPH	Findings
4/21/2015	297274	10 mg	100	10/2015	Agarwal	BUD > 180 day
4/27/2015	292778	10 mg	100	10/2015	Nguyen	BUD > 180 day
4/16/2015	297130	30 mg	100	10/2015	Wright	BUD > 180 day; No master formula for 30 mg
4/29/2015	297546	30 mg	100	10/2015	Nguyen	BUD > 180 day; No master formula for 30 mg
5/7/2015	297888	10 mg	30	10/2015	Nguyen	
5/18/2015	298252	20 mg	100	8/15/11/15	Agarwal	BUD unclear; No master formula for 20 mg
5/18/2015	298304	20 mg	200	11/2015	Agarwal	BUD > 180 day; No master formula for 20 mg
5/5/2015	597785	30 mg	100	11/2015	Agarwal	BUD > 180 day; No master formula for 30 mg
5/8/5015	297939	30 mg	90	11/2015	Nguyen	BUD > 180 day; No master formula for 30 mg
5/12/2015	297130	30 mg	100	11/2015	Agarwal	BUD > 180 day; No master formula for 30 mg

5/21/2015	298407	30 mg	90	11/2015	Nguyen	BUD > 180 day; No master formula for 30 mg
5/28/2015	298583	30 mg	100	11/2015	Wright	BUD > 180 day; No master formula for 30 mg
6/1/2015	297546	30 mg	90	11/2015	Wright	No master formula for 30 mg
6/5/2015	297785	30 mg	90	12/15	Wright	BUD > 180 day; No master formula for 30 mg

36. Respondent Nguyen informed the inspector that she investigated domperidone in May, 2015 and discovered it was illegal in the United States. Respondent Nguyen stated that Respondent Pharmacy stopped filling domperidone prescriptions on June 4, 2015.

FIRST CAUSE FOR DISCIPLINE

(Against Respondents Drug Co. Pharmacy, Nguyen, Agarwal and Wright)

(Sold Misbranded Drugs)

37. Respondents are subject to disciplinary action under Code section 4301(j) for violating statutes regulating controlled substances and dangerous drugs, in that Respondents sold misbranded drugs, as defined by Health & Safety Code section 111400 and United States Code, title 21, section 352(f) in violation of Health and Safety Code section 111440, as set forth in paragraphs 29 through 36, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Against Respondents Drug Co. Pharmacy, Nguyen, Agarwal and Wright)

(Delivered or Proffered for Delivery Misbranded Drugs)

38. Respondents are subject to disciplinary action under Code section 4301(j), for violating statutes regulating controlled substances and dangerous drugs, in that Respondents delivered or proffered for delivery misbranded drugs, as defined by Health & Safety Code section 111400, in violation of Health and Safety Code section 111450, as set forth in paragraphs 29 through 36, which are incorporated herein by reference.

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THIRD CAUSE FOR DISCIPLINE

(Against Respondents Drug Co. Pharmacy, Nguyen, Agarwal and Wright)

(Commission of Prohibited Acts)

39. Respondents are subject to disciplinary action under Code sections 4301(o) and/or 4169(a)(3), and Health and Safety Code section 11335, in that Respondents purchased domperidone powder and dispensed compounded drug capsules containing domperidone without having an approved Investigational New Drug application on file, as set forth in paragraphs 29 through 36, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Against Respondents Drug Co. Pharmacy, Nguyen, Agarwal and Wright)

(Unprofessional Conduct)

40. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct in that they engaged in the activities described in paragraphs 29 through 36 above, which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Against Respondents Drug Co. Pharmacy and Nguyen)

(Failure to Prepare Written Master Formula)

41. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1735.2(d), by compounding domperidone on ten occasions without first preparing the a written master formula as described in paragraphs 29 through 36 above, which are incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Against Respondents Drug Co. Pharmacy and Nguyen)

(Unlawful Extension of the BUD)

42. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1735.2(d), by assigning a beyond use date that was greater than 180 days from the compounded date as described in paragraphs 29 through 36 above, which are incorporated herein by reference.

DISCIPLINARY CONSIDERATIONS

43. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, Complainant alleges that on or about November 9, 2015, the Board issued Modified Citation number CI 2011 48851 and a fine against Respondent Pharmacy for violating Business and Professions Code sections 4126.5(a)(4), 4059(b), 4301(o), 4081(a), 4059.5(e) and California Code of Regulations, title 16, section 1718. The fine has been paid in full.

44. To determine the degree of discipline, if any, to be imposed on Respondent Nguyen, Complainant alleges that on or about September 4, 2015, Citation number CI 2012 53976 became final against Respondent Nguyen. The Citation alleged that Respondent Nguyen violated Business and Professions Code sections 4126.5(a)(4), 4059(b), 4301(o), 4081(a), 4059.5(e) and California Code of Regulations, title 16, section 1718.

OTHER MATTERS

45. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 48533 issued to Vieran Corp., dba Drug Co. Pharmacy, and Hashem Heiati and/or Phuong Dung Nguyen, while acting as the manager, administrator, owner, member, officer, director, associate, or partner of Vieran Corp., dba Drug Co. Pharmacy, had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 48533 issued to Vieran Corp., dba Drug Co. Pharmacy was revoked, suspended or placed on probation, Hashem Heiati and/or Phuong Dung Nguyen 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 48533 issued to Vieran Corp., dba Drug Co. Pharmacy is placed on probation or until Pharmacy Permit Number PHY 48533 issued to Vieran Corp., dba Drug Co. Pharmacy is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 48533 issued to Vieran Corp., to do business as Drug Co. Pharmacy.

2. Revoking or suspending Pharmacist License No. RPH 50748 issued to Phuong Dung Nguyen.

3. Revoking or suspending Pharmacist License RPH 66992 issued to Rohinee Agarwal.

4. Revoking or suspending Pharmacist License No. RPH 32151 issued to Howard Stanley Wright.

5. Ordering Respondents 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;

6. Prohibiting Respondents Hashem Heiati and/or Phuong Dung Nguyen from serving as a manager, administrator, owner, member, officer, director, associate or partner of a licensee for a period not to exceed five years in the case of probation, or in the case of revocation, until the license is reinstated.

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

DATED: 5/21/16

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

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