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8 **BEFORE THE BOARD OF PHARMACY**
9 **STATE OF CALIFORNIA**

10 In the Matter of the Interim Suspension Order Case No. 5630
11 Against:

12 **OROVILLE HOSPITAL PHARMACY** **ACCUSATION**
13 **2767 Olive Highway**
14 **Oroville, CA 95966**
15 **Original Permit No. HSP 41557**
16 **Original Sterile Compounding Permit No.**
17 **LSC 100404**

18 **DANIEL QUOC NGUYEN**
19 **1825 Ringnecked Pheasant Court**
20 **Gridley, CA 95948**
21 **Pharmacist License No. RPH 43487**

22 **VICTOR MICHAEL MINETTI**
23 **1392 Eagle Ln.**
24 **Plumas Lake, CA 95961**
25 **Pharmacist License No. RPH 35419**

26 **SUSAN SCHMIDT**
27 **167 Solana Dr**
28 **Oroville, CA 95966**
Pharmacist License No. RPH 58496

CHAD RAMOS
23 Avenida Brisa Ct.
Chico, CA 95928
Pharmacist License No. RPH 67245

1 **SON NGUYEN**
2 **767 Bridlewood Ct.**
3 **Chico, CA 95926**
4 **Pharmacist License No. RPH 62061**

5 **SAMUEL TONG**
6 **3249 Mystery Run**
7 **Chico, CA 95973**
8 **Pharmacist License No. RPH 62917**

9 **JASMINE DONG**
10 **2090 Sea Cliff Way**
11 **San Bruno, CA 94066**
12 **Pharmacist License No. RPH 69270**

13 Respondents.

14 Complainant alleges:

15 **PARTIES**

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

18 2. On or about August 30, 1996, the Board of Pharmacy issued Original Permit Number HSP
19 41557 to Oroville Hospital Pharmacy (Respondent Oroville). The Permit was in full force and
20 effect at all times relevant to the charges brought herein and will expire on August 1, 2016, unless
21 renewed.

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

26 4. On or about July 26, 1990, the Board of Pharmacy issued Pharmacist License No. RPH
27 43487 to Daniel Quoc Nguyen, (Respondent Daniel Nguyen). The Pharmacist License was in
28 full force and effect at all times relevant to the charges brought herein and will expire on July 31,
2016, unless renewed.

1 5. On or about August 13, 1990, the Board of Pharmacy issued Pharmacist License No. RPH
2 35419 to Victor Michael Minetti, (Respondent Minetti). The Pharmacist License was in full force
3 and effect at all times relevant to the charges brought herein and will expire on February 29,
4 2018, unless renewed.

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

9 7. On or about July 19, 2012, the Board of Pharmacy issued Pharmacist License No. RPH
10 67245 to Chad Miller Ramos, (Respondent Ramos). The Pharmacist License was in full force
11 and effect at all times relevant to the charges brought herein and will expire on September 30,
12 2017, unless renewed.

13 8. On or about December 26, 2008, the Board of Pharmacy issued Pharmacist License No.
14 RPH 62061 to Son Thia Nguyen, (Respondent Son Nguyen). The Pharmacist License was in full
15 force and effect at all times relevant to the charges brought herein and will expire on March 31,
16 2018, unless renewed.

17 9. On or about August 13, 2009, the Board of Pharmacy issued Pharmacist License No. RPH
18 62917 to Samuel Tong, (Respondent Tong). The Pharmacist License was in full force and effect
19 at all times relevant to the charges brought herein and will expire on July 31, 2017, unless
20 renewed.

21 10. On or about August 21, 2013, the Board of Pharmacy issued Pharmacist License No. RPH
22 69270 to Jasmine Brittany Dong, (Respondent Dong). The Pharmacist License was in full force
23 and effect at all times relevant to the charges brought herein and will expire on December 31,
24 2016, unless renewed.

25 JURISDICTION

26 11. This Accusation is brought before the Board of Pharmacy (Board), Department of
27 Consumer Affairs, under the authority of the following laws. All section references are to the
28 Business and Professions Code unless otherwise indicated.

1 12. Section 4300 of the Code states in pertinent part:

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

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

5 "(1) Suspending judgment.

6 "(2) Placing him or her upon probation.

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

9 "(4) Revoking his or her license.

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

11 13. Section 4301 of the Code states:

12 "The board shall take action against any holder of a license who is guilty
13 of unprofessional conduct or whose license has been procured by fraud or
misrepresentation or issued by mistake. Unprofessional conduct shall include, but is
14 not limited to, any of the following:

15 "(a) Gross immorality.

16 "(b) Incompetence.

17 "(c) Gross negligence.

18 "(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
19 a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

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

21 "(j) The violation of any of the statutes of this state, or any other state, or
22 of the United States regulating controlled substances and dangerous drugs.

23 "(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
24 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
25 federal regulatory agency.

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

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

28

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

2 (a) The board may institute any action or actions as may be provided by
3 law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical
4 preparations and drugs that do not conform to the standard and tests as to quality and
5 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).

6 15. Section 4073 of the Code provides:

7 (a) A pharmacist filling a prescription order for a drug product prescribed by its trade
8 or brand name may select another drug product with the same active chemical
9 ingredients of the same strength, quantity, and dosage form, and of the same generic
10 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.

11 (b) In no case shall a selection be made pursuant to this section if the prescriber
12 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

13 Marked, "Do not substitute"; provided that the prescriber personally initials the box
14 or checkmark. To indicate that a selection may not be made pursuant to this section for
an electric data transmission prescription as defined in subdivision (c) of section
15 440, a prescriber may indicate "Do not substitute," or words similar meaning, in the
16 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.

17 (c) Selection pursuant to this section is within the discretion of the pharmacist, except
18 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
19 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
20 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
21 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
22 professional fee that may be charged by the pharmacist.

23 (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
24 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..

25 (e) When a substitution is made pursuant to this section, the use of the cost-saving
26 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
27 prescriber orders otherwise.
28

1 16. Health and Safety Code Section 111295 provides:

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

4 17. Health and Safety Code Section 111255 provides:

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

8 18. California Code of Regulations Section 1707.1 provides:

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

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

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

18 (B) For each prescription dispensed by the pharmacy:

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

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

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

24 4. The prescription number for each prescription; and

25 5. The information required by section 1717.

26 (C) Any of the following which may relate to drug therapy: patient
27 allergies, idiosyncrasies, current medications and relevant prior medications including
28 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

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

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

6 20. California Code of Regulations Section 1716 provides:

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

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

13 21. California Code of Regulations Section 1735.2 provides:

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

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

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

26 (1) is sufficient for administration or application to patients in the
27 prescriber's office, or for distribution of not more than a 72-hour supply to the
28 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.

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

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

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

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

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

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

14 (h) Every compounded drug product shall be given an expiration date
15 representing the date beyond which, in the professional judgment of the pharmacist
16 performing or supervising the compounding, it should not be used. This "beyond use
17 date" of the compounded drug product shall not exceed 180 days from preparation or
18 the shortest expiration date of any component in the compounded drug product,
19 unless a longer date is supported by stability studies of finished drugs or compounded
20 drug products using the same components and packaging. Shorter dating than set
21 forth in this subsection may be used if it is deemed appropriate in the professional
22 judgment of the responsible pharmacist.

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

26 (i) Prior to allowing any drug product to be compounded in a pharmacy,
27 the pharmacist-in-charge shall complete a self-assessment for compounding
28 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:

23 (a) Pharmacies compounding sterile injectable products for future use
24 pursuant to section 1735.2 shall, in addition to those records required by section
25 1735.3, make and keep records indicating the name, lot number, amount, and date on
26 which the products were provided to a prescriber.

27 (b) In addition to the records required by section 1735.3 and subdivision
28

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

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

4 (2) Refrigerator and freezer temperatures.

5 (3) Certification of the sterile compounding environment.

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

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

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

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

12 **FACTUAL BACKGROUND**

13 23. On or about July 6, 2015, Board of Pharmacy inspectors performed an inspection of
14 Oroville Hospital Pharmacy (LSC 100404) located at 2767 Olive Highway, Oroville, California.
15 The initial inspection revealed violations of pharmacy law pertaining to the Oroville Pharmacy's
16 compounding of drugs and the storage of said drugs. An inspection was performed on July 30,
17 2015 and violations were reviewed with the Pharmacist-in-Charge Daniel Nguyen and his staff
18 and a Cease and Desist Order was issued. On September 18, 2015, a follow-up inspection was
19 performed in which it was discovered there were several continuing violations pertaining to the
20 compounding of sterile drugs.

21 **INSPECTION OF JULY 6 AND JULY 30, 2015**

22 **FIRST CAUSE FOR DISCIPLINE**

23 **(Drugs Lacking in Quality or Strength)**

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

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

8 **SECOND CAUSE FOR DISCIPLINE**

9 **(Unprofessional Conduct/ False Documents)**

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

14 A. Compounding self-assessment: On or about July 13, 2013 and June
15 30, 2015, Pharmacist-in Charge (hereinafter PIC) Nguyen signed the Compounding
16 self-assessment form indicating the pharmacy was in compliance with pharmacy
17 laws, when in truth and in fact, it was not.

18 B. PIC Nguyen provided a document entitled Policy and Procedure
19 review on July 30, 2015, which indicated he had reviewed the policies and procedures
20 on July 16, 2015, when the same document was provided to the Board on July 23,
21 2015, without a signature.

22 C. On July 6, 2015, the cleaning log for the compounding area for July of
23 2015 listed four of six days in which there was no documentation of cleaning. On July
24 30, 2015, the same log had blank dates filled in on the log, thereby falsifying the
25 cleaning log.

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

29 **THIRD CAUSE FOR DISCIPLINE**

30 **(Unprofessional Conduct/ Insufficient Training of Staff)**

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

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

3 **SIXTH CAUSE FOR DISCIPLINE**

4 **(Unprofessional Conduct/ Failure to label Compounded drug products)**

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

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

15 **SEVENTH CAUSE FOR DISCIPLINE**

16 **(Unprofessional Conduct/ Compounding in an unsafe environment)**

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

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

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

3 **EIGHTH CAUSE FOR DISCIPLINE**

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

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

9 **NINTH CAUSE FOR DISCIPLINE**

10 **(Unprofessional Conduct/ Quality Assurance)**

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

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

22 **TENTH CAUSE FOR DISCIPLINE**

23 **(Unprofessional Conduct/ Patient Medical Records)**

24 37. Respondent Oroville Hospital and PIC Nguyen are subject to disciplinary action pursuant
25 to Business and Professions Code section 4301 (j) and (o) in conjunction with Title 16, California
26 Code of Regulations section 1707.1 for unprofessional conduct in that they failed to maintain
27 patient records in an electronic or manual form to identify compounded medications patients
28

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

3 **ELEVENTH CAUSE FOR DISCIPLINE**

4 **(Unprofessional Conduct/ PIC Nguyen)**

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

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

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

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

12 D. PIC Nguyen failed to maintain medication profiles.

13 **TWELFTH CAUSE FOR DISCIPLINE**

14 **(Unprofessional Conduct/ Staff Pharmacist Victor Minetti)**

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

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

21 B. On or about July 6, 2015, Respondent Minetti, while working at
22 Oroville Hospital Pharmacy located at 2767 Olive Highway, Oroville compounded
23 drug products without maintaining pharmacy records to include a master formula,
24 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.

25 **THIRTEENTH CAUSE FOR DISCIPLINE**

26 **(Unprofessional Conduct/ Staff Pharmacists)**

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

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

4 **FOURTEENTH CAUSE FOR DISCIPLINE**

5 **(Unprofessional Conduct/ Staff Pharmacists)**

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

11 **INSPECTION OF SEPTEMBER 18, 2015**

12 **FIFTEENTH CAUSE FOR DISCIPLINE**

13 **(Gross Negligence/Incompetence)**

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

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

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

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

28 **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

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

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

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

10 C. Iron Sucrose was compounded improperly for the following patients:
11 M.G. on or about July 7 and 9, 2015, M.V. on or about July 28, 2015, R.T. on or
12 about July 29, 2015, T.R. on or about July 7, 2015, T.D. on or about August 3 and
13 13, 2015, C.S. on or about August 13, 2015, and R.R. on August 13, 2015. Iron
14 Sucrose was compounded in 100 ml of sodium chloride instead of the prescribed
15 250ml. The volume altered the final concentration of the compounded drug product.

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

19 SEVENTEENTH CAUSE FOR DISCIPLINE

20 (Gross Negligence/Incompetence/ Pharmacist Identifiers)

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

26 EIGHTEENTH CAUSE FOR DISCIPLINE

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

28 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.

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

3 **NINETEENTH CAUSE FOR DISCIPLINE**

4 **(Unprofessional Conduct/Variation from Prescription)**

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

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

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

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

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

18 E. On or about September 18, 2015 and September 21, 2015, Respondent
19 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.

20 **TWENTIETH CAUSE FOR DISCIPLINE**

21 **(Unprofessional Conduct/Variation from Prescription)**

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

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

28 B. Respondent Susan Schmidt had errors on the following compounded

1 prescriptions: September 17, 2015 reference number 205647v7; August 17, 2015,
2 reference number 14275v441; July 22, 2015, reference number 37484v86; July 21,
3 2015, reference numbers 37484v77 and 154055v2.

4 **TWENTY-FIRST CAUSE FOR DISCIPLINE**

5 **(Unprofessional Conduct/Variation from Prescription)**

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

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

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

14 **TWENTY-SECOND CAUSE FOR DISCIPLINE**

15 **(Unprofessional Conduct/Variation from Prescription)**

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

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

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

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

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

28 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.

1 **TWENTY-THIRD CAUSE FOR DISCIPLINE**

2 **(Unprofessional Conduct/Variation from Prescription)**

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

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

9 B. On or about September August 13, 2015, Respondent Son Nguyen
10 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

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

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

14 **TWENTY-FOURTH CAUSE FOR DISCIPLINE**

15 **(Unprofessional Conduct/Review of Compounded Products)**

16 51. Respondents Victor Minetti, Susan Schmidt, Chad Ramos, Son Nguyen, Samuel Tong,
17 and Jasmine Dong are subject to disciplinary action pursuant to Business and Professions Code
18 section 4301 (j) and (o) in conjunction with Title 16, California Code of Regulation section
19 1751.3 (b) and 1735.2 (f) in that records obtained from February 26, 2015 to September 21, 2015,
20 demonstrate that Respondent Schmidt failed to properly review compounded products in that
21 there were calculation errors in compounded products dispensed; components and quantities
22 listed on compounding logs did not correspond to the stated strength of the final product or label.

23 **OTHER MATTERS**

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

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

3 Additionally, Respondent Daniel Quoc Nguyen was issued Citation No. CI 2013 61899
4 and fined in the amount of \$2,500 for a violation of Business and Professions Code section 4312
5 subd, (a) & (e) for having an issued and valid permit when the pharmacy was not built or open.
6

7 **PRAYER**

8 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and
9 that following the hearing, the Board of Pharmacy issue a decision:

10 1. Revoking or suspending Original Permit Number HSP 41557, issued to Oroville
11 Hospital Pharmacy;

12 2. Revoking or suspending Original Sterile Compounding Permit Number LSC
13 100404, issued to Oroville Hospital Pharmacy;

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

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

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

20 6. Revoking or suspending Pharmacist License No. RPH 67245 issued to Chad
21 Miller

22 Ramos;

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

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

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

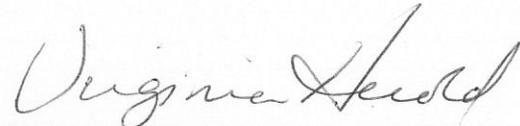
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10. Ordering Respondents Oroville Hospital; Daniel Quoc Nguyen; Victor Michael Minetti; Susan Schmidt; Chad Miller Ramos; Son Thia Nguyen; and Jasmine Brittany Dong to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement 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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