KAMALA D. HARRIS
Attorney General of California
ARMANDO ZAMBRANO
Supervising Deputy Attorney General
ALVARO MEJIA
Deputy Attorney General
State Bar No. 216956
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-0083
Facsimile: (213) 897-2804
Attorneys for Complainant

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

In the Matter of the Accusation Against: **INSTITUTIONAL PHARMACY SOLUTIONS** **6520 N. Irwindale Ave., Ste 228** **Irwindale, CA 91702** **Pharmacy Permit No. PHY 50371,** **and** **MINH TRI VAN NGUYEN** **2473 Halsey Ave.** **New Orleans, LA 70114** **Pharmacist License No. RPH 61858** Respondent.	Case No. 5240 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about October 7, 2010, the Board of Pharmacy issued Pharmacy Permit Number PHY 50371 to Institutional Pharmacy Solutions ("Respondent Institutional Pharmacy"). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2016, unless renewed.

3. On or about October 23, 2008, the Board of Pharmacy issued Pharmacist License Number RPH 61858 to Minh Tri Van Nguyen ("Respondent Nguyen"). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2016, 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, 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.

"(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."

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STATUTES AND REGULATIONS

7. 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:

. . . .

"(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.

"(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

. . . .

"(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."

8. Section 4076 of the Code states, in pertinent part:

"(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

. . . .

(7) The strength of the drug or drugs dispensed."

9. California Code of Regulations, title 16, section 1717.3 states:

"(a) No person shall dispense a controlled substance pursuant to a preprinted multiple check-off prescription blank.

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"(b) A person may dispense a dangerous drug, that is not a controlled substance, pursuant to a preprinted multiple checkoff prescription blank and may dispense more than one dangerous drug, that is not a controlled substance, pursuant to such a blank if the prescriber has indicated on the blank the number of dangerous drugs he or she has prescribed.

"(c) "Preprinted multiple checkoff prescription blank," as used in this section means any form listing more than one dangerous drug where the intent is that a mark next to the name of a drug i.e., a "checkoff," indicates a prescription order for that drug."

10. California Code of Regulations, title 16, section 1735.2, subdivision (h) states:

"(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."

11. California Code of Regulations, title 16, section 1735.3, subdivision (a) states:

"(a) For each compounded drug product, the pharmacy records shall include:

"(1) The master formula record.

"(2) The date the drug product was compounded.

"(3) The identity of the pharmacy personnel who compounded the drug product.

"(4) The identity of the pharmacist reviewing the final drug product.

"(5) The quantity of each component used in compounding the drug product.

"(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia--National

Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

"(7) A pharmacy assigned reference or lot number for the compounded drug product.

"(8) The expiration date of the final compounded drug product.

"(9) The quantity or amount of drug product compounded.

12. California Code of Regulations, title 16, section 1735.6 states:

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

"(b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.

"(c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy."

13. United States Code, title 21, section 353 states, in pertinent part:

"(c) Sales restrictions.

"(1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d), the term "drug sample" means a unit of a drug, subject to subsection (b), which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.

. . . .

"(d) Distribution of drug samples.

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"(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term "distribute" does not include the providing of a drug sample to a patient by a--

"(A) practitioner licensed to prescribe such drug,

"(B) health care professional acting at the direction and under the supervision of such a practitioner, or

"(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).

"(2) (A) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. . . ."

14. Code of Federal Regulations, title 21, section 1306.04 states:

"(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his 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. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

"(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

"(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the

Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.28 of this chapter."

COST RECOVERY

15. 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

CONTROLLED SUBSTANCE

16. Ketamine is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (g) and is a dangerous drug pursuant to Business and Professions Code section 4022.

FIRST CAUSE FOR DISCIPLINE

(Unlawful Use of Pre-Printed, Multi-Check Off Prescription Blanks for Controlled Substances)

17. Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1717.3, on the grounds of unprofessional conduct in that during routine Board inspections of Respondent Institutional Pharmacy on November 15, 2012 and January 9, 2013, a Board Inspector discovered that Respondent Institutional Pharmacy accepted prescription orders for compounded drugs containing Ketamine, a Schedule III controlled substance, on pre-printed, multiple check-off prescription blanks. Multiple dangerous drugs were dispensed by the Respondents pursuant to the prescription blanks, but the prescriber did not indicate on the prescription blanks the number of dangerous drug that he or she had prescribed.

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SECOND CAUSE FOR DISCIPLINE

(Fraud or Deceit)

18. Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivisions (f) and (g) on the grounds of unprofessional conduct in that during a routine Board inspection of Respondent Institutional Pharmacy on November 15, 2012, a Board Inspector discovered that Respondent Institutional Pharmacy had pre-printed order forms listing compounded formulations giving indications (i.e., uses of the compounded drug product) not approved by the Federal Drug Administration.

THIRD CAUSE FOR DISCIPLINE

(Improper Distribution of Drug Samples)

19. Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivision (j), in conjunction with United States Code, title 21, section 353, subdivisions (c) and (d), on the grounds of unprofessional conduct in that Respondent Institutional Pharmacy distributed samples of drugs to prescribers at no charge. Applicable rules and regulations prohibit the distribution of drug samples by anyone other than: (1) practitioners licensed to prescribe such drugs; (2) health care professionals acting at the direction and under the supervision of such a practitioner; (3) a pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner; or (4) the manufacturer or authorized distributor of record of the drug. Respondent Pharmacy does not fall into any of these categories. Nevertheless, as a result of a routine Board inspection of Respondent Institutional Pharmacy on November 15, 2012 and subsequent investigation, a Board Inspector discovered that Respondent Institutional Pharmacy distributed unauthorized samples of multiple compounded drugs. Furthermore, during 2012, Respondent Institutional Pharmacy sent sales representatives to make presentations about Respondent Institutional Pharmacy's products, specifically cancer chemotherapy drugs, and subsequently distributed by mail, samples of the products to attendees of the presentations.

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FOURTH CAUSE FOR DISCIPLINE

(Dispensing Controlled Substances Without a Prescription)

20. Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivision (j), in conjunction with Code of Federal Regulations, title 21, section 1306.04, on the on the grounds of unprofessional conduct in that on or about November 15, 2012, a routine Board inspection of Respondent Institutional Pharmacy revealed that the pharmacy dispensed a compounded drug product, to wit, Rx# 102530, containing Ketamine, a Schedule III controlled substance, for the purpose of supplying an individual practitioner a prescription to be generally dispensed to patients.

FIFTH CAUSE FOR DISCIPLINE

(Compounding Facilities and Equipment)

21. Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.6, in that on or about November 15, 2012, a routine Board inspection of Respondent Institutional Pharmacy revealed that the equipment in Respondent Institutional Pharmacy was not maintained according to manufacturer's specifications. Respondent Institutional Pharmacy was using alcohol to clean the powder hood and scale when the manufacturer's manual stated, "10% bleach/water or acrylic cleaner. No solvents of any kind." The routine inspection also revealed that the calibration and cleaning of equipment was not documented and that the weighing scale and powder hood showed powder residue under the scale platform and the side walls of the hood.

SIXTH CAUSE FOR DISCIPLINE

(Prescription Container Not Meeting Labeling Requirements)

22. Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Code section 4076, subdivision (a)(7), on the grounds of unprofessional conduct in that on or about January 9, 2013, a routine Board inspection of Respondent Institutional Pharmacy revealed that the prescription containers labels failed to indicate the strength of the drugs dispensed.

SEVENTH CAUSE FOR DISCIPLINE

(No Expiration Date for Compounded Drugs)

23. Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.2, subdivision (h), on the grounds of unprofessional conduct in that on or about January 9, 2013, a routine Board inspection of Respondent Institutional Pharmacy revealed that the compounding worksheet for Lot #551 for peripheral neuropathy cream, dispensed as RX #103382, did not have an expiration date.

EIGHTH CAUSE FOR DISCIPLINE

(Improper Record Keeping of Compounded Drugs)

24. Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.3, subdivision (a)(1), on the grounds of unprofessional conduct in that on or about January 9, 2013, a routine Board inspection of Respondent Institutional Pharmacy revealed that the master formula record for Lot #1331 was not available.

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 50371, issued to Institutional Pharmacy Solutions;

2. Revoking or suspending Pharmacist License Number RPH 61858, issued to Minh Tri Van Nguyen;

3. Ordering Respondent Institutional Pharmacy Solutions 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;

4. Ordering Respondent Minh Tri Van 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;

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

DATED: 4/8/16

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

DOJ Matter ID: LA2014512809
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