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9	BEFORE THE BOARD OF PHARMACY	
10	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA	
	STATE OF CALIFO	I I
11	In the Matter of the Accusation Against:	Case No. 4971
12	THANH TAM PHARMACY, INC.,	
13	DBA PACIFIC PHARMACY 9898 Bolsa Avenue	ACCUSATION
14	Westminster, CA 92683	
15	Pharmacy Permit No. PHY 50504	
16	LINDA OANH NGUYEN 9246 Gardenia Avenue	
17	Fountain Valley, CA 92708	
18	Pharmacist License No. RPH 92708	
19	CAN VINH VOUNG 12081 Jennifer Lane	
20	Garden Grove, CA 92640	
21	Pharmacist License No. RPH 44286	
22	Respondents.	
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		Accusation

#### **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.
- 2. On or about October 21, 2009, the Board issued Pharmacy Permit Number PHY 48979 to Thanh Tam Pharmacy, Inc., dba Pacific Pharmacy with Kimdzung Nguyen designated as the Pharmacist-in-Charge. On or about January 24, 2011, there was a change in ownership of that pharmacy which resulted in the Board issuing Pharmacy Permit Number PHY 50504 to Thanh Tam Pharmacy, Inc., dba Pacific Pharmacy (Respondent Pacific Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2015, unless renewed.
- 3. On or about March 8, 1996, the Board of Pharmacy issued Pharmacist License Number RPH 48563 to Linda Oanh Nguyen (Respondent Linda Nguyen). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2015, unless renewed.
- 4. On or about June 21, 1991, the Board of Pharmacy issued Pharmacist License Number RPH 44286 to Can Vinh Voung (Respondent Can Vuong). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2015, unless renewed.

## **JURISDICTION**

- 5. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.
- 6. 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.].
- 7. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

## 8. 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.

## STATUTORY AND REGULATORY PROVISIONS

## 9. 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, or 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 any other state or federal regulatory agency.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

### 10. Section 4113(c) of the Code 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.

## 11. Section 4125(a) of the Code states:

Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a reoccurrence.

## 12. Section 4306.5 of the Code states, in pertinent part:

Unprofessional conduct for a pharmacist may include any of the following:

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Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

## 13. Health and Safety Code section 11153(a) states:

A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

## 14. Health and Safety Code section 11165(d) states, in pertinent part:

To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedule in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

## 15. Section 1715(a) of title 16, California Code of Regulations states:

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.

## 16. Section 1761 of title 16, California Code of Regulations 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.
- (b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

## 17. Section 1707.3 of title 16, California Code of Regulations states:

Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems.

## 18. Section 1304.04 of title 21, Code of Federal Regulations states in pertinent part:

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

## 19. Section 1304.11(a) of title 21, Code of Federal Regulations states:

General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees or the registrant and

intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substance is in the possession or under the control of the registrant are stored at a location of which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

**COST RECOVERY** 

20. 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.

## **DRUG**

21. <u>Phenergan with Codeine</u> is the brand name for promethazine with codeine, a Schedule V controlled substance pursuant to Health and Safety Code section 111058(c)(1) and is a dangerous drug pursuant to Business and Professions Code section 4022.

#### **FACTUAL ALLEGATIONS**

- 22. From March 26, 2011 through May 26, 2012, Respondent Linda Nguyen was the Pharmacist-in-Charge (PIC) of Respondent Pacific Pharmacy. From July 1, 2012 and at all times thereafter, Respondent Can Vuong was the PIC of Respondent Pacific Pharmacy.
- 23. In 2011, Respondents Pacific Pharmacy and Linda Nguyen co-mingled records and inventories for Schedule III, Schedule IV and Schedule V controlled substances with the records for other dangerous drugs.
- 24. In 2013, Respondents Pacific Pharmacy and Can Vuong did not fully complete a self-assessment detailing Respondent Pacific Pharmacy's compliance with federal and state pharmacy law. Respondent Pacific Pharmacy and Can Vuong also did not have a quality assurance program which documented and assessed medication errors to determine the cause and to make an appropriate response. Respondent Can Vuong admitted to the Board inspector that they had failed to implement this program.

- 25. From 2011 through 2013, Respondents did not provide any information for each prescription dispensed for a Schedule II, Schedule III or Schedule IV controlled substance to the Department of Justice on a weekly basis for inclusion in the Controlled Substance Utilization Review and Evaluation System ("CURES").
- 26. On or about September 19, 2012, Respondents Pacific Pharmacy and Can Vuong did not accurately document their biennial inventory of the pharmacy's controlled substances in that they did not indicate if the inventory was taken at the opening or close of business on the inventory date.
- 27. In 2013, Respondents Pacific Pharmacy and Can Vuong did not provide requested records to the Board on multiple occasions, including patient profiles and physician profiles or only provided incomplete records.
- 28. Respondents carried only the generic promethazine with codeine which tastes better than other brands, and ordered promethazine with codeine from multiple wholesalers. The volume of promethazine with codeine dispensed by Respondents was much higher than the volume dispensed from neighboring pharmacies.
- 29. From March 26, 2011 to June 6, 2011, Respondents Pacific Pharmacy and Linda Nguyen dispensed 308 prescriptions for approximately 308 pints (145,684mls) of promethazine with codeine after the receipt of prescriptions issued by Dr. T.R., who subsequently surrendered his DEA registration on July 8, 2011 for cause.
- 30. Patients with prescriptions ordered by Dr. T.R., paid for the above-referenced prescriptions in cash, without seeking reimbursement from their insurance carriers. Most of the prescriptions had the patient's names handwritten on the back of the prescriptions. The majority of these prescriptions were written for the same large quantity (one pint) with the same directions for use (one teaspoon, four times a day) and the same estimated days' supply (twenty four). The patients' residences were located far away from Dr. T.R.'s office and an average of twenty six miles from Respondent Pacific Pharmacy. Patients received prescriptions from Dr. T.R. for the same duplicative drug therapy, promethazine with codeine, during successive months.

Respondents Pacific Pharmacy and Linda Nguyen did not contact Dr. T.R. or review CURES prior to filling the prescriptions.

- 31. From January 24, 2012 through May 13, 2013, Respondents Pacific Pharmacy and Can Vuong or Linda Nguyen dispensed 299 prescriptions of approximately 141,328mls of promethazine with codeine after the receipt of prescriptions issued by Dr. H.S. or his physician assistant, H.T.M. Some of these patients were former patients of Dr. T.R. Patients received prescriptions for duplicative drug therapies consisting of promethazine with codeine and antibiotics during successive months.
- 32. Patients paid for the above-referenced prescriptions in cash ordered by Dr. H.S. or his physician assistant, H.T.M. without seeking reimbursement from their insurance carriers. The patients' residences were located far away from Dr. H.S. or his physician assistant, H.T.M.'s office and an average of twenty eight miles away from Respondent Pacific Pharmacy. Respondents Pacific Pharmacy and Can Vuong did not contact Dr. H.S. or his physician assistant, H.T.M. or review CURES prior to filling the prescriptions.

## FIRST CAUSE FOR DISCIPLINE

## (Failure to Report Dispensing of Controlled Prescriptions to CURES against Respondents)

33. Respondents are subject to disciplinary action under Code section 4301(j), for violating Health and Safety Code section 11165(d), in that they failed to provide any information for each prescription dispensed of a Schedule II, Schedule III or Schedule IV controlled substance to the Department of Justice on a weekly basis for inclusion in CURES, as set forth in paragraphs 22 through 32 above, which are incorporated herein by reference.

## SECOND CAUSE FOR DISCIPLINE

## (Failure to Properly Conduct Biennial Inventory of Controlled Substances against Respondent Pacific Pharmacy and Can Vuong)

34. Respondents Pacific Pharmacy and Can Vuong are subject to disciplinary action under Code section 4301(o), for violating title 21, Code of Federal Regulations, section 1304.11(a), in that they failed to indicate whether the biennial inventory of controlled substances

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conducted on September 19, 2012, had been done at either the opening or closing of business, as set forth in paragraphs 22 through 32 above, which are incorporated herein by reference.

## THIRD CAUSE FOR DISCIPLINE

## (Failure to Complete a Self-Assessment of Compliance with Federal and State Pharmacy Law against Respondents Pacific Pharmacy and Can Vuong)

35. Respondents Pacific Pharmacy and Can Vuong are subject to disciplinary action under Code section 4301(o), for violating title 16, California Code of Regulations, section 1715(a) in that they failed to have or fully complete a self-assessment of Respondent Pacific Pharmacy's compliance with federal and state pharmacy laws, as set forth in paragraphs 22 through 32 above, which are incorporated herein by reference.

## FOURTH CAUSE FOR DISCIPLINE

## (Failure to Institute a Quality Assurance Program against Respondents Pacific Pharmacy and Can Vuong)

36. Respondents Pacific Pharmacy and Can Vuong are subject to disciplinary action under Code section 4301(o), for violating Business and Professions Code section 4125(a), in that they failed to institute a quality assurance program designed to assess medication errors, as set forth in paragraphs 22 through 32 above, which are incorporated herein by reference.

## FIFTH CAUSE FOR DISCIPLINE

## (Failure to Maintain Segregated Records of Controlled Substances against Respondents Pacific Pharmacy and Linda Nguyen)

37. Respondents Pacific Pharmacy and Linda Nguyen are subject to disciplinary action under Code section 4301(o), for violating title 21, Code of Federal Regulations, section 1304.4(f), in that they co-mingled the inventories and records for Schedule III, Schedule IV and Schedule V controlled substances with the records for other dangerous drugs, as set forth in paragraphs 22 through 32 above, which are incorporated herein by reference.

## SIXTH CAUSE FOR DISCIPLINE

(Subverting Investigation of Board against Respondent Pacific Pharmacy and Can Vuong)

38. Respondents Pacific Pharmacy and Can Vuong are subject to disciplinary action under Code section 4301(q), for unprofessional conduct in that they subverted an investigation of the Board by failing to produce requested records in a timely manner, produced incomplete records or did not produce the requested records at all, as set forth in paragraphs 22 through 32 above, which are incorporated herein by reference.

## SEVENTH CAUSE FOR DISCIPLINE

(Failing to Comply with Corresponding Responsibility

for Legitimate Controlled Substance Prescriptions against Respondents)

39. Respondents are subject to disciplinary action under Code section 4301(j), for violating Health and Safety Code section 11153(a), in that they failed to comply with their corresponding responsibility to ensure that controlled substances were dispensed for a legitimate medical purpose when Respondents furnished prescriptions for controlled substances even though "red flags" were present, as set forth in paragraphs 22 through 32 above, which are incorporated herein by reference.

### EIGHTH CAUSE FOR DISCIPLINE

(Dispensing Controlled Substance Prescriptions with Significant Errors, Omissions, Irregularities, Uncertainties, Ambiguities or Alterations against Respondents)

40. Respondents are subject to disciplinary action under Code section 4301(o), for violating title 16, California Code of Regulations, sections 1761(a) and (b) in that they dispensed prescriptions for a controlled substance, promethazine with codeine, which contained significant errors, omissions, irregularities, uncertainties, ambiguities or alterations, as set forth in paragraphs 22 through 32 above, which are incorporated herein by reference.

## NINTH CAUSE FOR DISCIPLINE

## (Failure to Review Patients' Medication Record Before Prescription Drugs Delivered against Respondents)

41. Respondents are subject to disciplinary action under Code section 4301(o), for violating title 16, California Code of Regulations, section 1707.3, in that they dispensed prescriptions for drugs, without review of patients' medication records before each prescription drug was delivered. Such a review would have revealed numerous "red flags," as set forth in paragraphs 22 through 32 above, which are incorporated herein by reference.

## TENTH CAUSE FOR DISCIPLINE

# (Failure to Exercise or Implement Best Professional Judgment or Corresponding Responsibility when Dispensing Controlled Substances against Respondents Linda Nguyen and Can Vuong)

42. Respondents Linda Nguyen and Can Vuong are subject to disciplinary action under Code section 4301(o), for violating Business and Professions Code section 4306.5(a) and (b), in that they failed to exercise or implement his or her best professional judgment or corresponding responsibility when dispensing controlled substances, as set forth in paragraphs 22 through 32 above, which are incorporated herein by reference.

## **ELEVENTH CAUSE FOR DISCIPLINE**

## (Unprofessional Conduct against Respondents Linda Nguyen and Can Vuong)

43. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct in that they engaged in the activities described in paragraphs 22 through 32 above, which are incorporated herein by reference.

#### **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 50504, issued to Thanh Tam Pharmacy, Inc. dba Pacific Pharmacy;

Accusation