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

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|---|---|
| In the Matter of the Accusation Against:<br><br>**WEST COAST PHARMACY, INC.,**<br>**dba WEST COAST PHARMACY**<br>**LOAN MONG LE, PRES./SECY.**<br>**KIM NGUYEN,**<br>**aka KIM KHANH NGUYEN, PIC**<br>**5731 Watt Avenue**<br>**North Highlands, CA 95660**<br><br>**Pharmacy Permit No. PHY 50531,**<br><br>**KIM KHANH NGUYEN**<br>**9642 McKenna Drive**<br>**Elk Grove, CA 95757**<br><br>**Pharmacist License No. RPH 54305,**<br><br>**and**<br><br>**LOAN MONG LE**<br>**3760 Monteverde Drive**<br>**Lincoln, CA 95648**<br><br>**Pharmacist License No. RPH 50209**<br><br>Respondents. | Case No. 5610<br><br>**A C C U S A T I O N** |

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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 January 19, 2011, the Board issued Pharmacy Permit Number PHY 50531 to West Coast Pharmacy, Inc., doing business as West Coast Pharmacy ("Respondent West Coast Pharmacy"), with Loan Mong Le ("Respondent Le") as president and secretary. On or about July 7, 2014, Kim Nguyen, also known as Kim Khanh Nguyen ("Respondent Nguyen"), became the pharmacist-in-charge. Respondent West Coast Pharmacy filed a discontinuance of business that became effective on November 16, 2015. The pharmacy permit was cancelled on December 16, 2015. The pharmacy permit was in full force and effect at all times relevant to the charges brought herein.

3. On or about April 15, 2003, the Board issued Pharmacist License Number RPH 54305 to Respondent Nguyen. The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2017, unless renewed.

4. On or about August 18, 1998, the Board issued Pharmacist License Number RPH 50209 to Respondent Le. The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2018, unless renewed.

## JURISDICTION

5. 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.

6. Section 4300 states, in pertinent part:

> (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.

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(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 . . .

7. Section 4300.1 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

8. Section 4301 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:

. . . .

(b) Incompetence.

(c) Gross negligence.

. . . .

(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 by any other state or federal regulatory agency . . . .

9. Section 4081 states, in pertinent part:

(a) 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.

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

10. Section 4105, subdivision (a), states:

All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

11. Section 4113, subdivision (c), states that "[t]he 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."

12. Section 4115 states, in pertinent part:

(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

. . . .

(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

. . . .

(f)(1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a

single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117 . . .

13. Section 4156 states:

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter

14. Section 4306.5 states, in pertinent part:

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

. . . .

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services . . .

15. Section 4342, subdivision (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 (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

16. Health and Safety Code section 11153, subdivision (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.

17. Health and Safety Code section 111295 states that "[i]t is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

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18. Title 21, Code of Federal Regulations ("CFR"), section 1301.75, subdivision (b), states that "[c]ontrolled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances."

19. Title 16, California Code of Regulations ("CCR"), section 1707.2 states, in pertinent part:

> (a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:
>
> (1) upon request; or
>
> (2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.
>
> (b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:
>
> (A) whenever the prescription drug has not previously been dispensed to a patient; or
>
> (B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy . . .

20. Title 16, CCR, section 1711 states, in pertinent part:

> (a) 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.
>
> (b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.
>
> (c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.
>
> (2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

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(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

. . . .

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;

2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);

3. the findings and determinations generated by the quality assurance review; and,

4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created . . .

21. Title 16, CCR, section 1714 states, in pertinent part:

. . . .

(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

. . . .

(d) 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 . . .

22. Title 16, CCR, section 1715.6 states that "[t]he owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths."

23. Title 16, CCR, section 1735.2 states, in pertinent part:

. . . .

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

(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.

. . . .

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

24. Title 16, CCR, section 1761 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.

25. Title 16, CCR, section 1793.2 states, in pertinent part:

"Nondiscretionary tasks" as used in Business and Professions Code section 4115, include:

(a) removing the drug or drugs from stock . . .

**COST RECOVERY**

26. Section 125.3 provides, in pertinent part, that a 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 CLASSIFICATIONS**

27. "Guaifenesin with codeine syrup" is a Schedule V controlled substance as designated by Health and Safety Code section 11058, subdivision (c)(1), and is used to treat cough.

28. "Percolone/Roxicodone" are brand names for oxycodone. Oxycodone is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (b)(1)(M). Oxycodone is used to treat pain.

29. "Phenergan" is a brand name for promethazine. Promethazine with codeine syrup is a Schedule V controlled substance as designated by Health and Safety Code section 11058, subdivision (c)(1), and is used to treat cough.

30. "Norco" is a brand name for hydrocodone bitartrate and acetaminophen and is used to treat pain. Norco is a Schedule II controlled substance pursuant to Title 21, CFR, section 1308.12.

31. "Xanax," a brand name for alprazolam, is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(1). Xanax is used to treat anxiety.

32. "Dolophine", a brand name for methadone, is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (c)(14). Dolophine is used to treat pain.

33. "Soma", a brand name for carisoprodol, is a Schedule IV Controlled Substance as designated by Title 21, CFR, section 1308.14, subdivision (c)(6), and is used to treat muscle spams.

34. All of the above controlled substances are dangerous drugs pursuant to section 4022.

**STATEMENT OF FACTS**

35. On or about June 2, 2015, a Board inspector went to West Coast Pharmacy to conduct an inspection. There were several employees working in the pharmacy at that time, including pharmacy technicians, TCH K., TCH O.G., TCH S., and TCH J.G. Respondent Nguyen was the only pharmacist on duty.

36. The inspector observed two large safes located near the south side counter. The left safe contained Schedule III to V controlled substances and certain expensive non-controlled medications; the right safe contained Schedule II controlled substances. The doors to both safes were unlocked during the entire inspection. The inspector observed TCH K. remove controlled substances from the safes, take them to the front filling counter, and replace drugs in the safes throughout the inspection. The safes were not visible from the front filling counter where Respondent Nguyen was working. Respondent Nguyen admitted that the safes were unlocked while she was in the pharmacy and that the technicians had access to them. On two occasions, the inspector observed delivery drivers enter the pharmacy (the drivers collected prescriptions for delivery) and visit with pharmacy employees. One of the drivers walked past the drug safes and entered the bathroom.

37. The inspector asked Respondent Nguyen if there were ever any prescription errors made in the pharmacy. Respondent Nguyen admitted that some prescription errors had occurred within the last year, that the most recent error had occurred within the last month, and that she did not document the error.

38. TCH S. was working next to the cash register and handled almost all of the transactions. The inspector observed TCH S. repeatedly ask patients who were picking up medications whether they had any questions for the pharmacist. TCH S. told the inspector later that she was trained to ask the question on new prescriptions, which had an "N" on the receipt.

After each transaction, TCH S. put a portion of the receipt in the trash. The inspector retrieved 15 receipts, 14 of which were marked with an "N", indicating that they were new prescriptions. The inspector did not see Respondent Nguyen consult any patients during the entire inspection.

39. TCH K. was working at the front counter, filling prescriptions and placing the baskets to her left or on the floor for Respondent Nguyen to verify. On multiple occasions, the inspector observed TCH O.G. pull drugs from the drug shelves or the drug order delivery totes and place them in prescription baskets. TCH O.G. would then take the baskets to the front filling counter and place them on the counter or on the floor between Respondent Nguyen and TCH K.

40. The inspector reviewed various prescription documents on file at the pharmacy, including prescription number 228880, dated May 26, 2015, which had been written for 100 tablets of oxycodone 30 mg. Respondent Nguyen told the inspector that she filled the prescription and that it was dispensed to the patient. Respondent Nguyen stated that she did not fill all controlled substance prescriptions. Respondent Nguyen retrieved a copy of a prescription dated May 7, 2015, that she refused to fill after calling the prescriber and determining that it had been forged. The forged prescription matched prescription number 228880 in several respects. Respondent Nguyen admitted that she should have verified the prescription.

41. The inspector examined the compounding area and found that there was no compounding self assessment in the pharmacy. There were also expired drugs and drug products above and below the compounding counter, which the inspector later determined had been used in the preparation of certain compounded prescriptions and dispensed to patients. Several expired drugs were labeled with a retest date.[1] The inspector asked Respondent Nguyen if any of the drugs which were past their retest date had been tested. Respondent Nguyen admitted that they had not been tested.

42. When the pharmacy was closed, the inspector had Respondent Nguyen complete a count of the stock on hand of four drugs, methadone 10 mg, hydrocodone/APAP 10/325 mg, oxycodone 30 mg and alprazolam 2 mg. Respondent Nguyen counted the pharmacy's inventory

[1] Drugs which are labeled with a retest date must be tested for stability before the retest date is reached. Without a stability test, the drugs are not assured to be of suitable integrity.

of the drugs and noted them on a form provided by the inspector. Respondent Nguyen gave the inspector a controlled substance inventory dated May 29, 2014. The inspector requested the pharmacy's disposition records for the period from May 29, 2014 to June 2, 2015.

43. On or about June 3, 2015, the inspector called Respondent Nguyen and requested copies of two completed Report of Theft or Loss of Controlled Substances (DEA 106) forms which he found during the inspection. Respondent Nguyen faxed the inspector copies of both forms, one dated September 4, 2014, and the other dated October 9, 2014. The forms indicated that the pharmacy had been broken into at night and that certain controlled substances, guaifenesin/codeine syrup, promethazine/codeine syrup, carisoprodol 350 mg, and alprazolam (in various doses), had been stolen. Respondent Nguyen told the inspector she completed the DEA forms and estimated the total loss on each form. Respondent Nguyen admitted that she did not conduct a subsequent inventory to determine the exact amount of the losses or report the thefts to the Board. That same day, Respondent Nguyen provided the inspector with the pharmacy's disposition records, an invoice for controlled substances received on June 3, 2015, a drug inventory conducted by Respondent Nguyen on June 3, 2015, and a dispensing record for June 3, 2015. Respondent Nguyen admitted the thefts were not reported to the Board.

44. In or about June 2015, the inspector requested and obtained sales and credit information from three of the pharmacy's wholesalers.

45. On or about July 27, 2015, the inspector received an email from Respondent Nguyen, admitting that minor errors had occurred in the pharmacy, such as miscounts, "wrong NDC's" or wrong sizes, and that she had not completed incident reports of the errors.

46. The inspector determined based on the dispensing records, the records provided by the wholesalers, the drug inventories, the DEA 106 forms, and the June 3, 2015 invoice that the pharmacy had significant shortages of 5 of 12 controlled substances and notable overages of 5 of the 12 drugs for the audit period from May 29, 2014 to June 3, 2015, as set forth below in paragraph 49, subparagraph (b).

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## FIRST CAUSE FOR DISCIPLINE

**(Failure to Maintain Pharmacy, Fixtures, and Equipment so that Drugs Were Safely and Properly Secured)**

47. Respondents West Coast Pharmacy, Nguyen and Le are subject to disciplinary action pursuant to section 4301, subdivisions (o) and (j), for unprofessional conduct, in that Respondents failed to maintain the pharmacy and its facilities, space, fixtures and/or equipment so that drugs were safely and properly secured, in violation of Title 16, CCR, section 1714, subdivision (b), and failed to store Schedule II, III, IV, and V Controlled Substances in securely locked, substantially constructed cabinets, in violation of Title 21, CFR, section 1301.75, subdivision (b), as follows:

a. On or about September 4, 2014, Respondent Nguyen completed a DEA 106 form, indicating that the pharmacy had been broken into at night and that 2,365 milliliters (ml) of guaifenesin/codeine syrup and 6,622 ml of promethazine/codeine syrup had been taken. Further, Respondents failed to safely and properly secure the pharmacy to prevent additional thefts of controlled substances, as follows: On or about October 9, 2014, Respondent Nguyen completed a DEA 106 form, indicating that the pharmacy had once again been broken into at night and that 500 tablets of alprazolam 0.25 mg, 500 tablets of alprazolam 0.5 mg, 2,000 tablets of alprazolam 1 mg, 500 tablets of alprazolam 2 mg, 1,000 tablets of carisoprodol 350 mg, and 1,892 ml of guaifenesin/codeine syrup had been taken.

b. Respondents stored their complete inventory of controlled substances in two safes which were unlocked, as set forth in paragraph 35 above, and placed the safes in a location or position, enabling pharmacy technicians to access the controlled substances without being observed and supervised by a pharmacist. Further, on two occasions during the inspection of June 2, 2015, delivery drivers entered the pharmacy and had access to the drug stock area and safes without supervision by the pharmacist.

c. On and between May 29, 2014 and June 3, 2015, Respondents failed to maintain their premises so that drugs were secured from theft or other types of losses, resulting in significant shortages of the following controlled substances:

| Drug | Units | Shortage |
|---|---|---|
| alprazolam 0.25 mg | Tablets | -258 |
| alprazolam 0.5 mg | Tablets | -1,537 |
| alprazolam 2 mg | Tablets | -855 |
| oxycodone 30 mg | Tablets | -30 |
| | **Total** | **- 2,680** |
| promethazine/codeine liquid | ml | -10,381 |
| | **Total** | **-10,381** |

**SECOND CAUSE FOR DISCIPLINE**

**(Failure to Report Loss of Controlled Substances)**

48. Respondents West Coast Pharmacy, Nguyen and Le are subject to disciplinary action pursuant to section 4301, subdivision (o), for unprofessional conduct, in that Respondents violated Title 16, CCR, section 1715.6 by failing to report to the Board the thefts or losses of the controlled substances guaifenesin/codeine syrup, promethazine/codeine syrup, carisoprodol 350 mg, and alprazolam (various doses), as documented on the DEA 106 forms, within thirty (30) days of discovery of the losses.

**THIRD CAUSE FOR DISCIPLINE**

**(Failure to Maintain a Current Inventory of All Dangerous Drugs)**

49. Respondents West Coast Pharmacy, Nguyen and Le are subject to disciplinary action pursuant to section 4301, subdivision (o), for unprofessional conduct, in that Respondents violated sections 4081, subdivision (a), and 4105, subdivision (o), by failing to maintain an accurate or current inventory of all dangerous drugs in the pharmacy, as follows:

a. Respondents failed to conduct an inventory of their drug stock following the thefts of the controlled substances documented on the DEA 106 forms, as set forth in paragraph 43 above.

b. On and between May 29, 2014 and June 3, 2015, Respondents failed to maintain an accurate or current inventory of all dangerous drugs in the pharmacy, resulting in significant shortages and overages of the following controlled substances:

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| Drug | Shortage or Overage |
|---|---|
| alprazolam 0.25 mg | -258 tablets |
| alprazolam 0.5 mg | -1,537 tablets |
| alprazolam 1 mg | 261 tablets |
| alprazolam 2 mg | -855 tablets |
| guaifenesin/codeine liquid | 2,636 ml |
| hydrocodone/APAP 10/325 mg | 441 tablets |
| hydrocodone/APAP 5/325 mg | 755 tablets |
| methadone 10 mg | 120 tablets |
| oxycodone 30 mg | -30 tablets |
| promethazine/codeine liquid | -10,381 ml |

**FOURTH CAUSE FOR DISCIPLINE**

**(Failure to Provide Oral Consultation to Patients)**

50. Respondents West Coast Pharmacy, Nguyen and Le are subject to disciplinary action pursuant to section 4301, subdivision (o), for unprofessional conduct, in that Respondents violated Title 16, CCR, section 1707.2, subdivisions (a)(1) and (2) and (b)(1)(A) and (B), as follows: On or about June 2, 2015, during the inspection of West Coast Pharmacy, Respondent Nguyen failed to provide any oral consultations to patients despite the fact that at least 14 patients had picked up prescriptions which had been marked as new, as set forth in paragraph 38 above. Further, TCH S. was observed screening patients with new prescriptions by asking if they had any questions for the pharmacist.

**FIFTH CAUSE FOR DISCIPLINE**

**(Failure to Comply with Quality Assurance Program)**

51. Respondents West Coast Pharmacy, Nguyen and Le are subject to disciplinary action pursuant to section 4301, subdivision (o), for unprofessional conduct, in that Respondents violated Title 16, CCR, section 1711, as follows: Respondents failed to complete or have available at the pharmacy any records pertaining to medication errors, quality assurance reports or quality assurance reviews despite the fact that prescription errors had occurred in the pharmacy during the year prior to June 2, 2015, including miscounts, "wrong NDC's" or wrong sizes.

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**SIXTH CAUSE FOR DISCIPLINE**

**(Violation of the Pharmacy Law/Pharmacy Technician to Pharmacist Ratio)**

52. Respondents West Coast Pharmacy, Nguyen and Le are subject to disciplinary action pursuant to section 4301, subdivision (o), for unprofessional conduct, in that Respondents violated section 4115, subdivisions (d) and (f)(1), as follows: On or about June 2, 2015, during the inspection of West Coast Pharmacy, Respondents authorized or allowed TCH K. and TCH O.G. to perform pharmacy technician duties at the same time (TCH K. was observed filling prescriptions while TCH O.G. was removing dangerous drugs from the drug stock to be used for filling prescriptions) when, in fact, Respondent Nguyen was the only pharmacist on duty.

**SEVENTH CAUSE FOR DISCIPLINE**

**(Failure to Exercise Corresponding Responsibility with Regard to the Dispensing or Furnishing of Controlled Substances)**

53. Respondents West Coast Pharmacy, Nguyen and Le are subject to disciplinary action pursuant to sections 4301 and 4306.5 for unprofessional conduct in that Respondents failed to exercise or implement their best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances and dangerous drugs, as follows: On or about May 26, 2015, Respondents dispensed prescription number 228880 for 100 tablets of oxycodone for a patient without verifying the legitimacy of the prescription or ensuring that it was issued for a legitimate medical purpose despite irregularities in the prescription, including the distance from the prescriber and the patient to the pharmacy and the similarity between the prescription and the forged prescription dated May 7, 2015, identified in paragraph 40 above. The two prescriptions had the same pre-printed prescriber information, general format, prescription pad identifying number, drug, quantity, strength, and general directions. Further, the handwriting and signatures appeared the same.

**EIGHTH CAUSE FOR DISCIPLINE**

**(Dispensing a Prescription Containing Significant Error, Omission, Irregularity, etc.)**

54. Respondents West Coast Pharmacy, Nguyen and Le are subject to disciplinary action pursuant to section 4301, subdivision (o), for unprofessional conduct, in that Respondents

violated Title 16, CCR, section 1761, subdivision (a), as follows: Respondents dispensed a prescription containing significant irregularities without contacting the prescriber to obtain the information needed to validate the prescription, as set forth in paragraph 53 above.

**NINTH CAUSE FOR DISCIPLINE**

**(Failure to Complete Compounding Self-Assessment)**

55. Respondents West Coast Pharmacy, Nguyen and Le are subject to disciplinary action pursuant to section 4301, subdivision (o), for unprofessional conduct, in that Respondents violated Title 16, CCR, section 1735.2, subdivision (j), as follows: Respondents failed to complete or have available at the pharmacy a compounding self assessment, as set forth in paragraph 41 above.

**TENTH CAUSE FOR DISCIPLINE**

**(Compounding Prescription Drug Preparations Using Expired Drugs)**

56. Respondents West Coast Pharmacy, Nguyen and Le are subject to disciplinary action pursuant to section 4301, subdivision (o), for unprofessional conduct, in that Respondents violated Health and Safety Code section 111295 and Title 16, CCR, section 1735.2, subdivision (h), as follows:

a. Respondents and/or their pharmacy technicians compounded the following prescription drug preparations using drugs that were beyond their expiration date. Consequently, the drugs were adulterated and unsafe for patient use. Further, Respondents failed to test the expired drugs for stability, dispensed the prescriptions to patients, and gave the drugs a longer beyond use date than the expired components used in the drug preparations.

| Date | Ingredient | Lot No. | Documented expiration date | Beyond use date given for prescription |
|---|---|---|---|---|
| 03/27/2015 | estriol powder | 11151225 | 11/23/2014 | 09/27/2015 |
| 03/27/2015 | testosterone powder | 1302190904 | 06/08/2014 | 09/27/2015 |
| 04/23/2015 | testosterone cypionate powder | 1210010079 | 06/19/2014 | None documented |
| 05/08/2015 | testosterone powder | 1302190904 | 06/08/2014 | 11/08/2015 |
| 05/15/2015 | estriol powder | 11151225 | 11/23/2014 | 10/2015 |
| 05/15/2015 | testosterone powder | 1302190904 | 06/08/2014 | 10/2015 |
| 05/18/2015 | testosterone cypionate powder | 1210010079 | 06/19/2014 | 10/2015 |

b. Respondents and/or their pharmacy technicians prepared 13 compounded prescription preparations and stored them for future use in jars that were labeled for individual patients, some of which were dated as far back as June 22, 2011 (the beyond use dates on the prescription labels were handwritten). Further, some of these labeled compounded prescriptions had the date changed several times with progressively longer dates, and five of the products were expired past the last handwritten date. In addition, Respondents failed to conduct any stability studies to extend the beyond use dates of these compounded drug products.

**ELEVENTH CAUSE FOR DISCIPLINE**

**(Failure to Store Drugs/Components Used in Compounding in a Manner to Maintain their Integrity, Potency, Quality, and Labeled Strength)**

57. Respondents West Coast Pharmacy, Nguyen and Le are subject to disciplinary action pursuant to section 4301, subdivision (o), for unprofessional conduct, in that Respondents violated section 4342, subdivision (a), Health and Safety Code section 111295, and Title 16, CCR, section 1735.2, subdivision (g), as follows:

a. Respondents stored the following expired drugs, commonly used in compounding prescription preparations, on the drug stock shelves intermingled with non-expired drugs. Further, Respondents failed to test any drugs for stability in order to extend the manufacturer's labeled expiration dates.

| Drug | Package Size | Expiration or retest date |
|---|---|---|
| cyclobenzaprine HCL | 25 grams | Exp. 08/2014 |
| testosterone cypionate | 25 grams | Retest 06/19/2014 |
| testosterone micronized | 100 grams | Retest 06/08/2014 |
| 7-keto DHEA micronized | 25 grams | Retest 06/05/2014 |
| lidocaine HCL | 100 grams | Retest 12/27/2014 |
| liothyronine sodium | 250 milligrams | Retest 05/31/2014 |
| nifedipine | 5 grams | Retest 03/30/2014 |
| methyltestosterone | 5 grams | Exp. 12/2014 |
| amitriptyline HCL | 25 grams | Retest 03/2015 |

b. Respondents and/or their employees prepared 13 compounded prescription preparations and stored them for future use in jars that were labeled for individual patients, some of which were dated as far back as June 22, 2011. Further, five of the products were expired past

the last handwritten date on the prescription label.

c. Respondents stored a 30 gram size jar in the compounding area that was labeled "Biest" without any indication on the label as to the active ingredients, manufacturer, lot number or expiration date of the prescription drugs it contained. Further, on or about May 18, 2015, Respondents' employee, TCH J.G., used the "Biest" to compound a prescription preparation.

**TWELFTH CAUSE FOR DISCIPLINE**

**(Incompetence)**

58. Respondents West Coast Pharmacy, Nguyen and Le are subject to disciplinary action pursuant to section 4301, subdivision (b), for unprofessional conduct, in that Respondents committed acts or omissions constituting incompetence, as set forth in paragraphs 47 to 57 above.

**THIRTEENTH CAUSE FOR DISCIPLINE**

**(Gross Negligence)**

59. Respondents West Coast Pharmacy, Nguyen and Le are subject to disciplinary action pursuant to section 4301, subdivision (c), for unprofessional conduct, in that Respondents committed acts or omissions constituting gross negligence, as set forth in paragraphs 47 to 57 above.

**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 50531, issued to West Coast Pharmacy, Inc., doing business as West Coast Pharmacy;

2. Revoking or suspending Pharmacist License Number RPH 54305, issued to Kim Nguyen, also known as Kim Khanh Nguyen;

3. Revoking or suspending Pharmacist License Number RPH 50209, issued to Loan Mong Le;

4. Ordering West Coast Pharmacy, Inc., doing business as West Coast Pharmacy, Kim Nguyen, also known as Kim Khanh Nguyen, and Loan Mong Le to pay the Board of Pharmacy

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the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: 2/5/16

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

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