XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General
KEVIN W. BELL
Deputy Attorney General
State Bar No. 192063
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 445-6064
Facsimile: (916) 327-8643
E-mail: Kevin.Bell@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Accusation Against: **DISCOUNT PHARMACY AND MEDICAL SUPPLY; VAN THI NGUYEN,** **OWNER/PHARMACIST-IN-CHARGE** **703 FULTON STREET NO. 201** **FRESNO, CA 93728** **PHARMACY LICENSE NO. PHY 43116** **AND** **VAN THI NGUYEN,** **1445 N. OXFORD AVE** **CLOVIS, CA 93619** **LICENSE NO. RPH 48645** Respondents.	Case No. 6032 **ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about September 5, 1997, the Board of Pharmacy issued Pharmacy Permit Number PHY 43116 to Van T. Nguyen, Discount Pharmacy and Medical Supply (Respondent). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2017, unless renewed.

3. On or about March 21, 1996, the Board of Pharmacy issued Original Pharmacist License Number RPH 48645 to Van Thi Nguyen (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2018, unless renewed.

JURISDICTION

4. 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.

5. Section 4300 of the Code states:

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

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

(1) Suspending judgment.

(2) Placing him or her upon probation.

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

(4) Revoking his or her license.

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

6. 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.

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

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 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 as follows:

(1) Where a probationary license is issued or where as exhisting 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 AND REGULATORY PROVISION

California Business and Professions Code

8. 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 issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

...

(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.

...

9. Section 4113, subdivision (c) of the Code states 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.

10. Section 4081 of the Code states:

(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.

11. Section 4115 of the Code states:

(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.

...

(e) No person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

12. Section 4306.5 of the Code provides in pertinent part that unprofessional conduct for a pharmacist may include any of the following:

(a) 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.

(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.

(c) 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.

California Code of Regulations

13. California Code of Regulations, title 16, section 1709.1, subdivision (a), states that:

The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.

14. California Code of Regulations, title 16, section 1711, states in pertinent part that:

(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.
...

(c) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.
...

(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.

...

15. California Code of Regulations, title 16, section 1714, subdivision (b), states that:

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.

16. California Code of Regulations, title 16, section 1715 states in pertinent part that

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

...

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

17. California Code of Regulations, title 16, section 1761, states that:

(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.

California Health and Safety Code

18. Health and Safety Code section 11153, subdivision (a), states, in pertinent part that:

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 . . . ."

//

COST RECOVERY

19. Code 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.

CONTROLLED SUBSTANCES

20. "Alprazolam" is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(1).

21. "Hydrocodone/Acetaminophen" is a Schedule III controlled substance as designated by Health and Safety Code section 11056, subdivision (e)(5), and a Schedule II controlled substance as designated by Title 21 Code of Federal Regulations 1308.12.

22. "Promethazine with Codeine Syrup" is a Schedule V controlled substance as designated by Health and Safety Code section 11058, subdivision (c)(1).

STATEMENT OF FACTS

23. An audit of controlled substances conducted by Board Inspector S.K. found Respondents ordered high quantities of Promethazine with Codeine Syrup. The review of Respondent's CURES[1] data showed that Respondent had dispensed numerous controlled substance prescriptions from prescribers in the Southern California area, which is more than 200 miles from Respondent. A review of the audit uncovered indications of possible trends of dispensing controlled substances with apparent irregularities and red flags of abuse or misuse, including controlled substances prescribed by out of area prescribers and dispensed to out of area patients. Based on that information the Board opened an investigation.

24. On or about June 30, 2016, Board Inspectors S.K. and I.T. went to Discount Pharmacy and Medical Supply, located at 703 Fulton Street No. 201, Fresno, CA 93728, to

[1] The Controlled Substance Utilization Review and Evaluation System (CURES) is a database containing information on Schedule II through IV controlled substances dispensed in California. It is a valuable investigative, preventive, and educational tool for the healthcare community, regulatory boards, and law enforcement.

conduct an inspection. Present were Van Nguyen, Pharmacist-in-Charge (Respondent), S.S., TCH, and K.T., pharmacy clerk.

25. Upon arrival, Inspectors S.K. and I.T. observed unlicensed pharmacy clerk K.T. counting ibuprofen 800 mg tablets from a 500 tablet bottle, repackaging 90 tablets at a time into 40 dram-size vials. K.T. told inspector S.K. that she had worked for Respondent for three weeks; that she was not a pharmacist technician; that had never enrolled in pharmacy technician training program or school; and that she had never received any training prior to starting work at Respondent's place of business. Inspector observed a document posted on the wall directly in front of and to the left of K.T. entitled "Pharmacy Clerk Policies and Procedures" that stated in part "May Not: Count, pour, mix, and pre-pack any medications under any form." Respondent told Inspector S.K. that she allowed K.T. to count medications because Respondent was busy, and Respondent did not think that counting medications was considered filling.

26. During the inspection Inspectors S.K. and I.T. observed shelves on the west wall of the pharmacy which held baskets of the following prescription and non-prescription drugs, the following of which were not labeled:

a. HCTZ 25 mg (prescription)

b. ibuprofen 800 mg (prescription)

c. docusate sodium 100 mg (non-prescription)

d. loratadine 10 mg ((non-prescription)

e. Vitamin D3 2000 IU (non-prescription)

27. During the inspection Respondent gave Inspector S.K. a binder which contained a copy of a self-assessment of the pharmacy's compliance with state and federal pharmacy law dated June 29, 2013. There was no current self-assessment maintained in the pharmacy. When asked about the current self-assessment, Respondent stated that she took it home to fill out but was too busy and did not complete it.

28. During the inspection, Inspector S.K. reviewed the records of Respondent related to prescription errors, and noted that there were no completed reports or reviews of prescription errors. Respondent stated that they had very few errors. When asked, Respondent stated that the

last error occurred about one month prior involving the miscount of metformin (a prescription diabetes drug). Respondent stated that she did not complete an error report, and had never completed any error reports for prescription errors.

29. Inspector S.K. reviewed Respondent's electronic dispensing records from February 15, 2014 through June 30, 2016, as well as CURES records from June 1, 2013 through June 20, 2016. The inspector identified two prescribers, Dr. Clyde Arnold and Salvatore DiRaffaele, PA, as having prescribed an unusually high number of controlled substance prescriptions.

30. Dr. Clyde Arnold is licensed by the California Medical Board as a practicing physician and surgeon. On October 16, 2014, an Order was issued by the Los Angeles Superior Court for Dr. Arnold to no longer write prescriptions. On December 15, 2014, an Accusation was filed which detailed gross negligence, incompetence, excessive prescribing, and unprofessional conduct related to the treatment of patients with controlled substances. On August 27, 2016, Dr. Clyde Arnold signed a Stipulated Surrender of License, which became effective on September 23, 2016 when the California Medical Board adopted its Decision and Order in that matter. As to the prescriptions written by Dr. Arnold and filled by Respondents:

a. Dr. Clyde Arnold has a listed address in Los Angeles, 225 miles away from Respondents, with a three hour and forty-five minute time of travel.

b. Between February 20, 2014 and September 19, 2014, 200 prescriptions written by Dr. Arnold were dispensed to 32 different patients by Respondents.

c. All of these patients had addresses in the greater Los Angeles area, which is over a three hour drive from Respondents.

d. All of these patients were prescribed only one or a combination of three drugs, all commonly sought drugs of abuse: hydrocodone/APAP 10/325 (the highest strength available), alprazolam 2 mg (the highest strength available), and promethazine/codeine syrup.

e. There were numerous instances where groups of identical or similar prescriptions were processed by Respondents in the same day and in sequential order.

f. No non-controlled substances were prescribed.

f. All of the prescriptions were for cash payment.

g. There was in insufficient verification and/or resolution of the irregularities, drug interactions, and red flags of abuse. Also, Salvatore DiRaffaele, PA stated he would have identified any calls seeking verification as fraudulent prescriptions.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct –Corresponding Responsibility)

32. Respondents Discount Pharmacy and Medical Supply and Van Nguyen are subject to disciplinary action pursuant to Code sections 4301 and 4306.5, subsection (b) for unprofessional conduct, in that Respondents failed to exercise or implement their corresponding responsibility with regard to the dispensing or furnishing of controlled substances and dangerous drugs for a legitimate medical purpose, as follows: On or about and between February 20, 2014 and September 24, 2014, Respondents dispensed at least 775 prescriptions for hydrocodone/APAP 10/325, alprazolam 2 mg, and promethazine/codeine syrup in a manner as set forth in paragraphs 27-29 above, in violation of Health and Safety Code section 11153, subdivision (a) and Title 21, Code of Federal Regulations, section 1306.04, subsection (a).

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Failure to Exercise Best Professional Judgment)

33. Respondents Discount Pharmacy and Medical Supply and Van Nguyen are subject to disciplinary action pursuant to sections 4301 and 4306.5, subsection (b) for unprofessional conduct, in that Respondents failed to exercise or implement their best professional judgment with regard to the dispensing or furnishing of controlled substances and dangerous drugs, as follows: On or about and between February 20, 2014 and September 24, 2014, Respondents dispensed at least 775 prescriptions for hydrocodone/APAP 10/325, alprazolam 2 mg, and promethazine/codeine syrup in a manner as set forth in paragraphs 27-29 above, in violation of Health and Safety Code section 11153, subdivision (a) and Title 21, Code of Federal Regulations, section 1306.04, subsection (a).

//

g. All of the prescriptions were for cash payment.

h. There was no indications of verification and/or resolution of the irregularities, drug interactions, and red flags of abuse.

31. Salvatore DiRaffaele, PA is a licensed physician's assistant and is listed on the prescription forms of Dr. Steven M. Kaye, who is licensed by the California Medical Board as a practicing physician and surgeon. The inspector contacted Salvatore DiRaffaele, who told him that he no longer worked for Dr. Kaye; that while working for Dr. Kaye prescription pads with his name on it had been stolen; that he was aware of many fraudulent prescriptions; and that whenever pharmacies would call him regarding those prescriptions he would confirm they were fraudulent. As to the prescriptions written by Salvatore DiRaffaele, PA and Dr. Kaye and filled by Respondents:

a. The address listed on the prescription forms for Dr. Kaye and Salvatore DiRaffaele, PA shows offices in the Los Angeles communities of Van Nuys, Woodland Hills, Valley Village, and Anaheim, locations that are all over three hours away from Respondents.

b. Between February 26, 2014 and September 24, 2014, 575 prescriptions allegedly written by Salvatore DiRaffaele, PA and Dr. Kaye were dispensed to 110 different patients by Respondents.

c. All of these patients except one had addresses in the greater Los Angeles area, which is over a three hour drive from Respondents: the only patient from outside of the Los Angeles area had an address in Conyers, Georgia.

d. Of the 575 prescriptions, 3 were allegedly written by Dr. Kaye and 572 were written by Salvatore DiRaffaele, PA. All but ten of the 572 prescriptions written by Salvatore DiRaffaele, PA were for only one or a combination of three drugs, all commonly sought drugs of abuse: hydrocodone/APAP 10/325 (the highest strength available), alprazolam 2 mg (the highest strength available), and promethazine/codeine syrup.

e. There were numerous instances where groups of identical or similar prescriptions were processed by Discount Pharmacy in the same day and in sequential order.

THIRD CAUSE FOR DISCIPLINE

(Clearly Excessive Furnishing of Controlled Substances)

34. Respondents Discount Pharmacy and Medical Supply and Van Nguyen are subject to disciplinary action pursuant to section 4301, subdivisions (d), for unprofessional conduct, in that on or about and between February 20, 2014 and September 24, 2014, Respondents clearly excessively furnished controlled substances, including hydrocodone/APAP 10/325, alprazolam 2 mg, and promethazine/codeine syrup in a manner as set forth in paragraphs 27-29 above, in violation of Health and Safety Code section 11153, subdivision (a) as set forth in paragraphs 27-29 above.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct –

Failure to Comply With All State and Federal Laws and Regulations)

35. Respondents Discount Pharmacy and Van Nguyen are subject to disciplinary action under section 4113, subsection (c) for their failure to comply with all state and federal laws and regulations pertaining to the practice of pharmacy based on the following:

a. Respondents Discount Pharmacy and Van Nguyen allowed an unlicensed employee to perform duties of a pharmacy technician in violation of Code section 4115(a) and (e) as set forth in paragraph 23 above;

b. Respondents Discount Pharmacy and Van Nguyen failed to maintain their facilities, space, fixtures and equipment so that drugs are properly prepared, maintained, secured, and distributed in violation of California Code of Regulations, title 16, section 1714, subdivision (b) as set forth in paragraph 24 above;

c. Respondents Discount Pharmacy and Van Nguyen failed to establish and participate in an established quality assurance program which documents and assesses medication errors in violation of California Code of Regulations, title 16, section 1711 as set forth in paragraph 26 above; and

d. Respondents Discount Pharmacy and Van Nguyen failed to complete (before July 1 of every odd-numbered year) and keep on file (for a period of three years) a self-

assessment of the pharmacy's compliance with federal and state pharmacy law in violation of California Code of Regulations, title 16, section 1715 as set forth in paragraph 25 above.

OTHER MATTERS

36. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 43116 issued to Discount Pharmacy and Medical Supply, Van T. 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 43116 is placed on probation or until Pharmacy Permit Number PHY 43116 is reinstated if it is revoked.

37. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 43116 issued to Discount Pharmacy and Medical Supply, while Van T. Nguyen has been an officer and owner and had knowledge of or knowingly participated in any conduct for which the license was disciplined, Van T. 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 43116 is placed on probation or until Pharmacy Permit Number PHY 43116 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 43116 and License Number RPH 48645, issued to Van T. Nguyen, Discount Pharmacy and Medical Supply;

2. Revoking or suspending Pharmacist License Number RPH 48645, issued to Van T. Nguyen;

3. Prohibit Van T. Nguyen from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43116 is placed on probation or until Pharmacy Permit Number PHY 43116 is reinstated if it is revoked.

4. Ordering Van T. Nguyen 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; and,

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

DATED: 5/15/17

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

SA2017105063
NguyenAccusation2.docx