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BEFORE THE BOARD OF PHARMACY
STATE OF CALIFORNIA

In the Matter of the Interim Suspension Order Against: **OROVILLE HOSPITAL PHARMACY** **2767 Olive Highway** **Oroville, CA 95966** **Original Permit No. HSP 41557** **Original Sterile Compounding Permit No. LSC 100404** **DANIEL QUOC NGUYEN** **1825 Ringnecked Pheasant Court** **Gridley, CA 95948** **Pharmacist License No. RPH 43487** **VICTOR MICHAEL MINETTI** **1392 Eagle Ln.** **Plumas Lake, CA 95961** **Pharmacist License No. RPH 35419** **SUSAN SCHMIDT** **167 Solana Dr** **Oroville, CA 95966** **Pharmacist License No. RPH 58496** **CHAD RAMOS** **23 Avenida Brisa Ct.** **Chico, CA 95928** **Pharmacist License No. RPH 67245**	Case No. 5630 **ACCUSATION**

SON NGUYEN
767 Bridlewood Ct.
Chico, CA 95926
Pharmacist License No. RPH 62061

SAMUEL TONG
3249 Mystery Run
Chico, CA 95973
Pharmacist License No. RPH 62917

JASMINE DONG
2090 Sea Cliff Way
San Bruno, CA 94066
Pharmacist License No. RPH 69270

Respondents.

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 August 30, 1996, the Board of Pharmacy issued Original Permit Number HSP 41557 to Oroville Hospital Pharmacy (Respondent Oroville). The Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2016, unless renewed.

3. On or about June 30, 2014, the Board of Pharmacy issued Original Sterile Compounding Permit Number LSC 100404 to Oroville Hospital Pharmacy (Respondent Oroville). The Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2016, unless renewed.

4. On or about July 26, 1990, the Board of Pharmacy issued Pharmacist License No. RPH 43487 to Daniel Quoc Nguyen, (Respondent Daniel Nguyen). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2016, unless renewed.

5. On or about August 13, 1990, the Board of Pharmacy issued Pharmacist License No. RPH 35419 to Victor Michael Minetti, (Respondent Minetti). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 29, 2018, unless renewed.

6. On or about August 3, 2006, the Board of Pharmacy issued Pharmacist License No. RPH 58496 to Susan Schmidt, (Respondent Schmidt). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2017, unless renewed.

7. On or about July 19, 2012, the Board of Pharmacy issued Pharmacist License No. RPH 67245 to Chad Miller Ramos, (Respondent Ramos). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2017, unless renewed.

8. On or about December 26, 2008, the Board of Pharmacy issued Pharmacist License No. RPH 62061 to Son Thia Nguyen, (Respondent Son Nguyen). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2018, unless renewed.

9. On or about August 13, 2009, the Board of Pharmacy issued Pharmacist License No. RPH 62917 to Samuel Tong, (Respondent Tong). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2017, unless renewed.

10. On or about August 21, 2013, the Board of Pharmacy issued Pharmacist License No. RPH 69270 to Jasmine Brittany Dong, (Respondent Dong). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on December 31, 2016, unless renewed.

JURISDICTION

11. 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.

12. 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.

13. Section 4301 of the Code states:

"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:

"(a) Gross immorality.

"(b) Incompetence.

"(c) Gross negligence.

"(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.

"(p) Actions or conduct that would have warranted denial of a license.

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

14. Section 4342 of the Code states in pertinent part:

(a) 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).

15. Section 4073 of the Code provides:

(a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription

Marked, "Do not substitute"; provided that the prescriber personally initials the box or checkmark. To indicate that a section may not be made pursuant to this section for an electric data transmission prescription as defined in subdivision (c) of section 440, a prescriber may indicate "Do not substitute," or words similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that prohibition on substitution be manually initialed by the prescriber.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The person who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section. In no case shall the pharmacist select a drug product pursuant to this section unless the drug product selected costs the patient less than the prescribed drug product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 1400) of Part 3 of Division 9 of the Welfare and Institution Code..

(e) When a substitution is made pursuant to this section, the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug product shall be indicated on the prescription label, except where the prescriber orders otherwise.

16. Health and Safety Code Section 111295 provides:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

17. Health and Safety Code Section 111255 provides:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

18. California Code of Regulations Section 1707.1 provides:

(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.

(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours.

(A) The patient's full name and address, telephone number, date of birth (or age) and gender;

(B) For each prescription dispensed by the pharmacy:

1. The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;

2. The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;

3. The date on which a drug was dispensed or refilled;

4. The prescription number for each prescription; and

5. The information required by section 1717.

(C) Any of the following which may relate to drug therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.

(D) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

(2) The patient medication record shall be maintained for at least one year from the date when the last prescription was filled.

19. California Code of Regulations Section 1712 provides:

(a) Any requirement in this division for a pharmacist to initial or sign a prescription record or prescription label can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means. The computer

used to record the reviewing pharmacist's identity shall not permit such a record to be altered after it is made.

(b) The record of the reviewing pharmacist's identity made in a computer system pursuant to subdivision (a) of this section shall be immediately retrievable in the pharmacy.

20. California Code of Regulations Section 1716 provides:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code..

Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription

21. California Code of Regulations Section 1735.2 provides:

(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" as used in Business and Professions Code section 4052(a) (1) means that amount of compounded drug product that:

(1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and

(2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

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

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

(4) Inactive ingredients to be used.

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

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

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

(e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.

(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

(g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia 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.

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

(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.

22. California Code of Regulations Section 1751.1 provides:

(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.

(b) In addition to the records required by section 1735.3 and subdivision

(a). for sterile products compounded from one or more non-sterile ingredients, the following records must be made and kept by the pharmacy:

(1) The training and competency evaluation of employees in sterile product procedures.

(2) Refrigerator and freezer temperatures.

(3) Certification of the sterile compounding environment.

(4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.

(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

FACTUAL BACKGROUND

23. On or about July 6, 2015, Board of Pharmacy inspectors performed an inspection of Oroville Hospital Pharmacy (LSC 100404) located at 2767 Olive Highway, Oroville, California. The initial inspection revealed violations of pharmacy law pertaining to the Oroville Pharmacy's compounding of drugs and the storage of said drugs. An inspection was performed on July 30, 2015 and violations were reviewed with the Pharmacist-in-Charge Daniel Nguyen and his staff and a Cease and Desist Order was issued. On September 18, 2015, a follow-up inspection was performed in which it was discovered there were several continuing violations pertaining to the compounding of sterile drugs.

INSPECTION OF JULY 6 AND JULY 30, 2015

FIRST CAUSE FOR DISCIPLINE

(Drugs Lacking in Quality or Strength)

24. Respondent Oroville Hospital is subject to disciplinary action under Business and Professions Code section 4342 section in conjunction Health and Safety Code Section 111295 and 111255, in that on or about July 30, 2015, sterile compounded drugs were stored under conditions which did not conform to the standard set forth to maintain quality and strength of the drugs. The circumstances are as follows:

25. On or about July 30, 2015, pharmacists at Oroville Hospital stored the dry powdered form of piperacillin/tazobactamTI, ceftriaxone, cefoxitin, ceftazidime, ceftarolin fosamil, aztreonam, oxacillin, meropenem, ampicillin/sulbactam, doxycycline, and azithromycin under refrigerated conditions of 4 to 6 degrees Celsius instead of at room temperature of 15 to 30 degrees Celsius. These drugs were stored in the refrigerator for an unknown and undocumented length of time. In addition, vancomycin and penicillin G were thawed in the refrigerator and kept beyond the acceptable 30 and 14 days expiration date, respectively.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct/ False Documents)

26. Respondent Oroville Hospital and Pharmacist-in Charge (hereinafter PIC) Nguyen are subject to disciplinary action pursuant to section 4301 subdivisions (c) and (g) for unprofessional conduct for knowingly making or signing any certificate or other document that falsely represents the existence or non- existence of a state of facts as set forth more specifically below:

A. Compounding self-assessment: On or about July 13, 2013 and June 30, 2015, Pharmacist-in Charge (hereinafter PIC) Nguyen signed the Compounding self-assessment form indicating the pharmacy was in compliance with pharmacy laws, when in truth and in fact, it was not.

B. PIC Nguyen provided a document entitled Policy and Procedure review on July 30, 2015, which indicated he had reviewed the policies and procedures on July 16, 2015, when the same document was provided to the Board on July 23, 2015, without a signature.

C. On July 6, 2015, the cleaning log for the compounding area for July of 2015 listed four of six days in which there was no documentation of cleaning. On July 30, 2015, the same log had blank dates filled in on the log, thereby falsifying the cleaning log.

D. Training of compounding personnel: On July 6, 2015 and July 21, 2015, PIC Nguyen had not ensured all personnel had demonstrated written competence of the handling of sterile compounded products, including cytotoxic agents. In fact, there was no evidence of training for any cytotoxic compounding personnel.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct/ Insufficient Training of Staff)

27. Respondent Oroville Hospital and PIC Nguyen are subject to disciplinary action pursuant to Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulations, sections 1751.6 and 1735.7 for unprofessional conduct in that they failed to

properly train staff assigned to compounding drug products: The compounding staff repeatedly demonstrated they had no training in aseptic garbing, the documentation required of sterile compounding products, and requirements appropriate for cleaning the compounding area and equipment.

Additionally, respondents failed to properly train staff and ensure demonstrated written competence of the safe compounding of cytotoxic agents.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct/ Compounding Limitations)

28. Respondent Oroville Hospital and PIC Nguyen are subject to disciplinary action pursuant to Business and Professions Code section 4301 subdivisions (c) and (g) for unprofessional conduct in that during the Inspection on July 6, 2015, the Board of Pharmacy Inspectors found compounded drug products which had beyond use dates on the products that exceeded expectations outlined in California Code of Regulations Section 1735.2 (h) as it relates to California Code of Regulations section 1751.4 (a) and 1250.4. Additionally the compounding area was dirty, all areas were not non-porous, an air conditioner was vented through a window located to the right of the laminar flow hood blowing directly in front of the hood, and a biological safety cabinet was located in a non-ISO environment.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct/ Sterile Recordkeeping Requirements)

29. Respondent Oroville Hospital and PIC Nguyen are subject to disciplinary action pursuant to Business and Professions Code section 4301 (o) and (j) in conjunction with Title 16, California Code of Regulations section 1751.1 for unprofessional conduct in that they failed to comply with sterile injectable recordkeeping requirements as set forth below:

30. On or about July 6, 2015, and July 30, 2015, during Board inspections it was found that Oroville Pharmacy through its staff compounded drug products without maintaining pharmacy records to include a master formula, date the drug product was compounded, the identity of the pharmacy personnel who compounded the drug product, the identity of the pharmacist reviewing the final drug product, the manufacturer, expiration date and lot number of each component, the

pharmacy assigned reference or lot number for the compounded drug product, the quantity or amount of drug product compounded and all records were not retrievable for three years.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct/ Failure to label Compounded drug products)

31. Respondent Oroville Hospital and PIC Nguyen are subject to disciplinary action pursuant to Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulations section 1735.4 for unprofessional conduct in that they dispensed compounded products without appropriate labeling. The circumstances are as follows:

32. On or about on July 6, 2015, compounded drug product labels intended for dispensing to patients in the infusion center did not contain a patient name, the pharmacy name, compounded by the pharmacy, directions, total volume dispensed, name of the prescriber, and the date of issue. In additions, drugs were compounded for future use and stored in the refrigerator without any label affixed to the container in order to identify the compounded drug.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct/ Compounding in an unsafe environment)

33. Respondent Oroville Hospital and PIC Nguyen are subject to disciplinary action pursuant to Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulations section 1751.4 for unprofessional conduct in they permitted compounding of sterile injectable products where it was known, or reasonably should be known that the compounding environment failed to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products dispensed compounded products without appropriate labeling. The circumstances are as follows:

34. On or about July 6, 2015, compounding at Oroville Hospital was conducted in a designated area that was not clean, the designated area was not cleaned weekly, and an air conditioner was vented from a window located next to the laminar flow hood. The staff was not garbed appropriately, in that, masks, beard covers, head covers, and sterile gloves were

not worn in order to facilitate an aseptic environment. Additionally, Process validation as outlined in the policies and procedures for Oroville Hospital was not followed.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct/ Failure to maintain policies and procedures for cytotoxic agents)

35. Respondent Oroville Hospital and PIC Nguyen are subject to disciplinary action pursuant to Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulations section 1751.3 (a) (5) (c) for unprofessional conduct in that they failed to maintain policies and procedures for cytotoxic agents as required by law.

NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct/ Quality Assurance)

36. Respondent Oroville Hospital and PIC Nguyen are subject to disciplinary action pursuant to Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulation section 1751.7 for unprofessional conduct in that hospital staff conducted cytotoxic compounding despite the fact that no personnel had completed a validation process in the biologic safety cabinet used for compounding cytotoxic drug products and a validation process had not been conducted in the prior twelve months as required by regulation.

Additionally, respondents failed to produce a documented quality assurance plan for cleaning and sanitization of the parenteral medication preparation area. Daily cleaning was not completed or documented completed medium samples were incubated but not evaluated as required by the policies and procedures in place. Batch compounding was conducted under "immediate use" conditions without periodic end product testing for sterility.

TENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct/ Patient Medical Records)

37. Respondent Oroville Hospital and PIC Nguyen are subject to disciplinary action pursuant to Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulations section 1707.1 for unprofessional conduct in that they failed to maintain patient records in an electronic or manual form to identify compounded medications patients

received. Additionally the hospital pharmacy did not maintain records to record the identity of compounding personnel.

ELEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct/ PIC Nguyen)

38. Respondent PIC Nguyen is subject to disciplinary action pursuant to Business and Professions Code section 4306.5 (a) for unprofessional conduct as follows;

A. PIC Nguyen failed to maintain medication in that he failed medication profiles to identify patient specific sterile compounded products.

B. PIC Nguyen failed to store dangerous drugs under controlled room temperature, thus demonstrating a lack of knowledge of storage conditions.

C. PIC Nguyen failed to ensure proper incubation and evaluation of media samples provided to the lab of compounded drugs thereby rendering the samples invalid.

D. PIC Nguyen failed to maintain medication profiles.

TWELFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct/ Staff Pharmacist Victor Minetti)

39. Respondent Minetti is subject to disciplinary action pursuant to Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulations sections 1735.4 (a) and 1751.1, for unprofessional conduct as follows:

A. On or about July 6, 2015, Respondent Minetti dispensed dexamethasone which was compounded for infusion but he failed to list a patient name, the pharmacy name, that it was compounded by the pharmacy, directions, total volume dispensed, name of the prescriber, and the date of issue.

B. On or about July 6, 2015, Respondent Minetti, while working at Oroville Hospital Pharmacy located at 2767 Olive Highway, Oroville compounded drug products without maintaining pharmacy records to include a master formula, date the drug product was compounded, the identity of the pharmacy personnel who compounded the drug product, the identity of the pharmacist reviewing the final drug product, the manufacturer, expiration date and lot number of each component, the pharmacy assigned reference or lot number for the compounded drug product, the quantity or amount of drug product compounded.

THIRTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct/ Staff Pharmacists)

40. Respondent Schmidt, Tong, and Dong are subject to disciplinary action pursuant to Business and Professions code section 4306.5 (b) in conjunction with Title 16, California Code

of Regulations section 1735.2 (f) for unprofessional conduct in that they supervised compounding and/ or compounded drugs on July 6, 2015, at Oroville Hospital under conditions which did not meet the minimum requirements for compounding products.

FOURTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct/ Staff Pharmacists)

41. Respondent Ramos and Son Nguyen are subject to disciplinary action pursuant to Business and Professions code section 4306.5 (b) in conjunction with Title 16, California Code of Regulations section 1735.2 (f) for unprofessional conduct in that they supervised and/ or compounded drugs on July 30, 2015, at Oroville Hospital under conditions which did not meet the minimum requirements for compounded products.

INSPECTION OF SEPTEMBER 18, 2015

FIFTEENTH CAUSE FOR DISCIPLINE

(Gross Negligence/Incompetence)

42. Respondent Oroville Hospital and PIC Nguyen are subject to disciplinary action under Business and Professions Code section 4301 (b) and (c) for gross negligence and/ or incompetence in the dispensing of compounded drug products. The circumstances are as follows:

A. Respondents Oroville Hospital and PIC Nguyen permitted the dispensing of compounded drugs that were expired in that they were dispensed compounded drugs as immediate use when they were dispensed after an hour had expired.

B. Respondents Oroville Hospital and PIC Nguyen permitted the dispensing of medium risk compounded drugs when the documentation maintained by the pharmacy supported low risk compounding.

C. Respondents Oroville Hospital and PIC Nguyen the dispensing of chemotherapy drugs which were not have proper documentation or demonstrated compounding processes as required by statute.

SIXTEENTH CAUSE FOR DISCIPLINE

(Gross Negligence/Incompetence/Compounding)

43. Respondent Oroville Hospital and PIC Nguyen are subject to disciplinary action pursuant to Business and Professions Code section 4301 (b) and (c) for gross negligence and/ or

incompetence in that they permitted the dispensing of compounded drug products which did not ensure the integrity, potency, and quality of compounded Bevacizumab, Zometa, Iron sucrose, vancomycin, Ancef, and Claforan. The circumstances are as follows:

A. On or about July 7, 2015 and September 17, 2015, Bevacizumab, was compounded for patient FS with a total volume of 114ml instead of 100ml The volume altered the final concentration of the compounded drug product.

B. On or about September 17, 2015, Zometa was compounded for patient J.M. in 100ml of sodium chloride instead of the prescribed 250ml. The volume altered the final concentration of the compounded drug product.

C. Iron Sucrose was compounded improperly for the following patients: M.G. on or about July 7 and 9, 2015, M.V. on or about July 28, 2015, R.T. on or about July 29, 2015, T.R. on or about July 7, 2015, T.D. on or about August 3 and 13, 2015, C.S. on or about August 13, 2015, and R.R. on August 13, 2015. Iron Sucrose was compounded in 100 ml of sodium chloride instead of the prescribed 250ml. The volume altered the final concentration of the compounded drug product.

D. Vancomycin, Ancef, and Clarforan, were not reconstituted with the manufacturer's instruction thereby altering the integrity, potency, and quality of the final product.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Gross Negligence/Incompetence/ Pharmacist Identifiers)

44. Respondent Oroville Hospital and PIC Nguyen are subject to disciplinary action pursuant to Business and Professions Code section 4301 (b) and (c) for gross negligence and/ or incompetence in that they failed to maintain records which identified the identity of the reviewing pharmacist on a prescription or prescribers order in violation of Title 16 California Code of Regulations section 1712 (a).

EIGHTEENTH CAUSE FOR DISCIPLINE

(Gross Negligence/Incompetence/Failure to comply with Review Process for Compounding)

45. Respondent Oroville Hospital and PIC Nguyen are subject to disciplinary action pursuant to Business and Professions Code section 4301 (b) and (c) for gross negligence in conjunction with Title 16, California Code of Regulations section 1735.2 and 1751.3 (b), in that from February 26, 2015 to September 21, 2015, compounded drugs did not meet the requirements for proper preparation and review in that there were calculation errors such that the final drug product strengths did not correspond with the components and qualities listed on the compounding logs.

Such errors should have been reviewed by a pharmacist prior to dispensing said compounded drugs to patients.

NINETEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct/Variation from Prescription)

46. Respondent Victor Minetti is subject to disciplinary action pursuant to Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulations section 1716 and 1735.2 (f) in that he compounded the following drugs incorrectly and failed to obtain consent of the prescriber for the deviation:

A. On or about July 11, 2015, in reference number 6849057, Respondent Victor Minetti compounded potassium phosphate prescribed as 163.5mm but the final product was potassium phosphate 32.7 mm.

B. On or about August 16, 2015, in reference number 8571v64, Respondent Victor Minetti compounded lacosamide 200mg with a 20ml dose but labeled it lacosamide 100mg.

C. On or about August 16, 2015, in reference number 122885v71, Respondent Victor Minetti compounded with octreotide 200 mcg in 250ml NS but labeled the final product octreotide 625mg.

D. On or about September 18, 2015 and September 21, 2015, Respondent Victor Minetti compounded Bevacizumab with a total volume of 114ml instead of 100ml. The volume altered the final concentration of the compounded drug product.

E. On or about September 18, 2015 and September 21, 2015, Respondent Victor Minetti compounded Iron Sucrose in 100ml of sodium chloride instead of the prescribed 250ml. of sodium chloride. The volume altered the final concentration of the compounded drug product.

TWENTIETH CAUSE FOR DISCIPLINE

(Unprofessional Conduct/Variation from Prescription)

47. Respondent Susan Schmidt is subject to disciplinary action pursuant to Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulation section 1716 and 1735.2 in that she compounded the following drugs incorrectly and failed to obtain consent of the prescriber for the deviation:

A. Respondent Susan Schmidt failed to constitute vancomycin in accordance with the manufacturers reference numbers 8582v41 and 25816v26, thereby altering the final compounded drug product

B. Respondent Susan Schmidt had errors on the following compounded

prescriptions: September 17, 2015 reference number 205647v7; August 17, 2015, reference number 14275v441; July 22, 2015, reference number 37484v86; July 21, 2015, reference numbers 37484v77 and 154055v2.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct/Variation from Prescription)

48. Respondent Samuel Tong is subject to disciplinary action pursuant to Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulation section 1716 and 1735.2 in that he compounded the following drugs incorrectly and failed to obtain consent of the prescriber for the deviation:

A. On or about July 11, 2015, Respondent Samuel Tong compounded KCL 20meq instead of the stated product of KCL 10meq.

B. On or about July 11, 2015, Respondent Samuel Tong compounded Folic acid 5mg. instead of the stated product Folic acid 2mg.

TWENTY-SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct/Variation from Prescription)

49. Respondent Jasmine Dong is subject to disciplinary action pursuant to Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulation section 1716 and 1735.2 in that she compounded the following drugs incorrectly and failed to obtain consent of the prescriber for the deviation:

A. On or about July 10, 2015, Respondent Jasmine Dong compounded Versed 25 mg but labeled the final product Versed 100 mg.

B. On or about July 10, 2015, Respondent Jasmine Dong compounded Glassia 7.6gm but labeled the final product Glassia1gm.

C. On or about July 10, 2015, Respondent Jasmine Dong compounded vancomycin 750mg instead of the stated product vancomycin 1750mg.

D. On or about July 10, 2015, Respondent Jasmine Dong compounded sodium phosphate 30mm but labeled the final product sodium phosphate 20mm.

E. On or about August 18, 2015, Respondent Jasmine Dong compounded hydromorphone 12.5mg but labeled the final product Dilaudid 50mg.

F. On or about July 22, 2015, Respondent Jasmine Dong compounded Emend without a stated strength but labeled the final product Emend 150 mg.

TWENTY-THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct/Variation from Prescription)

50. Respondent Son Nguyen is subject to disciplinary action pursuant to Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulation section 1716 and 1735.2 in that he compounded the following drugs incorrectly and failed to obtain consent of the prescriber for the deviation:

A. On or about September 17, 2015, Respondent Son Nguyen compounded Bevacizumab with a volume of 114m., instead of 100ml. The volume altered the final concentration of the compounded drug product

B. On or about September August 13, 2015, Respondent Son Nguyen compounded Iron Sucrose in 100ml of sodium instead of the prescribed 250ml of sodium. The volume altered the final concentration of the compounded drug product

C. On or about July 30, 2015, Respondent Son Nguyen compounded Crofad 4mg in 50ml of NS instead of the prescribed Crofab 2mg in 250ml NS.

D. On an unknown date, Respondent Son Nguyen compounded penicillin 10MU instead of the prescribed penicillin 6 MU.

TWENTY-FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct/Review of Compounded Products)

51. Respondents Victor Minetti, Susan Schmidt, Chad Ramos, Son Nguyen, Samuel Tong, and Jasmine Dong are subject to disciplinary action pursuant to Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulation section 1751.3 (b) and 1735.2 (f) in that records obtained from February 26, 2015 to September 21, 2015, demonstrate that Respondent Schmidt failed to properly review compounded products in that there were calculation errors in compounded products dispensed; components and quantities listed on compounding logs did not correspond to the stated strength of the final product or label.

OTHER MATTERS

To determine the degree of discipline, if any, to be imposed on Respondent Daniel Quoc Nguyen, Complainant alleges that on or about January 28, 1993, in a prior disciplinary action entitled In the Matter of the Accusation Against: Daniel Quoc Nguyen before the Board of Pharmacy, in Case Number 1612, Respondent's license was revoked stayed and placed on three years probation for stealing testosterone, Anadrol and Nolvadex in 1991 while employed at CVS

Pharmacies in Orange County. That decision is now final and is incorporated by reference as if fully set forth.

Additionally, Respondent Daniel Quoc Nguyen was issued Citation No. CI 2013 61899 and fined in the amount of $2,500 for a violation of Business and Professions Code section 4312 subd, (a) & (e) for having an issued and valid permit when the pharmacy was not built or open.

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 Original Permit Number HSP 41557, issued to Oroville Hospital Pharmacy;

2. Revoking or suspending Original Sterile Compounding Permit Number LSC 100404, issued to Oroville Hospital Pharmacy;

3. Revoking or suspending Pharmacist License No. RPH 43487 to Daniel Quoc Nguyen;

4. Revoking or suspending Pharmacist License No. RPH 35419 issued to Victor Michael Minetti;

5. Revoking or suspending Pharmacist License No. RPH 58496 issued to Susan Schmidt;

6. Revoking or suspending Pharmacist License No. RPH 67245 issued to Chad Miller Ramos;

7. Revoking or suspending Pharmacist License No. RPH 62061 issued to Son Thia Nguyen;

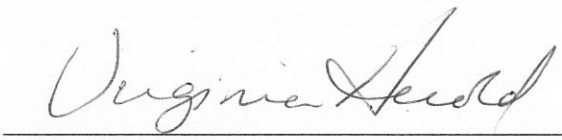
8. Revoking or suspending Pharmacist License No. RPH 62917 to Samuel Tong,

9. Revoking or suspending Pharmacist License No. RPH 69270 issued to Jasmine Brittany Dong;

10. Ordering Respondents Oroville Hospital; Daniel Quoc Nguyen; Victor Michael Minetti; Susan Schmidt; Chad Miller Ramos; Son Thia Nguyen; and Jasmine Brittany Dong 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;

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

DATED: 6/13/16



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

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