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

In the Matter of the Accusation Against:

OROVILLE HOSPITAL PHARMACY 2767 Olive Highway Oroville, CA 95966

Original Permit No. HSP 41557 Original Sterile Compounding License No. LSC 100404 Case No. 5630 & 5643

OAH No. 2016120865

STIPULATED SETTLEMENT AND DISCIPLINARY ORDER

(OROVILLE HOSPITAL PHARMACY ONLY)

Respondent.

DECISION AND ORDER

The attached Stipulated Settlement of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on August 10, 2017.

It is so ORDERED on July 11, 2017.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

1	XAVIER BECERRA	
2.	Attorney General of California KENT D. HARRIS	
3	Supervising Deputy Attorney General ELENA L. ALMANZO	
4	Deputy Attorney General State Bar No. 131058	
5	1300 I Street, Suite 125 P.O. Box 944255	
6	Sacramento, CA 94244-2550 Telephone: (916) 322-5524	
7	Faesimile: (916) 327-8643 Attorneys for Complainant	
8		RE THE
9	BOARD OF	PHARMACY ONSUMER AFFAIRS
10		CALIFORNIA
11		:
12	In the Matter of the Accusation Against:	Case No. 5630 & 5643
	OROVILLE HOSPITAL PHARMACY	OAH No. 2016120865
13	2767 Olive Highway Oroville, CA 95966	STIPULATED SETTLEMENT AND
14	Original Permit No. HSP 41557	DISCIPLINARY ORDER
15	Original Sterile Compounding Permit No. LSC 100404	(OROVILLE HOSPITAL PHARMACY ONLY)
16 17	Respondent.	·
18	IT IS HEREBY STIPULATED AND AG	REED by and between the parties to the above-
19	entitled proceedings that the following matters a	re true:
20	PAF	RTIES .
21	Virginia Herold (Complainant) is th	e Executive Officer of the Board of Pharmacy
22	(Board). She brought this action solely in her of	ficial capacity and is represented in this matter by
23	Xavier Becerra, Attorney General of the State of	f California, by Elena L. Almanzo, Deputy
24	Attorney General.	1
25	2. Respondent Oroville Hospital Pharr	nacy is represented in this proceeding by attorney
26	Peter Osinoff, Bonne, Bridges, Mueller, O'Keef	e & Nichols, whose address is: 355 South Grand
27	Ave., Ste. 1750, Los Angeles, CA 90071-1562	
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- 3. On or about August 30, 1996, the Board issued Original Permit No. HSP 41557 to Oroville Hospital Pharmacy. The Original Permit will expire August 1, 2017, unless renewed.
- 4. On or about June 30, 2014, the Board issued Original Sterile Compounding Permit No. LSC 100404 to Oroville Hospital Pharmacy. The Original Sterile Compounding Permit will expire August 1, 2017, unless renewed.

JURISDICTION

- 5. The First Amended Accusation No. 5630 & 5643 was filed before the Board, and is currently pending against Respondent. The First Amended Accusation and all other statutorily required documents were properly served on Respondent on September 27, 2016. Respondent Oroville Hospital Pharmacy timely filed its Notice of Defense contesting the Accusation.
- 6. A copy of the First Amended Accusation No. 5630 & 5643 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 7. Respondent Oroville Hospital Pharmacy has carefully read, fully discussed with counsel, and understands the charges and allegations in the First Amended Accusation No. 5630 & 5643. Respondent Oroville Hospital Pharmacy has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 8. Respondent Oroville Hospital Pharmacy is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.
- 9. Respondent Oroville Hospital Pharmacy voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

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CULPABILITY

- 10. Respondent Oroville Hospital Pharmacy understands and agrees that the charges and allegations in the Frist Amended Accusation No. 5630 & 5643, if proven at a hearing, constitute cause for imposing discipline upon its Original Permit, as well as, for its Original Sterile Compounding Permit.
- 11. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondent Oroville Hospital Pharmacy agrees that, at a hearing, Complainant could establish a factual basis for the charges in the First Amended Accusation, and that Respondent Oroville Hospital Pharmacy hereby gives up its right to contest those charges.
- 12. Respondent Oroville Hospital Pharmacy further agrees that in any future proceedings before the Board all allegations set forth in the First Amended Accusations shall be deemed admitted.
- 13. Respondent Oroville Hospital Pharmacy agrees that its Original Permit and its Original Sterile Compounding Permit are subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

Oroville Hospital Pharmacy understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent Oroville Hospital Pharmacy or its counsel. By signing the stipulation, Respondent Oroville Hospital Pharmacy understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

which involves respondent's Permit or Sterile Compounding Permit or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent owner shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent owner shall pay to the board its costs of investigation and prosecution in the amount of \$35,113. Respondent owner shall make said payments as follows: payment within thirty days of the effective date of

board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent owner shall not relieve respondent of their

the decision. There shall be no deviation from this schedule absent prior written approval by the

The filing of bankruptcy by respondent owner shall not relieve respondent of their responsibility to reimburse the board its costs of investigation and prosecution.

6. Probation Monitoring Costs

Respondent owner shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. Status of License

Respondent owner shall, at all times while on probation, maintain current licensure with the board. If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent owner's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent owner's license shall be subject to all terms and conditions of this probation not previously satisfied.

8: License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent owner discontinue business, respondent owner may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and

renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. Notice to Employees

Respondent owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent owner shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such

notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. Posted Notice of Probation

Respondent owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. Violation of Probation

If a respondent owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent license, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent owner violates probation in any respect, the board, after giving respondent owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary

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order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and the charges and allegations in the First Amended Accusation shall be deemed true and correct.

Consultant for Owner or Pharmacist-in-Charge

During the period of probation, Respondent shall retain an independent consultant who specializes in compounding at its own expense, who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by Respondent with state and federal laws and regulations governing the practice of a compounding pharmacy and for compliance by Respondent with the obligations of a pharmacist-in-charge. A physical inspection shall be completed by the consultant on a quarterly basis. The consultant shall be a pharmacist licensed by and not on probation with any board of pharmacy and whose name shall be submitted to the Board or its designee for prior approval within (30) days of the effective date of this decision. Respondent may submit the names and obtain approval of two consultants. Any consultant who is not licensed in California may not participate in or supervise any activity constituting the practice of pharmacy in California, and shall, within 30 days of the effective date of this decision, sign and return to the Board an acknowledgement stating that the consultant has reviewed and is familiar with all California statutes and regulations governing practices being overseen by the consultant, including compounding practices. During the period of probation, the Board or its designee retains the discretion to reduce the frequency of the pharmacist consultant's review of Respondent's operations. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

14. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent license will be fully restored.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Peter Osinoff, Bonne, Bridges, Mueller, O'Keefe & Nichols. I understand the stipulation and the effect it will have on my Original Permit and Original Sterile Compounding Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 06/01/2017 OROVILLE HOSPITAL PHARMACY Respondent

I have read and fully discussed with Respondent Oroville Hospital Pharmacy the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.

I approve its form and content.

DATED: 6/1/17

PETER OSINOFF, BONNE, BRIDGES, MUEILER, O'KEEFE & NICHOLS
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy,

Dated: 6/2/17

Respectfully submitted,

XAVIBR BECERRA Attorney General of California KENT D. HARRIS Supervising Deputy Attorney General

Deputy Attorney General Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 5630 & 5643

:		
1	KAMALA D. HARRIS	•
2	Attorney General of California KENT D. HARRIS	
3	Supervising Deputy Attorney General ELENA L. ALMANZO	
4	Deputy Attorney General State Bar No. 131058	
5	1300 I Street, Suite 125 P.O. Box 944255	,
6	Sacramento, CA 94244-2550 Telephone: (916) 322-5524	
	Facsinile: (916) 327-8643	·
7	Attorneys for Complainant	LIND OW DIT A DRAWA CITY
8		ARD OF PHARMACY CALIFORNIA
9		reta
10	In the Matter of the Accusation Against:	Case Nos. 5630 & 5643
11	OROVILLE HOSPITAL PHARMACY	
12	2767 Olive Highway Oroville, CA 95966	FIRST AMENDED ACCUSATION
13	Original Permit No. HSP 41557 Original Sterile Compounding Permit No.	
14	LSC 100404	
15		
16	DANIEL QUOC NGUYEN 1825 Ringnecked Pheasant Court	
17	Gridley, CA 95948 Pharmacist License No. RPH 43487	. "
18		
19	VICTOR MICHAEL MINETTI 1392 Eagle Ln.	
20	Plumas Lake, CA 95961 Pharmacist License No. RPH 35419	
21		
22	SUSAN SCHMIDT 167 Solana Dr	
23	Oroville, CA 95966 Pharmacist License No. RPH 58496	The same of the same special control and anticas is the same special of special specia
24	I HATHIAUST ENCORSE ING. INT. II 30470	
	CHAD RAMOS	
25	23 Avenida Brisa Ct. Chico, CA 95928	
26	Pharmacist License No. RPH 67245	
27		
28	The state of the s	
	(OROVILLE HOSPIT.	AL PHARMACY, et .al.) FIRST AMENDED ACCUSATION

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1	SON NGUYEN 767 Bridlewood Ct.	
3	Chico, CA 95926 Pharmacist License No. RPH 62061	
4	SAMUEL TONG 3249 Mystery Run	
5	Chico, ČA 95973 Pharmacist License No. RPH 62917	
7	JASMINE DONG 2090 Sea Cliff Way	
8	San Bruno, CA 94066 Pharmacist License No. RPH 69270	
10	Respondents.	
11		
12	Complainant alleges:	
13	PARTIES	
14	1. Virginia Herold (Complainant) brings this First Amended Accusation solely in her official	ι
15	capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.	
16	2. On or about August 30, 1996, the Board of Pharmacy issued Original Permit Number HSI	د [
17	41557 to Oroville Hospital Pharmacy (Respondent Oroville). The Permit was in full force and	
18	effect at all times relevant to the charges brought herein and will expire on August 1, 2016, unless] ş
19	renewed.	
20	3. On or about June 30, 2014, the Board of Pharmacy issued Original Sterile Compounding	
21	Permit Number LSC 100404 to Oroville Hospital Pharmacy (Respondent Oroville). The	
22	Compounding Permit was in full force and effect at all times relevant to the charges brought	
23	herein and will expire on August 1, 2016, unless renewed.	•
24	4. On or about July 26, 1990, the Board of Pharmacy issued Pharmacist License No. RPH	
25	43487 to Daniel Quoc Nguyen, (Respondent Daniel Nguyen). The Pharmacist License was in	
26	full force and effect at all times relevant to the charges brought herein and will expire on July 31	,
27	2016, unless renewed.	
28		

- 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.
- 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.
- 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.

1	12.	Section 4300 of the Code states in pertinent part:
2		"(a) Every license issued may be suspended or revoked.
3 4		"(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:
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 year.
8		"(4) Revoking his or her license.
9 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 not limited to, any of the following:
14		"(a) Gross immorality.
15		"(b) Incompetence.
16	!	"(c) Gross negligence.
17		"(f) The commission of any act involving moral turpitude, dishonesty,
18		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.
19		"(g) Knowingly making or signing any certificate or other document that
20		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 of the United States regulating controlled substances and dangerous drugs.
22		"(o) Violating or attempting to violate, directly or indirectly, or assisting
23 24		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
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		. • • • • • • • • • • • • • • • • • •

(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.

		(OROVILLE HOSPITAL PHARMACY, et. al.) FIRST AMENDED ACCUSATION
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28		(4) Inactive ingredients to be used.
27		(3) Expiration dating requirements.
26		(2) Equipment to be used.
25	-	(1) Active ingredients to be used.
24		prepared a written master formula record that includes at least the following elements:
23	4 20,000	(d) A days product shall not be compounded until the pharmacy has first
$2\dot{2}$	- - -	pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.
21		(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
20		(2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
19		prescriber's patients, as estimated by the prescriber; and
18	,	(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
17	<u>.</u>	section 4052(a) (1) means that amount of compounded drug product that:
15	, 	(c) A "reasonable quantity" as used in Business and Professions Code
14 15		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.
13		(b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription
12	-	the prescription prior to compounding.
11		patient where the prescriber has approved use of a compounded drug product ermer orally or in writing. Where approval is given orally, that approval shall be noted on
10		(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
9	21.	California Code of Regulations Section 1735.2 provides:
8		commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription
6		with Section 4073 of the Business and Professions Code Nothing in this regulation is intended to prohibit a pharmacist from exercising
5		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
4	20.	California Code of Regulations Section 1716 provides:
3		the pharmacy.
2		(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
1		used to record the reviewing pharmacist's identity shall not permit such a record to be altered after it is made.

(OROVILLE HOSPITAL PHARMACY, et .al.) FIRST AMENDED ACCUSATION

(OROVILLE HOSPITAL PHARMACY, et .al.) FIRST AMENDED ACCUSATION

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properly train staff assigned to compounding drug products: The compounding staff repeatedly demonstrated they had no training in asceptic 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

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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)

- 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)

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

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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 profiles to identify patient specific sterile compounded products.
8 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 media samples provided to the lab of compounded drugs thereby rendering the samples invalid.
11	D. PIC Nguyen failed to maintain medication profiles.
12	TWELFTH CAUSE FOR DISCIPLINE
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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 19	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.
20	D. On an about July 6, 2015. Respondent Minetti, while working at
21	Oroville Hospital Pharmacy located at 2767 Onve Highway, Orovine compounded
22	date the drug product was compounded, the identity of the pharmacist reviewing the final drug
23	product, the manufacturer, expiration date and lot mander of cach component, and pharmacy assigned reference or lot number for the compounded drug product, the
24	quantity or amount of drug product compounded.
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28	Business and Professions code section 4306.5 (b) in conjunction with Title 16, California Code
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	(OROVILLE HOSPITAL PHARMACY, et.al.) FIRST AMENDED ACCUSATION

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 compounded drugs as immediate use when they were dispensed after an hour had	 .
20	expired.	
21	B. Respondents Oroville Hospital and PIC Nguyen permitted the dispensing of medium risk compounded drugs when the documentation maintained	
22	by the pharmacy supported low risk compounding.	
23	C. Respondents Oroville Hospital and PIC Nguyen the dispensing of chemotherapy drugs which were not have proper documentation or demonstrated	
24	compounding processes as required by statute.	
25	SIXTEENTH CAUSE FOR DISCIPLINE	1
26	(Gross Negligence/Incompetence/Compounding)	.
27	43. Respondent Oroville Hospital and PIC Nguyen are subject to disciplinary action pursuant	
28	to Business and Professions Code section 4301 (b) and (c) for gross negligence and/or	
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	(OROVILLE HOSPITAL PHARMACY, et .al.) FIRST AMENDED ACCUSATIO	N

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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 10	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.		
11 12	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.		
13 14	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.		
15 16	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.		
17 18 19	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.		
-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 27	accordance with the manufacturers reference numbers 8582v41 and 25816v20,		
28	and the state of t		
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(OROVILLE HOSPITAL PHARMACY, et .al.) FIRST AMENDED ACCUSATION

1	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.
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3	TWENTY-FIRST CAUSE FOR DISCIPLINE
4	(Unprofessional Conduct/Variation from Prescription)
5	48. Respondent Samuel Tong 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	Regulation section 1716 and 1735.2 in that he compounded the following drugs incorrectly and
8	failed to obtain consent of the prescriber for the deviation:
9	A. On or about July 11, 2015, Respondent Samuel Tong compounded KCL 20meq instead of the stated product of KCL 10meq.
10 11	B. On or about July 11, 2015, Respondent Samuel Tong compounded Folic acid 5mg. instead of the stated product Folic acid 2mg.
12	TWENTY-SECOND CAUSE FOR DISCIPLINE
13	(Unprofessional Conduct/Variation from Prescription)
14	49. Respondent Jasmine Dong is subject to disciplinary action pursuant to Business and
15	Professions Code section 4301 (j) and (o) in conjunction with Title 16, California Code of
16	Regulation section 1716 and 1735.2 in that she compounded the following drugs incorrectly and
17	failed to obtain consent of the prescriber for the deviation:
18	A. On or about July 10, 2015, Respondent Jasmine Dong compounded Versed 25 mg but labeled the final product Versed 100 mg.
19 20	B. On or about July 10, 2015, Respondent Jasmine Dong compounded Glassia 7.6gm but labeled the final product Glassia1gm.
21	C. On or about July 10, 2015, Respondent Jasmine Dong compounded vancomycin 750mg instead of the stated product vancomycin 1750mg.
22	D. On or about July 10, 2015, Respondent Jasmine Dong compounded
23	sodium phosphate 30mm but labeled the final product sodium phosphate 20mm.
24	B. On or about August 18, 2015, Respondent Jasmine Dong compounded hydromorphone 12.5mg but labeled the final product Dilaudid 50mg.
25	F. On or about July 22, 2015, Respondent Jasmine Dong compounded
26	Emend without a stated strength but labeled the final product Emend 150 mg.
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	(OROVILLE HOSPITAL PHARMACY, et.al.) FIRST AMENDED ACCUSATION

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)

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