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

In the Matter of the Accusation Against:

Case No. 5000

FOUR FIFTY SUTTER PHARMACY and ELAINE CHAN, Owner

OAH No. 2015050642

Pharmacy Permit No. PHY 45225

STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RESPONDENT THINH PHU NGUYEN

ELAINE CHAN

Pharmacy Technician License No. TCH 36761

THINH PHU NGUYEN 106 Summerrain Drive South San Francisco, CA 94080

Pharmacist License No. RPH 64877

BRANDON VALOR BRODT

Pharmacist License No. RPH 43082

Respondents.

#### <u>DECISION AND ORDER</u>

The attached Stipulated Settlement and Disciplinary 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 p.m. on March 30, 2016.

It is so ORDERED on February 29, 2016.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

Βv

Amy Gutierrez, Pharm.D. Board President

1	KAMALA D. HARRIS	
2.	Attorney General of California DIANN SOKOLOFF	•
3	Supervising Deputy Attorney General CARTER OTT	
4	Deputy Attorney General State Bar No. 221660	
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9	BOARD OF	PHARMACY CONSUMER AFFAIRS
10		CALIFORNIA
11	In the Matter of the Accusation Against:	Case No. 5000
12	FOUR FIFTY SUTTER PHARMACY and	OAH No. 2015050642
13	ELAINE CHAN, Owner 450 Sutter Street, #710, 7th Floor	STIPULATED SETTLEMENT AND
14	San Francisco, California 94108	DISCIPLINARY ORDER AS TO RESPONDENT THINH PHU NGUYEN
15	Pharmacy Permit No. PHY 45225	
16	ELAINE CHAN 450 Sutter Street, Ste. 713, 7 <sup>th</sup> Floor	_
17	San Francisco, CA 94108	
18	Pharmacy Technician License No. TCH 36761	
19	THINH PHU NGUYEN	•
20	106 Summerrain Drive	
21	South San Francisco, CA 94080	
22	Pharmacist License No. RPH 64877	
23	BRANDON VALOR BRODT	
24	139 W. Richmond Avenue, #B Richmond, CA 94801	
25	Pharmacist License No. RPH 43082	
2.6 2.7	Respondents.	
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STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RESPONDENT THINH PHU NGUYEN
In the Matter of the Accusation and Petition to Revoke Probation Against Four Fifty Suiter Pharm. et al.

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the aboveentitled proceedings that the following matters are true:

#### PARTIES

- 1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy. She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Carter Ott, Deputy Attorney General.
- 1. On or about October 14, 2010, the Board of Pharmacy issued Pharmacist License No. RPH 64877 to Thinh Phu Nguyen (Respondent Nguyen). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this Second Amended Accusation and Petition to Revoke Probation and will expire on September 30, 2016, unless renewed. Respondent is represented by Jonathan Klein and Anne Marchant, Kelly, Hockel and Klein, PC, 44 Montgomery Street, Suite 1500, San Francisco, CA 94104.

#### JURISDICTION

2. Accusation and Petition to Revoke Probation No. 5000 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and properly served on Respondent on September 25, 2014. Respondent timely filed a Notice of Defense contesting that pleading. A First Amended Accusation and Petition to Revoke Probation was filed before the Board and served on Respondent on October 27, 2015. A Second Amended Accusation and Petition to Revoke Probation, the operative pleading, was filed before the Board and served on Respondent. A copy of Second Amended Accusation and Petition to Revoke Probation No. 5000 is attached as Exhibit A.

#### ADVISEMENT AND WAIVERS

- 3. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Second Amended Accusation and Petition to Revoke Probation No. 5000. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 4. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Second Amended Accusation and Petition to Revoke

 Probation; the right to be represented by counsel at his own expense; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his 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.

5. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

#### CULPABILITY

- 6. Respondent understands that the charges and allegations in the Second Amended Accusation and Petition to Revoke Probation No. 5000, if proven at hearing, constitute cause for imposing discipline upon his Pharmacists License. For the purpose of resolving the Second Amended Accusation and Petition to Revoke Probation No. 5000 without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Second Amended Accusation and Petition to Revoke Probation No. 5000 and that those charges constitute cause for discipline. Respondent gives up his right to contest that cause for discipline exists based on those charges.
- 7. Respondent agrees that his Pharmacist License is subject to discipline and he agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

#### CONTINGENCY

8. This stipulation shall be subject to approval by the Board. Respondent understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or her counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his 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.

- 9. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.
- 10. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 11. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

#### DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 64877, issued to Respondent Thinh Phu Nguyen, is revoked. However, the revocation is stayed and Respondent is placed on probation for three (3) years on the following terms and conditions.

#### 1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the Board, in writing, within seventy-two hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws.
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment.
- a conviction of any crime.

discipline, citation, or other administrative action filed by any state or federal agency which involves Respondent's Pharmacist License or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled súbstance.

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

#### 2. Report to the Board

Respondent 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 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 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 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 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. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

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#### 6. Notice to Employers

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number 5000 and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

Within thirty days of the effective date of this decision, and within fifteen days of Respondent undertaking any new employment, Respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during Respondent's tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 5000, and terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

If Respondent works for or is employed by or through a pharmacy employment service, Respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the Board of the terms and conditions of the decision in case number 5000 in advance of the Respondent commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty days of the effective date of this decision, and within fifteen days of Respondent undertaking any new employment by or through a pharmacy employment service, Respondent shall cause his direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that he or she has read the decision in case number 5000 and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any

position for which a pharmacist license is a requirement or criterion for employment, whether the Respondent is an employee, independent contractor or volunteer.

## 7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, Respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

#### 8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondent shall pay to the Board its costs of investigation and prosecution in the amount of \$2,400. Respondent shall make the payments on a payment plan approved by the Board. There shall be no deviation from this schedule absent prior written approval by the 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 shall not relieve Respondent of his responsibility to reimburse the Board its costs of investigation and prosecution.

#### 9. Probation Monitoring Costs

Respondent 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.

#### 10. Status of License

Respondent shall, at all times while on probation, maintain an active, current license with the Board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If Respondent's Pharmacist license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or

 otherwise, upon renewal or reapplication Respondent's Pharmacist license shall be subject to all terms and conditions of this probation not previously satisfied.

#### 11. License Surrender While on Probation

Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may tender their 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. This surrender constitutes a record of discipline and shall become a part of the Respondent's license history with the Board.

Upon acceptance of the surrender, Respondent shall relinquish his pocket and wall license to the Board within ten days of notification by the Board that the surrender is accepted. Respondent may not reapply for any license from the Board for three years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

## 12. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the Board in writing within ten days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the Board in writing within ten days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the Board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

#### 13. Tolling of Probation

Except during periods of suspension, Respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any

 month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, Respondent must nonetheless comply with all terms and conditions of probation.

Should Respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, Respondent must notify the Board in writing within ten days of the cessation of practice, and must further notify the board in writing within ten days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six months.

"Cessation of practice" means any calendar month during which Respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which Respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

#### 14. Violation of Probation

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and probation shall automatically be 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 violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary 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 Second Amended Accusation shall be deemed true and correct.

#### 15. Completion of Probation

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent's Pharmacist License will be fully restored.

#### 16. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporate currently or hereinafter licensed by the Board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the Board within ninety days following the effective date of this Decision and shall immediately thereafter provide written proof thereof to the Board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

#### 17. Remedial Education

Within sixty days of the effective date of this decision, Respondent shall submit to the Board or its designee, for prior approval, an appropriate program of remedial education related to pharmacy law and operations. The program of remedial education shall consist of at least 10 hours, which shall be completed within the first year of Respondent's probation, at Respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the Board, is provided to the Board or its designee.

Following the completion of each course, the Board or its designee may require the Respondent, at his own expense, to take an approved examination to test the Respondent's knowledge of the course. If the Respondent does not achieve a passing score on the examination,

this failure shall be considered a violation of probation. Any such examination failure shall require Respondent to take another course approved by the Board in the same subject area.

#### 18. Ethics Course

Within sixty calendar days of the effective date of this decision, Respondent shall enroll in a course in ethics, at Respondent's expense, approved in advance by the Board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the Board or its designee within five days after completing the course.

#### ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my counsel, Ionathan Klein and Anne Marchant, Kelly, Hockel and Klein, PC. I understand the stipulation and the effect it will have on my Pharmacist License. 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:	2102/E/SI	Shah Mayer	
		THINH PHU NOUYEN	
		Respondent	

I have read and fully discussed with Respondent Thinh Phu Nguyen the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12/3/2015 Con many many

KELLY, HOCKEL AND KLEIN, PC Counsel for Respondent

# The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy. Respectfully submitted, Dated: KAMALA D. HARRIS Attorney General of California DIANN ŠOKOLOFF Supervising Deputy Attorney General CARTER OTT Deputy Attorney General Attorneys for Complainant SF2013902016

1	KAMALA D. HARRIS Attorney General of California	
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7	Attorneys for Complainant	
8		RE THE
9	DEPARTMENT OF (	PHARMACY CONSUMER AFFAIRS
0	STATE OF C	CALIFORNIA
.1	In the Matter of the Accusation Against:	Case No. 5000
2	FOUR FIFTY SUTTER PHARMACY and	OAH No. 2015050642
3	ELAINE CHAN, Owner 450 Sutter Street, #710, 7th Floor	
4	San Francisco, California 94108	SECOND AMENDED ACCUSATION
5	Pharmacy Permit No. PHY 45225	AND PETITION TO REVOKE PROBATION
6	ELAINE CHAN 450 Sutter Street, Ste. 713, 7 <sup>th</sup> Floor	
17	San Francisco, CA 94108	
8	Pharmacy Technician License No. TCH 36761	
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0	106 Summerrain Drive South San Francisco, CA 94080	
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22		
23	BRANDON VALOR BRODT 139 W. Richmond Avenue, #B	
24	Richmond, CA 94801	
25	Pharmacist License No. RPH 43082	
26	Respondents.	
27		]
28		1
		ENDED ACCUSATION AND PETITION TO REVOKE PROBATION of the Accusation Against Four Fifty Sutter Pharmacy et al.

In the Matter of the Accusation Against Four Fifty Sutter Pharmacy et al.

Complainant alleges:

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#### **PARTIES**

- Virginia Herold (Complainant) brings this Second Amended Accusation and Petition to Revoke solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- 2. On or about March 7, 2001, the Board of Pharmacy issued Pharmacy Permit Number PHY 45225 to Four Fifty Sutter Pharmacy and Elaine Chan, Owner (Respondent FFSP). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in this Second Amended Accusation and Petition to Revoke Probation and will expire on March 1, 2016, unless renewed.
- 3. On or about January 2, 2002, the Board of Pharmacy issued Pharmacy Technician License No. 36761 to Elaine Chan (Respondent Chan). The Pharmacy Technician License was in full force and effect at all times relevant to the charges brought in this Second Amended Accusation and Petition to Revoke Probation and will expire on July 31, 2017, unless renewed.
- 4. On or about March 1, 1990, the Board of Pharmacy issued Pharmacist License No. RPH 43082 to Brandon Valor Brodt (Respondent Brodt). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this Second Amended Accusation and Petition to Revoke Probation and will expire on January 31, 2016, unless renewed.
- 5. On or about October 14, 2010, the Board of Pharmacy issued Pharmacist License No. RPH 64877 to Thinh Phu Nguyen (Respondent Nguyen). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this Second Amended Accusation and Petition to Revoke Probation and will expire on September 30, 2016, unless renewed.

#### **PRIOR DISCIPLINARY ACTION**

6. In a disciplinary action entitled "In the Matter of the Accusation against Four Fifty Sutter, Brandon Brodt, and Elaine Chan," Case No. 3797, the Board of Pharmacy issued a Decision and Order, effective June 20, 2013. The Board revoked Respondent FFSP's Pharmacy Permit. However, the Board stayed the revocation and placed Respondent FFSP's Pharmacy Permit on probation for five years with certain terms and conditions. The Board revoked

#### 10. Code section 4300.1 states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

#### STATUTORY PROVISIONS

- 11. Code section 4081 states, in part:
- "(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.
- "(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary foodanimal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.
  - 12. Code section 4105, subdivision (a), states:

"All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

13. Code section 4113, subdivision (c), states that the pharmacist-in-charge "shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

14. Code section 4125, subdivision (a), provides:

"Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence."

15. Code section 4301, states, in part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . . Unprofessional conduct shall include, but is not limited to, any of the following:

. .

"(c) Gross negligence.

. . .

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

. . .

- "(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency."
  - 16. Code section 4342 states:
- "(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).

- "(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321."
  - 17. Health and Safety Code section 11164 states, in part:

"Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

"(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

- "(1) The prescription shall be signed and dated by the prescriber in ink . . ."
- 18. Health and Safety Code section 11165, subdivision (d), states:

"For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

"(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

- "(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
- "(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
  - "(4) National Drug Code (NDC) number of the controlled substance dispensed.
  - "(5) Quantity of the controlled substance dispensed.
- "(6) International Statistical Classification of Diseases, 9<sup>th</sup> revision (ICD-9) or 10th revision (ICD-10) Code, if available.
  - "(7) Number of refills ordered.
- "(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
  - "(9) Date of origin of the prescription.
  - "(10) Date of dispensing of the prescription.

#### **REGULATORY PROVISIONS**

- 19. California Code of Regulations, title 16, section 1711, states, in part:
- "(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.
- "(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.
- "(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

- "(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:
- "(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.
  - "(B) Communicate to the prescriber the fact that a medication error has occurred.
- "(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.
- "(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.
- "(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.
- "(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:
  - "1. the date, location, and participants in the quality assurance review;
- "2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
  - "3. the findings and determinations generated by the quality assurance review; and,
- "4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

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"The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

- "(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.
- "(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error."
  - 20. California Code of Regulations, title 16, section 1714, states, in part:
- "(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.
- "(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes."
  - 21. California Code of Regulations, title 16, section 1715, states, in part:
- "(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
- "(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
  - "(1) A new pharmacy permit has been issued, or
- "(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy."

22. California Code of Regulations, title 16, section 1716, states, in part:

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

23. California Code of Regulations, title 16, section 1718, states:

"'Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

"The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory."

- 24. California Code of Regulations, title 16, section 1735.2, states, in part:
- "(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

. . .

"(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must

be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education."

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

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

. . .

- "(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted."
  - 26. California Code of Regulations, title 16, section 1774, subdivision (b), states:

"When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties."

- 27. Federal Code of Regulations, title 21, section 1304.04, states, in part:
- "(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

. . .

- "(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:
- "(1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy.

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- "(2) Paper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescription file.
- "(3) Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy.
- "(4) Paper prescriptions for Schedules III, IV, and V controlled substances shall be maintained at the registered location either in a separate prescription file for Schedules III, IV, and V controlled substances only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for noncontrolled substances. However, if a pharmacy employs a computer application for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.
- "(5) Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of part 1311 of this chapter. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the Administration or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled."

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#### **COST RECOVERY**

28. Code section 125.3 states, in part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

#### JUNE 11, 2012, INSPECTION

- 29. From on or about November 4, 2004, to January 1, 2013, Respondent Brodt was the Pharmacist-in-Charge (PIC) at Respondent FFSP.
- 30. On February 3, 2012, Respondent Brodt and Respondent FFSP dispensed prescription number 6431311 to Patient A<sup>1</sup> for orphenadrine 100 mg extended release instead of orphenadrine 100 mg immediate release as prescribed.
- 31. On or about June 11, 2012, a Board investigator conducted an inspection at Respondent FFSP after the Board received an online complaint from Patient A that the pharmacy charged patient A for unwanted medication and dispensed orphenadrine 100 mg that was not in accordance with a physician's written prescription.
  - 32. During the inspection, the investigator observed the following:
  - a. The premises was cluttered and disorganized despite written notice in 2009 and 2010.
- Respondent FFSP and Respondent Brodt did not conduct a quality assurance report and review of the February 3, 2012, medication error for prescription number 6431311 for orphenadrine 100 mg.
- c. Respondent FFSP and Respondent Brodt could not provide a dispensing record for prescription number 6431311.
- d. Multiple expired products were on Respondent FFSP's pharmacy shelves including, but not limited to, the following: glycerin (January 2006), alcohol (June 2009), ether (December 1992), water (March 2012), hydrogen peroxide (July 2004), bismuth subgallate (November 30, 2010), and sodium borate (March 31, 2010).

<sup>&</sup>lt;sup>1</sup> Patients are identified by number to protect their privacy.

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extended release instead of orphenadrine 100 mg immediate release, as prescribed. The underlying facts are set forth more particularly in paragraphs 29 through 32, above.

#### THIRD CAUSE FOR DISCIPLINE

#### (Missing Quality Assurance Review Report)

39. Respondent FFSP's license is subject to discipline for failing to prepare a medication error quality assurance review report in the pharmacy for the present year. (Bus. & Prof. Code, § 4301, subds. (j) and (o); Cal. Code Regs., tit. 16, §1711.) On or about February 3, 2012, Respondent FFSP committed a medication error regarding prescription number 6431311 for orphenadrine 100 mg. Respondent FFSP was required to prepare a report within two days of the date of the discovery of the error. However, during a Board inspection on or about June 11, 2012, Respondent FFSP did not have available a quality assurance review report on file and immediately retrievable. The underlying facts are set forth more particularly in paragraphs 29 through 32, above.

#### **FOURTH CAUSE FOR DISCIPLINE**

#### (Failure to Maintain Records of Dangerous Drugs)

40. Respondent FFSP's license is subject to discipline for failing to maintain records of dangerous drugs. (Bus. & Prof. Code, §§ 4301, subds. (j) and (o) and 4081, subd. (a).) During a Board inspection on or about June 11, 2012, Respondent FFSP did not have any dispensing records for prescription number 6431311 for orphenadrine available for Board review. The underlying facts are set forth more particularly in paragraphs 29 through 32, above.

#### FIFTH CAUSE FOR DISCIPLINE

#### (Expired Drugs in Inventory)

41. Respondent FFSP's license is subject to discipline for maintaining expired drugs in its inventory. (Bus. & Prof. Code, §§ 4301, subd. (o), and 4342, subd. (a).) During a Board inspection on or about June 11, 2012, a board investigator observed that Respondent FFSP maintained several expired pharmacy products. The underlying facts are set forth more particularly in paragraphs 29, 31, and 32, above.

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#### NINTH CAUSE FOR DISCIPLINE

#### (Failure to Maintain Records of Dangerous Drugs)

45. Respondent Brodt's license is subject to discipline for failing to maintain records of dangerous drugs. (Bus. & Prof. Code, §§ 4301, subds. (j) and (o), and 4081, subd. (a).) During a Board inspection on or about June 11, 2012, Respondent Brodt did not have any dispensing records for prescription number 6431311 for orphenadrine available for Board review. The underlying facts are set forth more particularly in paragraphs 29 through 32, above.

#### **TENTH CAUSE FOR DISCIPLINE**

#### (Expired Drugs in Inventory)

46. Respondent Brodt's license is subject to discipline for maintaining expired drugs in its inventory. (Bus. & Prof. Code, §§ 4301, subd. (o), and 4342, subd. (a).) During a Board inspection on or about June 11, 2012, a board investigator observed that Respondent Brodt maintained several expired pharmacy products. The underlying facts are set forth more particularly in paragraphs 29, 31 and 32, above.

#### JUNE 26, 2013, INSPECTION

- 47. From on or about January 1, 2013, to present, Respondent Nguyen was the PIC at FFSP.
- 48. On or about January 24, 2013, Respondent FFSP and Respondent Nguyen dispensed prescription number 4149633 for Patient B for a testosterone gel preparation and wrote an expiration date of July 2013. However, two ingredients expired on June 2013 and one ingredient did not have a documented expiration date.
- 49. On or about March 27, 2013, Respondent FFSP dispensed prescription number 4150016 for Patient B for Fortesta with directions to use four pumps a day, instead of the eight pumps a day as prescribed.
- 50. On or about April 19, 2013, Respondent FFSP dispensed prescription number 6143144 for Patient B for valacyclovir 1 gram once a day, instead of the prescribed 500 mg twice a day.

- 51. On or about May 13, 2013, Patient B informed Respondent FFSP of the medication errors.
- 52. On or about June 26, 2013, a Board investigator conducted an inspection at Respondent FFSP after the Board received an online complaint that the pharmacy dispensed medications that were not in accordance with a physician's written prescriptions.
  - 53. During the inspection, the investigator observed the following:
- a. Respondent FFSP and Respondent Nguyen were unable to provide a compounding log for prescription number 4146533 for Patient B for testosterone.
- b. Respondent Nguyen admitted that he assigned an expiration date to the compounded testosterone for prescription 4149633 for Patient B that was beyond the expiration date of multiple ingredients.
- c. On or about December 2 and 27, 2011, January 29, February 27, March 22, and April 17, 2012, Respondent FFSP dispensed testosterone gel to Patient B instead of testosterone powder as ordered by the original prescription, dated November 7, 2011. Respondent FFSP also dispensed the compound with incorrect directions for use, stating to use it once a day instead of twice a day. Respondent FFSP and Respondent Nguyen were unable to provide any documentation showing a change in dosage, form, or directions from the prescribing physician.
- d. Respondent FFSP and Respondent Nguyen could not provide to the Board a current biennial controlled substance inventory and a record of a biennial inventory for any time period.
- e. Respondent FFSP and Respondent Nguyen did not conduct a self-assessment of the pharmacy's compliance with federal and state pharmacy law within 30 days of January 1, 2013, when Respondent Nguyen became the new PIC. Respondent FFSP and Respondent Nguyen could not provide to the Board a copy of a completed current self-assessment that should have been conducted in July 2011.
- f. Respondent FFSP and Respondent Nguyen did not conduct a self-assessment of the pharmacy's compliance with compounding laws within 30 days of January 1, 2013, when Respondent Nguyen became the new PIC. Respondent FFSP and Respondent Nguyen could not

#### TWELFTH CAUSE FOR DISCIPLINE

#### (Failure to Prepare Controlled Substance Inventory Self-Assessment)

56. Respondent FFSP's license is subject to discipline for not providing controlled substance inventory self-assessments during an inspection. (Bus. & Prof. Code, § 4301, subds. (j) and (o); Cal. Code Regs., tit. 16, § 1715, subds. (a) and (b)(2).) By January 31 and July 1, 2013, Respondent FFSP was required to conduct controlled substance inventory self-assessments. During a Board inspection on or about June 26, 2013, Respondent FFSP did not have these self-assessments available for Board review. The underlying facts are set forth more particularly in paragraphs 37, 52, and 53, above.

#### THIRTEENTH CAUSE FOR DISCIPLINE

#### (Failure to Prepare Compounding Self-Assessment)

57. Respondent FFSP's license is subject to discipline for not providing copies of compounding self-assessments during an inspection. (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.2, subd. (j).) By January 31, 2013 and July 1, 2013, Respondent FFSP was required to conduct compounding self-assessments. During a Board inspection on or about June 26, 2013, Respondent FFSP did not have these assessments available for Board review. The underlying facts are set forth more particularly in paragraphs 37, 52, and 53, above.

#### FOURTEENTH CAUSE FOR DISCIPLINE

#### (Failure to Maintain Premises –Safe Practice of Pharmacy)

58. Respondent FFSP's license is subject to discipline for not maintaining the premises in a manner suitable for the safe practice of pharmacy. (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, §1714, subd. (b).) During a Board inspection on or about June 26, 2013, Respondent FFSP's facilities were cluttered and disorganized. The underlying facts are set forth more particularly in paragraphs 47, and 52 through 54, above.

#### FIFTEENTH CAUSE FOR DISCIPLINE

#### (Missing Quality Assurance Review Report)

59. Respondent FFSP's license is subject to discipline for failing to prepare a quality assurance review report in the pharmacy for the present year. (Bus. & Prof. Code, § 4301, subds.

(j) and (o); Cal. Code Regs., tit. 16, §1711.) On May 13, 2013, Respondent FFSP discovered that it made a medication error regarding prescription number 4150016 for Fortesta. Respondent FFSP was required to investigate and prepare a report. During a Board inspection on or about June 26, 2013, Respondent FFSP did not have available a quality assurance review report on file and immediately retrievable. The underlying facts are set forth more particularly in paragraphs 47 though 54, above.

#### SIXTEENTH CAUSE FOR DISCIPLINE

#### (Missing Original Prescription for Dangerous Drug)

60. Respondent FFSP's license is subject to discipline for failing to retain original documentation for the disposition of dangerous drugs. (Bus. & Prof. Code, §§ 4301, subds. (j) and (o) and 4105, subd. (a).) During a Board inspection on or about June 26, 2013, Respondent FFSP did not have available in readily retrievable form the original prescription number 6423645 for valacyclovir. The underlying facts are set forth more particularly in paragraphs 47 through 54, above.

#### SEVENTEENTH CAUSE FOR DISCIPLINE

#### (Expiration Date Error)

61. Respondent FFSP's license is subject to discipline for assigning an expiration date to a compounded drug product that was beyond the use date. (Bus. & Prof. Code, §§ 4301, subds. (j) and (o); Cal. Code Regs., tit. 16, § 1735.2, subd. (h).) On or about January 24, 2013, Respondent FFSP assigned an expiration date of July 2013 for a testosterone gel when the shortest expiration date of several of the gel's components was June 2013. The underlying facts are set forth more particularly in paragraphs 47 through 54, above.

#### EIGHTEENTH CAUSE FOR DISCIPLINE

#### (Labeling Error)

62. Respondent FFSP's license is subject to discipline for dispensing medication with instructions that deviated from the prescription as written by a physician. (Bus. & Prof. Code, § 4301, subds. (j) and (o); Cal. Code Regs., tit. 16, § 1716.) Respondent FFSP dispensed prescription number 4146533 as a testosterone gel to be used once a day instead of the

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#### TWENTIETH CAUSE FOR DISCIPLINE

#### (Failure to Transmit CURES Dispensing Data)

68. Respondent Brodt's license is subject to discipline for failing to comply with controlled substance laws. (Bus. & Prof. Code, § 4301, subds. (j) and (o), and Health & Saf. Code § 11165, subd. (d).) While acting as PIC, Respondent Brodt failed to submit controlled substance data to CURES within seven days after the dispensing controlled substances, as required. The underlying facts are set forth more particularly in paragraphs 63, 64, and 66, above.

#### TWENTY FIRST CAUSE FOR DISCIPLINE

#### (Failure to Transmit CURES Dispensing Data)

69. Respondent Nguyen's license is subject to discipline for failing to comply with controlled substance laws. (Bus. & Prof. Code, § 4301, subds. (j) and (o), and Health & Saf. Code § 11165, subd. (d).) During a Board inspection on or about October 8, 2013, Respondent Nguyen did not have available controlled substance dispensing data for Board review. While acting as PCI, Respondent Nguyen failed to submit controlled substance data to CURES within seven days after dispensing controlled substances, as required. The underlying facts are set forth more particularly in paragraphs 63, 64, and 66, above.

#### **JANUARY 21, 2015 INSPECTION**

70. On or about November 25, 2014, the Board discovered that Respondent FFSP had failed to include all prescriptions in its CURES report and was not transmitting data consistently on a weekly basis as required. On or about January 21, 2015, a Board investigator conducted an inspection at Respondent FFSP. The Board investigator asked Respondent's staff to logon to the CURES Prescription Drug Monitoring Program (PDMP) to confirm that randomly selected prescription documents for controlled substances that were dispensed from December 15, 2014 to January 12, 2015 were documented in the CURES database. Board investigators found that, of fifteen selected prescriptions, information for ten were not in the CURES PDMP. Ultimately, the Board investigator found that, from December 2013 to September 2014, Respondent FFSP failed to transmit controlled substance data consistently on a weekly basis, and had failed to transmit data for controlled substances dispensed on December 22, 23, 24, 30 and 31, 2014. When asked,

1	TWENTY FIFTH CAUSE FOR DISCIPLINE		
2	(Gross Negligence)		
3	75. Respondent Nguyen's license is subject to discipline for gross negligence. (Bus. &		
4	Prof. Code, § 4301, subd. (c).) The underlying facts are set forth more particularly in paragraphs		
5	70 through 71, above.		
6	TWENTY SIXTH CAUSE FOR DISCIPLINE		
7	(Failure to Transmit CURES Dispensing Data)		
8	76. Respondent Chan's license is subject to discipline for failing to comply with		
9	controlled substance laws. (Bus. & Prof. Code, § 4301, subds. (j) and (o), and Health & Saf.		
10	Code § 11165, subd. (d).) During an inspection on or about January 21, 2015, a Board		
11	investigator found that, while acting as the individual licensed owner of Respondent FFSP,		
12	Respondent FFSP failed to submit controlled substance data to CURES within seven days after		
13	dispensing controlled substances, as required. The underlying facts are set forth more particularly		
14	in paragraphs 70 through 71, above.		
15	TWENTY SEVENTH CAUSE FOR DISCIPLINE		
16	(Gross Negligence)		
17	77. Respondent Chan's license is subject to discipline for gross negligence. (Bus. & Prof		
18	Code, § 4301, subd. (c).) The underlying facts are set forth more particularly in paragraphs 70		
19	through 71, above.		
20			
21	PETITION TO REVOKE PROBATION		
22	78. Grounds exist for revoking the probation and re-imposing the order of revocation of		
23	Respondent FFSP's Pharmacy Permit.		
24	79. This Petition to Revoke Probation is brought before the Board under the probation		
25	terms and conditions of the Decision and Order for In the Matter of the Accusation against Four		
26	Fifty Sutter, Brandon Brodt, and Elaine Chan, Case No. 3797.		
27			
28	25		

80. At all times after the effective date of Respondent FFSP's probation, Condition 1 of the Disciplinary Order stated, in part, that: "Respondent shall obey all federal and state and regulations."

81. At all times after the effective date of Respondent FFSP's probation, Condition 11 of the Disciplinary Order stated that:

"Respondent FFSP's 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 FFSP's 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."

82. At all times after the effective date of Respondent FFSP's probation, Condition 12 of the Disciplinary Order stated that:

"If Respondent FFSP has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent FFSP's 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 FFSP violates probation in any respect, the Board, after giving Respondent FFSP's owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary 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 FFSP 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."

#### FIRST CAUSE TO REVOKE PROBATION

### (Failure to Obey All Laws)

83. Respondent FFSP's probation is subject to revocation because it failed to comply with Probation Condition 1, referenced above, by failing to comply with all laws and regulations, as more particularly set forth in paragraphs 29 through 77, above.

### SECOND CAUSE TO REVOKE PROBATION

### (Failure to Post Notice of Probation)

84. Respondent FFSP's probation is subject to revocation because it failed to comply with Probation Condition 11, referenced above, by failing to post the Notice of Probation, as more particularly set forth in paragraphs 52 and 53, above.

### THIRD CAUSE TO REVOKE PROBATION

### (Failure to Comply with Terms of Probation)

85. Respondent FFSP's probation is subject to revocation because it failed to comply with Probation Condition 12, referenced above, by failing to comply with any term or condition of probation, as more particularly set forth in paragraphs 29 through 77, above.

### **DISCIPLINARY CONSIDERATIONS**

- 86. To determine the degree of discipline, if any, to be imposed on Respondent FFSP, Complainant alleges that on or about June 15, 2007, in a prior action, the Board issued Citation Number CI 06 33185. The Board ordered a \$2,500 fine against Respondent FFSP. That Citation is now final and incorporated by reference as if fully set forth.
- 87. To determine the degree of discipline, if any, to be imposed on Respondent FFSP, Complainant alleges that on or about July 8, 2009, in a prior action, the Board issued Citation Number CI 08 38139. The Board and ordered a \$5,000.00 fine against Respondent FFSP. That Citation is now final and incorporated by reference as if fully set forth.
- 88. To determine the degree of discipline, if any, to be imposed on Respondent Chan, Complainant alleges that on or about May 21, 2013, in a disciplinary action entitled "In the Matter of the Accusation against Four Fifty Sutter, Brandon Brodt, and Elaine Chan," Case No. 3797, the Board issued a citation against Respondent Chan for subversion. The Board ordered a

\$5,000.00 fine against Respondent Chan. That Citation is now final and incorporated by reference as if fully set forth.

- 89. To determine the degree of discipline, if any, to be imposed on Respondent Brodt, Complainant alleges that on or about June 15, 2007, in a prior action, the Board issued Citation Number CI 06 33851. The Board ordered a \$1,000.00 fine against Respondent Brodt. That Citation is now final and incorporated by reference as if fully set forth.
- 90. To determine the degree of discipline, if any, to be imposed on Respondent Brodt, Complainant alleges that on or about July 8, 2009, in a prior action, the Board issued Citation Number CI 09 40780. The Board ordered a \$3,000.00 fine against Respondent Brodt. That Citation is now final and incorporated by reference as if fully set forth.
- 91. To determine the degree of discipline, if any, to be imposed on Respondent Nguyen, Complainant alleges that on or about March 13, 2014, in a prior action, the Board issued Citation Number CI 2013 58775. The Board ordered a \$3,875.00 fine against Respondent Nguyen. That Citation is now final and incorporated by reference as if fully set forth.

### **PRAYER**

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this Second Amended Accusation and Petition to Revoke Probation, and that following the hearing, the Board of Pharmacy issue a decision:

- Revoking the probation that was granted by the Board of Pharmacy in Case No. 3797 and imposing the disciplinary order that was stayed thereby revoking Pharmacy Permit No. PHY 45225 issued to Four Fifty Sutter Pharmacy and Elaine Chan, Owner;
- 2. Revoking or suspending Pharmacy Permit Number PHY 45225 issued to Four Fifty Sutter Pharmacy and Elaine Chan, Owner;
- 3. Revoking or suspending Pharmacy Technician License Number 367361 issued to Elaine Chan;
- Revoking or suspending Pharmacist License Number RPH 43082 issued to Brandon Valor Brodt;

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1	5.	Revoking or suspending Pharmacist License Number RPH 64877 issued to Thinh Phu		
2	Nguyen;			
3	6.	Ordering Four Fifty Sutter Pharmacy, Elaine Chan, Brandon Valor Brodt, and Thinh		
4	Phu Nguy	Phu Nguyen to pay the Board of Pharmacy the reasonable costs of the investigation and		
5	enforcement of this case, pursuant to Business and Professions Code section 125.3; and			
6	7.	Taking such other and further action as deemed necessary and proper.		
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10	DATED: _	VIRGINIA HEROLD		
11		Executive Officer Board of Pharmacy		
12		Department of Consumer Affairs State of California		
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24	Exhibit A
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26	Decision and Order
27	Board of Pharmacy Case No. 3797
28	30
	SECOND AMENDED ACCUSATION AND PETITION TO REVOKE PROBATION
	In the Matter of the Accusation Against Four Fifty Sutter Pharmacy et al.

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450 Sutter Street, Ste. 713, 7 <sup>th</sup> Floor	ON		
17   San Francisco, CA 94108			
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Pharmacy Technician License No. TCH 36761			
19 THINH PHU NGUYEN			
20   106 Summerrain Drive South San Francisco, CA 94080			
21 Pharmacist License No. RPH 64877			
BRANDON VALOR BRODT 139 W. Richmond Avenue, #B			
24   Richmond, CA 94801			
25   Pharmacist License No. RPH 43082			
Respondents.			
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#### **PARTIES**

- Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- On or about March 7, 2001, the Board of Pharmacy issued Pharmacy Permit Number 2. PHY 45225 to Four Fifty Sutter Pharmacy and Elaine Chan, Owner (Respondent FFSP). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in this Accusation and Petition to Revoke Probation and will expire on July 31, 2015, unless renewed.
- 3. On or about January 2, 2002, the Board of Pharmacy issued Pharmacy Technician License No. 36761 to Elaine Chan (Respondent Chan). The Pharmacy Technician License was in full force and effect at all times relevant to the charges brought in this Accusation and Petition to Revoke Probation and will expire on July 31, 2015, unless renewed.
- On or about March 1, 1990, the Board of Pharmacy issued Pharmacist License No. RPH 43082 to Brandon Valor Brodt (Respondent Brodt). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this Accusation and Petition to Revoke Probation and will expire on January 31, 2016, unless renewed.
- 5. On or about October 14, 2010, the Board of Pharmacy issued Pharmacist License No. RPH 64877 to Thinh Phu Nguyen (Respondent Nguyen). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this Accusation and Petition to Revoke Probation and will expire on September 30, 2014, unless renewed.

#### PRIOR DISCIPLINARY ACTION

6. In a disciplinary action entitled "In the Matter of the Accusation against Four Fifty Sutter, Brandon Brodt, and Elaine Chan," Case No. 3797, the Board of Pharmacy issued a Decision and Order, effective June 20, 2013. The Board revoked Respondent FFSP's Pharmacy Permit. However, the Board stayed the revocation and placed Respondent FFSP's Pharmacy Permit on probation for five years with certain terms and conditions. The Board revoked Respondent Brodt's Pharmacist License. However, the Board stayed the revocation and placed Respondent's Pharmacist License on probation for four years with certain terms and conditions.

The Board issued a citation against Respondent Chan. A copy of that Decision and Order is attached as exhibit A and is incorporated by reference.

#### JURISDICTION

- 7. The Board of Pharmacy (Board), Department of Consumer Affairs, brings this Accusation and Petition to Revoke Probation under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.
- 8. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].
  - 9. Code section 4300 states, in part:
  - "(a) Every license issued may be suspended or revoked.
- "(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
  - "(1) Suspending judgment.
  - "(2) Placing him or her upon probation.
  - "(3) Suspending his or her right to practice for a period not exceeding one year.
  - "(4) Revoking his or her license.
- "(5) Taking any other action in relation to disciplining him or her as the boarin its discretion may deem proper.

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- "(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions."
  - 10. Code section 4300.1 states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a

license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

### STATUTORY PROVISIONS

- 11. Code section 4081 states, in part:
- "(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.
- "(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary foodanimal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.
  - 12. Code section 4105, subdivision (a), states:
- "All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.
- 13. Code section 4113, subdivision (c), states that the pharmacist-in-charge "shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

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14. Code section 4125, subdivision (a), provides:

"Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence."

15. Code section 4301, states, in part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . . Unprofessional conduct shall include, but is not limited to, any of the following:

"(c) Gross negligence.

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

"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency."

- 16. Code section 4342 states:
- "(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).

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- "(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321." 17. Health and Safety Code section 11164 states, in part: "Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section. "(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:
  - "(1) The prescription shall be signed and dated by the prescriber in ink ..."
  - 18. Health and Safety Code section 11165, subdivision (d), states:

"For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

- "(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
- "(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number,

- "(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:
- "(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.
  - "(B) Communicate to the prescriber the fact that a medication error has occurred.
- "(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.
- "(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.
- "(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.
- "(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:
  - "1. the date, location, and participants in the quality assurance review;
- "2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
  - "3. the findings and determinations generated by the quality assurance review; and,
- "4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

"The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

- "(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.
- "(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error."
  - 20. California Code of Regulations, title 16, section 1714, states, in part:
- "(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.
- "(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes."
  - 21. California Code of Regulations, title 16, section 1715, states, in part:
- "(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
- "(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
  - "(1) A new pharmacy permit has been issued, or
- "(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy."

22. California Code of Regulations, title 16, section 1716, states, in part:

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

23. California Code of Regulations, title 16, section 1718, states:

"Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

"The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory."

- 24. California Code of Regulations, title 16, section 1735.2, states, in part:
- "(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

"(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies

developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital

Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) That

form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-

in-charge before any compounding is performed in the pharmacy. The second section must

be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education."

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

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

. . .

- "(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted."
  - 26. California Code of Regulations, title 16, section 1774, subdivision (b), states:
- "When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties."
  - 27. Federal Code of Regulations, title 21, section 1304.04, states, in part:
- "(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

- "(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:
- "(1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy.

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- "(2) Paper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescription file.
- "(3) Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy.
- "(4) Paper prescriptions for Schedules III, IV, and V controlled substances shall be maintained at the registered location either in a separate prescription file for Schedules III, IV, and V controlled substances only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for noncontrolled substances. However, if a pharmacy employs a computer application for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.
- "(5) Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of part 1311 of this chapter. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the Administration or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled."

#### COST RECOVERY

28. Code section 125.3 states, in part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

### JUNE 11, 2012, INSPECTION

- 29. From on or about November 4, 2004, to January 1, 2013, Respondent Brodt was the Pharmacist-in-Charge (PIC) at Respondent FFSP.
- 30. On February 3, 2012, Respondent Brodt and Respondent FFSP dispensed prescription number 6431311 to Patient A<sup>1</sup> for orphenadrine 100 mg extended release instead of orphenadrine 100 mg immediate release as prescribed.
- 31. On or about June 11, 2012, a Board investigator conducted an inspection at Respondent FFSP after the Board received an online complaint from Patient A that the pharmacy charged patient A for unwanted medication and dispensed orphenadrine 100 mg that was not in accordance with a physician's written prescription.
  - 32. During the inspection, the investigator observed the following:
  - a. The premises was cluttered and disorganized despite written notice in 2009 and 2010.
- b. Respondent FFSP and Respondent Brodt did not conduct a quality assurance report and review of the February 3, 2012, medication error for prescription number 6431311 for orphenadrine 100 mg.
- c. Respondent FFSP and Respondent Brodt could not provide a dispensing record for prescription number 6431311.
- d. Multiple expired products were on Respondent FFSP's pharmacy shelves including, but not limited to, the following: glycerin (January 2006), alcohol (June 2009), ether (December 1992), water (March 2012), hydrogen peroxide (July 2004), bismuth subgallate (November 30, 2010), and sodium borate (March 31, 2010).

<sup>&</sup>lt;sup>1</sup> Patients are identified by number to protect their privacy.

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extended release instead of orphenadrine 100 mg immediate release, as prescribed. The underlying facts are set forth more particularly in paragraphs 29 through 32, above.

### THIRD CAUSE FOR DISCIPLINE

### (Missing Quality Assurance Review Report)

39. Respondent FFSP's license is subject to discipline for failing to prepare a medication error quality assurance review report in the pharmacy for the present year. (Bus. & Prof. Code, § 4301, subds. (j) and (o); Cal. Code Regs., tit. 16, §1711.) On or about February 3, 2012, Respondent FFSP committed a medication error regarding prescription number 6431311 for orphenadrine 100 mg. Respondent FFSP was required to prepare a report within two days of the date of the discovery of the error. However, during a Board inspection on or about June 11, 2012, Respondent FFSP did not have available a quality assurance review report on file and immediately retrievable. The underlying facts are set forth more particularly in paragraphs 29 through 32, above.

### FOURTH CAUSE FOR DISCIPLINE

### (Failure to Maintain Records of Dangerous Drugs)

40. Respondent FFSP's license is subject to discipline for failing to maintain records of dangerous drugs. (Bus. & Prof. Code, §§ 4301, subds. (j) and (o) and 4081, subd. (a).) During a Board inspection on or about June 11, 2012, Respondent FFSP did not have any dispensing records for prescription number 6431311 for orphenadrine available for Board review. The underlying facts are set forth more particularly in paragraphs 29 through 32, above.

### FIFTH CAUSE FOR DISCIPLINE

#### (Expired Drugs in Inventory)

41. Respondent FFSP's license is subject to discipline for maintaining expired drugs in its inventory. (Bus. & Prof. Code, §§ 4301, subd. (o), and 4342, subd. (a).) During a Board inspection on or about June 11, 2012, a board investigator observed that Respondent FFSP maintained several expired pharmacy products. The underlying facts are set forth more particularly in paragraphs 29, 31, and 32, above.

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### (Failure to Maintain Premises)

42. Respondent Brodt's license is subject to discipline for not maintaining the premises in a manner suitable for the safe practice of pharmacy. (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, §1714, subd. (c).) During a Board inspection on or about June 11, 2012, Respondent Brodt was the PIC and Respondent FFSP's facilities were cluttered and disorganized. The underlying facts are set forth more particularly in paragraphs 29, 31, and 32, above

### SEVENTH CAUSE FOR DISCIPLINE

#### (Variation from Prescription)

43. Respondent Brodt's license is subject to discipline for deviating from the requirements of a prescription. (Bus. & Prof. Code, § 4301, subds. (j) and (o); Cal. Code Regs., tit. 16, § 1716.) On or about February 3, 2012, Respondent Brodt dispensed orphenadrine 100 mg extended release instead of orphenadrine 100 mg immediate release, as prescribed. The underlying facts are set forth more particularly in paragraphs 29 through 32, above.

### EIGHTH CAUSE FOR DISCIPLINE

#### (Missing Quality Assurance Review Report)

44. Respondent Brodt's license is subject to discipline for failing to prepare a medication error quality assurance review report in the pharmacy for the present year. (Bus. & Prof. Code, § 4301, subds. (j) and (o); Cal. Code Regs., tit. 16, §1711.) On or about February 3, 2012, Respondent Brodt committed a medication error regarding prescription number 6431311 for orphenadrine 100 mg. Respondent Brodt was required to prepare a report within two days of the date of the discovery of the error. However, during a Board inspection on or about June 11, 2012, Respondent Brodt did not have available a quality assurance review report on file and immediately retrievable. The underlying facts are set forth more particularly in paragraphs 29 through 32, above.

#### **NINTH CAUSE FOR DISCIPLINE**

### (Failure to Maintain Records of Dangerous Drugs)

45. Respondent Brodt's license is subject to discipline for failing to maintain records of dangerous drugs. (Bus. & Prof. Code, §§ 4301, subds. (j) and (o), and 4081, subd. (a).) During a Board inspection on or about June 11, 2012, Respondent Brodt did not have any dispensing records for prescription number 6431311 for orphenadrine available for Board review. The underlying facts are set forth more particularly in paragraphs 29 through 32, above.

### **TENTH CAUSE FOR DISCIPLINE**

### (Expired Drugs in Inventory)

46. Respondent Brodt's license is subject to discipline for maintaining expired drugs in its inventory. (Bus. & Prof. Code, §§ 4301, subd. (o), and 4342, subd. (a).) During a Board inspection on or about June 11, 2012, a board investigator observed that Respondent Brodt maintained several expired pharmacy products. The underlying facts are set forth more particularly in paragraphs 29, 31 and 32, above.

### JUNE 26, 2013, INSPECTION

- 47. From on or about January 1, 2013, to present, Respondent Nguyen was the PIC at FFSP.
- 48. On or about January 24, 2013, Respondent FFSP and Respondent Nguyen dispensed prescription number 4149633 for Patient B for a testosterone gel preparation and wrote an expiration date of July 2013. However, two ingredients expired on June 2013 and one ingredient did not have a documented expiration date.
- 49. On or about March 27, 2013, Respondent FFSP dispensed prescription number 4150016 for Patient B for Fortesta with directions to use four pumps a day, instead of the eight pumps a day as prescribed.
- 50. On or about April 19, 2013, Respondent FFSP dispensed prescription number 6143144 for Patient B for valacyclovir 1 gram once a day, instead of the prescribed 500 mg twice a day.

- 51. On or about May 13, 2013, Patient B informed Respondent FFSP of the medication errors.
- 52. On or about June 26, 2013, a Board investigator conducted an inspection at Respondent FFSP after the Board received an online complaint that the pharmacy dispensed medications that were not in accordance with a physician's written prescriptions.
  - 53. During the inspection, the investigator observed the following:
- a. Respondent FFSP and Respondent Nguyen were unable to provide a compounding log for prescription number 4146533 for Patient B for testosterone.
- b. Respondent Nguyen admitted that he assigned an expiration date to the compounded testosterone for prescription 4149633 for Patient B that was beyond the expiration date of multiple ingredients.
- c. On or about December 2 and 27, 2011, January 29, February 27, March 22, and April 17, 2012, Respondent FFSP dispensed testosterone gel to Patient B instead of testosterone powder as ordered by the original prescription, dated November 7, 2011. Respondent FFSP also dispensed the compound with incorrect directions for use, stating to use it once a day instead of twice a day. Respondent FFSP and Respondent Nguyen were unable to provide any documentation showing a change in dosage, form, or directions from the prescribing physician.
- d. Respondent FFSP and Respondent Nguyen could not provide to the Board a current biennial controlled substance inventory and a record of a biennial inventory for any time period.
- e. Respondent FFSP and Respondent Nguyen did not conduct a self-assessment of the pharmacy's compliance with federal and state pharmacy law within 30 days of January 1, 2013, when Respondent Nguyen became the new PIC. Respondent FFSP and Respondent Nguyen could not provide to the Board a copy of a completed current self-assessment that should have been conducted in July 2011.
- f. Respondent FFSP and Respondent Nguyen did not conduct a self-assessment of the pharmacy's compliance with compounding laws within 30 days of January 1, 2013, when Respondent Nguyen became the new PIC. Respondent FFSP and Respondent Nguyen could not

provide to the Board a copy of a completed current compounding self-assessment that should have been conducted in July 2011.

- g. Respondent FFSP and Respondent Nguyen Respondent FFSP and Respondent Nguyen did not conduct a quality assurance review report by May 15, 2013, within two business days of the date that they discovered that they dispensed prescription number 4150016 to Patient B for Fortesta with incorrect directions. Respondent FFSP and Respondent Nguyen were unable to provide to the Board a copy of a quality assurance review report.
- h. Respondent FFSP and Respondent Nguyen were unable to provide an original copy to the Board of prescription number 6423645 to Patient B for valacyclovir 500 mg with directions to take one tablet twice a day.
- i. Respondent FFSP's premises was cluttered and disorganized despite written notice in 2009, 2010, and 2012.
- j. A Notice of Probation was not posted at Respondent FFSP as required by Condition Number 11, of the Decision and Order *In the Matter of the Accusation against Four Fifty Sutter*, Case No. 3797.
- 54. On or about June 26, 2013, a Board investigator issued a notice of noncompliance to Respondent FFSP. The Board issued a citation against Respondent Nguyen, as set forth more particularly in paragraph 87, below.

### **ELEVENTH CAUSE FOR DISCIPLINE**

### (Failure to Provide Controlled Substance Inventories)

55. Respondent FFSP's license is subject to discipline for not providing controlled substance inventories during an inspection. (Bus. & Prof. Code, § 4301, subds. (j) and (o); Cal. Code Regs., tit. 16, § 1718; and 21 C.F.R. § 1304.04.) During a Board inspection on or about June 26, 2013, Respondent FFSP did not have available a current biennial inventory and there was no record of a biennial inventory for any time period. The underlying facts are set forth more particularly in paragraphs 47, 52, and 53, above.

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### TWELFTH CAUSE FOR DISCIPLINE

### (Failure to Prepare Controlled Substance Inventory Self-Assessment)

56. Respondent FFSP's license is subject to discipline for not providing controlled substance inventory self-assessments during an inspection. (Bus. & Prof. Code, § 4301, subds. (j) and (o); Cal. Code Regs., tit. 16, § 1715, subds. (a) and (b)(2).) By January 31 and July 1, 2013, Respondent FFSP was required to conduct controlled substance inventory self-assessments. During a Board inspection on or about June 26, 2013, Respondent FFSP did not have these self-assessments available for Board review. The underlying facts are set forth more particularly in paragraphs 37, 52, and 53, above.

### THIRTEENTH CAUSE FOR DISCIPLINE

### (Failure to Prepare Compounding Self-Assessment)

57. Respondent FFSP's license is subject to discipline for not providing copies of compounding self-assessments during an inspection. (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.2, subd. (j).) By January 31, 2013 and July 1, 2013, Respondent FFSP was required to conduct compounding self-assessments. During a Board inspection on or about June 26, 2013, Respondent FFSP did not have these assessments available for Board review. The underlying facts are set forth more particularly in paragraphs 37, 52, and 53, above.

### FOURTEENTH CAUSE FOR DISCIPLINE

### (Failure to Maintain Premises -Safe Practice of Pharmacy)

58. Respondent FFSP's license is subject to discipline for not maintaining the premises in a manner suitable for the safe practice of pharmacy. (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, §1714, subd. (b).) During a Board inspection on or about June 26, 2013, Respondent FFSP's facilities were cluttered and disorganized. The underlying facts are set forth more particularly in paragraphs 47, and 52 through 54, above.

### FIFTEENTH CAUSE FOR DISCIPLINE

#### (Missing Quality Assurance Review Report)

59. Respondent FFSP's license is subject to discipline for failing to prepare a quality assurance review report in the pharmacy for the present year. (Bus. & Prof. Code, § 4301, subds.

(j) and (o); Cal. Code Regs., tit. 16, §1711.) On May 13, 2013, Respondent FFSP discovered that it made a medication error regarding prescription number 4150016 for Fortesta. Respondent FFSP was required to investigate and prepare a report. During a Board inspection on or about June 26, 2013, Respondent FFSP did not have available a quality assurance review report on file and immediately retrievable. The underlying facts are set forth more particularly in paragraphs 47 though 54, above.

### SIXTEENTH CAUSE FOR DISCIPLINE

### (Missing Original Prescription for Dangerous Drug)

60. Respondent FFSP's license is subject to discipline for failing to retain original documentation for the disposition of dangerous drugs. (Bus. & Prof. Code, §§ 4301, subds. (j) and (o) and 4105, subd. (a).) During a Board inspection on or about June 26, 2013, Respondent FFSP did not have available in readily retrievable form the original prescription number 6423645 for valacyclovir. The underlying facts are set forth more particularly in paragraphs 47 through 54, above.

#### SEVENTEENTH CAUSE FOR DISCIPLINE

#### (Expiration Date Error)

61. Respondent FFSP's license is subject to discipline for assigning an expiration date to a compounded drug product that was beyond the use date. (Bus. & Prof. Code, §§ 4301, subds. (j) and (o); Cal. Code Regs., tit. 16, § 1735.2, subd. (h).) On or about January 24, 2013, Respondent FFSP assigned an expiration date of July 2013 for a testosterone gel when the shortest expiration date of several of the gel's components was June 2013. The underlying facts are set forth more particularly in paragraphs 47 through 54, above.

### EIGHTEENTH CAUSE FOR DISCIPLINE

### (Labeling Error)

62. Respondent FFSP's license is subject to discipline for dispensing medication with instructions that deviated from the prescription as written by a physician. (Bus. & Prof. Code, § 4301, subds. (j) and (o); Cal. Code Regs., tit. 16, § 1716.) Respondent FFSP dispensed prescription number 4146533 as a testosterone gel to be used once a day instead of the

testosterone powder to be used twice a day. The underlying facts are set forth more particularly in paragraphs 47 through 54, above.

### **OCTOBER 8, 2013, INSPECTION**

- 63. On or about October 8, 2013, Board investigators conducted an inspection at Respondent FFSP. Board investigators requested copies of transmission of controlled substance dispensing data to Controlled Substance Utilization Review and Evaluation System (CURES) for 2012 through 2013. Respondent FFSP, Respondent Brodt, and Respondent Nguyen were unable to provide proof of transmission of CURES reports.
- 64. On October 24, 2013, a Board investigator discovered that Respondent FFSP, Respondent Brodt, and Respondent Nguyen submitted controlled substance dispensing data to CURES on February 27, 2012, April 6, 2012, January 21, 2013, July 10, 2013, August 21, 22, and 29, 2013, and October 15, 22, and 23, 2013, instead of on a weekly basis as required. Respondent FFSP and Respondent Nguyen did not file a report for February 2013.
- 65. On or about November 5, 2013, a Board investigator issued a notice of noncompliance to Respondent FFSP and Respondent Nguyen.
- 66. On or about November 12, 2013, a Board investigator issued a notice of noncompliance to Respondent Brodt.

### NINETEENTH CAUSE FOR DISCIPLINE

### (Failure to Transmit CURES Dispensing Data)

67. Respondent FFSP's license is subject to discipline for failing to comply with controlled substance laws. (Bus. & Prof. Code, § 4301, subds. (j) and (o), and Health & Saf. Code § 11165, subd. (d).) During a Board inspection on or about October 8, 2013, Respondent FFSP did not have available controlled substance dispensing data for Board review. Respondent FFSP failed to submit controlled substance data to CURES within seven days after the date of dispensing controlled substances, as required. The underlying facts are set forth more particularly in paragraphs 63 through 65, above.

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### TWENTIETH CAUSE FOR DISCIPLINE

### (Failure to Transmit CURES Dispensing Data)

68. Respondent Brodt's license is subject to discipline for failing to comply with controlled substance laws. (Bus. & Prof. Code, § 4301, subds. (j) and (o), and Health & Saf. Code § 11165, subd. (d).) While acting as PIC, Respondent Brodt failed to submit controlled substance data to CURES within seven days after the dispensing controlled substances, as required. The underlying facts are set forth more particularly in paragraphs 63, 64, and 66, above.

### TWENTY FIRST CAUSE FOR DISCIPLINE

### (Failure to Transmit CURES Dispensing Data)

69. Respondent Nguyen's license is subject to discipline for failing to comply with controlled substance laws. (Bus. & Prof. Code, § 4301, subds. (j) and (o), and Health & Saf. Code § 11165, subd. (d).) During a Board inspection on or about October 8, 2013, Respondent Nguyen did not have available controlled substance dispensing data for Board review. While acting as PCI, Respondent Nguyen failed to submit controlled substance data to CURES within seven days after dispensing controlled substances, as required. The underlying facts are set forth more particularly in paragraphs 63, 64, and 66, above.

#### JANUARY 21, 2015 INSPECTION

70. On or about November 25, 2014, the Board discovered that Respondent FFSP had failed to include all prescriptions in its CURES report and was not transmitting data consistently on a weekly basis as required. On or about January 21, 2015, a Board investigator conducted an inspection at Respondent FFSP. The Board investigator asked Respondent's staff to logon to the CURES Prescription Drug Monitoring Program (PDMP) to confirm that randomly selected prescription documents for controlled substances that were dispensed from December 15, 2014 to January 12, 2015 were documented in the CURES database. Board investigators found that, of fifteen selected prescriptions, information for ten were not in the CURES PDMP. Ultimately, the Board investigator found that, from December 2013 to September 2014, Respondent FFSP failed to transmit controlled substance data consistently on a weekly basis, and had failed to transmit data for controlled substances dispensed on December 22, 23, 24, 30 and 31, 2014. When asked,

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### TWENTY FIFTH CAUSE FOR DISCIPLINE

#### (Gross Negligence)

75. Respondent Nguyen's license is subject to discipline for gross negligence. (Bus. & Prof. Code, § 4301, subd. (c).) The underlying facts are set forth more particularly in paragraphs 70 through 71, above.

### TWENTY SIXTH CAUSE FOR DISCIPLINE

### (Failure to Transmit CURES Dispensing Data)

76. Respondent Chan's license is subject to discipline for failing to comply with controlled substance laws. (Bus. & Prof. Code, § 4301, subds. (j) and (o), and Health & Saf. Code § 11165, subd. (d).) During an inspection on or about January 21, 2015, a Board investigator found that, while acting as the individual licensed owner of Respondent FFSP, Respondent FFSP failed to submit controlled substance data to CURES within seven days after dispensing controlled substances, as required. The underlying facts are set forth more particularly in paragraphs 70 through 71, above.

#### TWENTY SEVENTH CAUSE FOR DISCIPLINE

#### (Gross Negligence)

77. Respondent Chan's license is subject to discipline for gross negligence. (Bus. & Prof. Code, § 4301, subd. (c).) The underlying facts are set forth more particularly in paragraphs 70 through 71, above.

### PETITION TO REVOKE PROBATION

- 78. Grounds exist for revoking the probation and re-imposing the order of revocation of Respondent FFSP's Pharmacy Permit and Respondent Brodt's Pharmacist License.
- 79. This Petition to Revoke Probation is brought before the Board under the probation terms and conditions of the Decision and Order for *In the Matter of the Accusation against Four Fifty Sutter, Brandon Brodt, and Elaine Chan, Case No. 3797.*

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- 80. At all times after the effective date of Respondent FFSP's probation, Condition 1 of the Disciplinary Order stated, in part, that: "Respondent shall obey all federal and state and regulations."
- 81. At all times after the effective date of Respondent FFSP's probation, Condition 11 of the Disciplinary Order stated that:

"Respondent FFSP's 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 FFSP's 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."

82. At all times after the effective date of Respondent FFSP's probation, Condition 12 of the Disciplinary Order stated that:

"If Respondent FFSP has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent FFSP's 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 FFSP violates probation in any respect, the Board, after giving Respondent FFSP's owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary 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 FFSP 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."

- 83. At all times after the effective date of Respondent Brodt's probation, Condition 1 of the Disciplinary Order stated, in part, that: "Respondent shall obey all federal and state and regulations."
- 84. At all times after the effective date of Respondent Brodt's probation, Condition 14 of the Disciplinary Order stated that:

"If Respondent Brodt has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent Brodt, 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 Brodt violates probation in any respect, the Board, after giving Respondent Brodt notice and an opportunity to be heard, may revoke probation and carry out the disciplinary 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 Brodt 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."

#### FIRST CAUSE TO REVOKE PROBATION

#### (Failure to Obey All Laws)

85. Respondent FFSP's probation is subject to revocation because it failed to comply with Probation Condition 1, referenced above, by failing to comply with all laws and regulations, as more particularly set forth in paragraphs 29 through 77, above.

#### SECOND CAUSE TO REVOKE PROBATION

#### (Failure to Post Notice of Probation)

86. Respondent FFSP's probation is subject to revocation because it failed to comply with Probation Condition 11, referenced above, by failing to post the Notice of Probation, as more particularly set forth in paragraphs 52 and 53, above.

### THIRD CAUSE TO REVOKE PROBATION

(Failure to Comply with Terms of Probation)

87. Respondent FFSP's probation is subject to revocation because it failed to comply with Probation Condition 12, referenced above, by failing to comply with any term or condition of probation, as more particularly set forth in paragraphs 29 through 77, above.

### FOURTH CAUSE TO REVOKE PROBATION

(Failure to Obey All Laws)

88. Respondent Brodt's probation is subject to revocation because he failed to comply with Probation Condition 1, referenced above, by failing to comply with all laws and regulations, as more particularly set forth in paragraphs 37 through 46, 55 through 62, 67 through 69, and 72 through 77, above.

### FIFTH CAUSE TO REVOKE PROBATION

(Failure to Comply with Terms of Probation)

89. Respondent Brodt's probation is subject to revocation because he failed to comply with Probation Condition 14, referenced above, by failing to comply with any term or condition of probation, as more particularly set forth in paragraphs 85 through 88, above.

### **DISCIPLINARY CONSIDERATIONS**

- 90. To determine the degree of discipline, if any, to be imposed on Respondent FFSP, Complainant alleges that on or about June 15, 2007, in a prior action, the Board issued Citation Number CI 06 33185. The Board ordered a \$2,500 fine against Respondent FFSP. That Citation is now final and incorporated by reference as if fully set forth.
- 91. To determine the degree of discipline, if any, to be imposed on Respondent FFSP, Complainant alleges that on or about July 8, 2009, in a prior action, the Board issued Citation Number CI 08 38139. The Board and ordered a \$5,000.00 fine against Respondent FFSP. That Citation is now final and incorporated by reference as if fully set forth.
- 92. To determine the degree of discipline, if any, to be imposed on Respondent Chan, Complainant alleges that on or about May 21, 2013, in a disciplinary action entitled "In the Matter of the Accusation against Four Fifty Sutter, Brandon Brodt, and Elaine Chan," Case No. 28

3797, the Board issued a citation against Respondent Chan for subversion. The Board ordered a \$5,000.00 fine against Respondent Chan. That Citation is now final and incorporated by reference as if fully set forth.

- 93. To determine the degree of discipline, if any, to be imposed on Respondent Brodt, Complainant alleges that on or about June 15, 2007, in a prior action, the Board issued Citation Number CI 06 33851. The Board ordered a \$1,000.00 fine against Respondent Brodt. That Citation is now final and incorporated by reference as if fully set forth.
- 94. To determine the degree of discipline, if any, to be imposed on Respondent Brodt, Complainant alleges that on or about July 8, 2009, in a prior action, the Board issued Citation Number CI 09 40780. The Board ordered a \$3,000.00 fine against Respondent Brodt. That Citation is now final and incorporated by reference as if fully set forth.
- 95. To determine the degree of discipline, if any, to be imposed on Respondent Nguyen, Complainant alleges that on or about March 13, 2014, in a prior action, the Board issued Citation Number CI 2013 58775. The Board ordered a \$3,875.00 fine against Respondent Nguyen. That Citation is now final and incorporated by reference as if fully set forth.

#### PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this Accusation and Petition to Revoke Probation, and that following the hearing, the Board of Pharmacy issue a decision:

- 1. Revoking the probation that was granted by the Board of Pharmacy in Case No. 3797 and imposing the disciplinary order that was stayed thereby revoking Pharmacy Permit No. PHY 45225 issued to Four Fifty Sutter Pharmacy and Elaine Chan, Owner;
- 2. Revoking the probation that was granted by the Board of Pharmacy in Case No. 3797 and imposing the disciplinary order that was stayed thereby revoking Pharmacist License Number RPH 43082 issued to Brandon Valor Brodt;
- 3. Revoking or suspending Pharmacy Permit Number PHY 45225 issued to Four Fifty Sutter Pharmacy and Elaine Chan, Owner;

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### Exhibit A

**Decision and Order** 

Board of Pharmacy Case No. 3797

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FIRST AMENDED ACCUSATION AND PETITION TO REVOKE PROBATION In the Matter of the Accusation Against Four Fifty Sutter Pharmacy et al.

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

In the Matter of the Accusation Against:

Case No. 3797

#### FOUR FIFTY SUTTER PHARMACY

Elaine Chan Owner 450 Sutter Pharmacy, #710 San Francisco, CA 94108 Pharmacy License No. PHY 94108

#### **BRANDON BRODT**

450 Sutter Pharmacy, #712 7<sup>th</sup> Floor San Francisco, CA 94108 Pharmacist License No. RPH 43082

#### **ELAINE CHAN**

450 Sutter Pharmacy, #710 San Francisco, CA 94108 Pharmacy Technician License No. TCH 36761

Respondents.

#### **DECISION AND ORDER**

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

This decision shall become effective on June 20, 2013.

It is so ORDERED on May 21, 2013.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

& C. Wusi

Ву

STANLEY C. WEISSER Board President

1 2 3 4 5 6 7 8	KAMALA D. HARRIS Attorney General of California DIANN SOKOLOFF Supervising Deputy Attorney General TIMOTHY J. McDonough Deputy Attorney General State Bar No. 235850 1515 Clay Street, 20th Floor P.O. Box 70550 Oakland, CA 94612-0550 Telephone: (510) 622-2134 Facsimile: (510) 622-2270 E-mail: Tim.McDonough@doj.ca.gov Attorneys for Complainant	RE THE	
9	BOARD OF	PHARMACY	
10		CONSUMER AFFAIRS CALIFORNIA	
11			
12	In the Matter of the Accusation Against:	Case No. 3797	
13	FOUR FIFTY SUTTER PHARMACY Elaine Chan Owner	OAH No. 2012020427 STIPULATED SETTLEMENT AND	
14	450 Sutter Pharmacy, # 710	DISCIPLINARY ORDER	
15	San Francisco, CA 94108 Pharmacy License No. PHY 45225,		
16	DD ANDON DDODT		
17 18	BRANDON BRODT 450 Sutter Street, #712 7th Floor San Francisco, California 94108 Pharmacist No. RPH 43082, and		
19	ELAINE CHAN		
20	875 Payne Street Sunnyvale, CA 94087	·	
21	Pharmacy Technician No. TCH 36761		
22	Respondents.		
23			
24	IT IS HEREBY STIPULATED AND AG	REED by and between the parties to the above-	
25	entitled proceedings that the following matters are true:		
26	PARTIES		
27	1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy		
28	<u> </u>	ficial capacity and is represented in this matter by	
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į		STIPULATED SETTLEMENT (3797)	

Kamala D. Harris, Attorney General of the State of California, by Timothy J. McDonough, Deputy Attorney General.

- 2. On or about March 7, 2001, the Board issued Pharmacy License No. 45225 to Four Fifty Sutter Pharmacy (Respondent FFSP). Four Fifty Sutter Pharmacy is owned by Pharmacy Technician Elaine Chan. The Pharmacy License was in full force and effect at all times relevant to the charges brought in Accusation No. 3797 and will expire on March 1, 2013, unless renewed.
- 3. On or about March 1, 1990, the Board issued Pharmacist License No. 43082 to Brandon Brodt (Respondent Brodt). The Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 3797 and will expire on January 31, 2014, unless renewed.
- 4. On or about January 2, 2002, the Board of Pharmacy issued Pharmacy Technician License No. 36761 to Elaine Chan (Respondent Chan). The Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 3797 and will expire on July 31, 2013, unless renewed.

All three Respondents are represented in this proceeding by attorney Sandra McIntosh, whose address is:

Trepel, Greenfield, Sullivan & Draa LLP 55 South Market Street 15th Floor San Jose, CA 95113

#### JURISDICTION

- 5. Accusation No. 3797 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against all Respondents. The Accusation and all other statutorily required documents were properly served on Respondents on August 22, 2011. Respondents timely filed a Notice of Defense contesting the Accusation.
- 6. A copy of Accusation No. 3797 is attached as exhibit A and incorporated by reference.

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#### ADVISEMENT AND WAIVERS

- 7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in Accusation No. 3797. Respondents have also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 8. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at their own expense; the right to confront and cross-examine the witnesses against them, the right to present evidence and to testify on their 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. Respondents voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

#### CULPABILITY

- 10. Respondents understand that the charges and allegations in Accusation No. 3797, if proven at a hearing, constitute cause for imposing discipline upon their Pharmacist, Pharmacy, and Pharmacy Technician Licenses. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation and that those charges constitute cause for discipline. Respondents give up their right to contest that cause for discipline exists based on those charges.
- 11. Respondent FFSP agrees that its Pharmacy License is subject to discipline and agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.
- 12. Respondent Brodt agrees that his Pharmacist License is subject to discipline and he agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

13. Respondent Chan agrees to settle the Accusation against her Pharmacy Technician License by accepting the issuance of a citation for violating Business and Professions Code section 4301, subdivision (q).

#### **CONTINGENCY**

- 14. This stipulation shall be subject to approval by the Board. Respondents understand and agree that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their 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.
- 15. The parties understand and agree that facsimile copies of this Stipulated Settlement and Disciplinary Order, including facsimile signatures thereto, shall have the same force and effect as the originals.
- 16. This Stipulated Settlement and Disciplinary Order are intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 17. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

#### CITATION IN SETTLEMENT FOR RESPONDENT CHAN

1. Respondent Chan agrees to settle the Accusation against her Pharmacy Technician License by accepting the issuance of a citation and fine for violating Business and Professions

Code section 4301, subdivision (q). The administrative fine will be \$5,000 and Respondent Chan will be permitted to make payments on a payment plan approved by the Board to be paid in full within 24 months of the effective date of this decision. Respondent Chan agrees not to appeal this citation and fine.

#### **DISCIPLINARY ORDER FOR 450 SUTTER PHARMACY**

IT IS HEREBY ORDERED that Pharmacy License No. 45225 issued to Respondent FFSP is revoked. However, the revocation is stayed and Respondent FFSP is placed on probation for five (5) years on the following terms and conditions.

#### 1. Obey All Laws

Respondent FFSP shall obey all state and federal laws and regulations.

Respondent FFSP's owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the

  Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- □ a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacy license 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 FFSP's 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 FFSP's owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure

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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 FFSP's 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 FFSP's 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 FFSP's owner shall pay to the board its costs of investigation and prosecution in the amount of \$14,481.50. Respondent FFSP shall make payments on a payment plan approved by the Board. There shall be no deviation from this schedule absent prior written approval by the 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 FFSP shall not relieve Respondent FFSP of their responsibility to reimburse the Board its costs of investigation and prosecution.

#### 6. Probation Monitoring Costs

Respondent FFSP's 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.

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7. Status of License

Respondent FFSP shall, at all times while on probation, maintain current licensure with the Board. If Respondent FFSP's 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 Respondent FFSP shall remain on probation as determined by the Board. Failure to maintain current licensure shall be considered a violation of probation.

If Respondent FFSP'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 FFSP 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 FFSP's owner discontinue business, Respondent FFSP's 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 FFSP will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, Respondent FFSP's 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 FFSP's 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 FFSP's 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

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days of its provision to the pharmacy's ongoing patients, Respondent FFSP's 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 FFSP's owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondent FFSP's 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 FFSP's 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 FFSP's 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 FFSP's 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 FFSP's 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 FFSP's owner 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 FFSP or respondent FFSP'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 FFSP's 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 FFSP's 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 Respondent FFSP has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent FFSP's 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 FFSP violates probation in any respect, the Board, after giving Respondent FFSP's owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary 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 FFSP 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.

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13. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, Respondent FFSP's Pharmacy license will be fully restored.

#### 14. Community Services Program

Within sixty (60) days of the effective date of this decision, Respondent FFSP's owner shall submit to the Board or its designee, for prior approval, a community service program in which Respondent FFSP shall provide free health-care related services to a community or charitable facility or agency for at 50 hours per year for each year of probation.

Within thirty (30) days of Board approval thereof, Respondent FFSP's owner shall submit documentation to the Board demonstrating commencement of the community service program. Respondent FFSP's owner shall report on progress with the community service program in the quarterly reports.

Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

#### 15. Separate File of Records

Respondent FFSP shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

### 16. Monetary Contribution to Community

Respondent FFSP shall contribute to the general community \$21,000 in free, pharmacy-related services during the first 2 years of its probationary period. Respondent FFSP's owner shall report on progress with the monetary contribution to the community in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

#### DISCIPLINARY ORDER FOR PHARMACIST BRANDON BRODT

IT IS HEREBY ORDERED that Pharmacist License No. 43082 issued to Respondent Brandon Brodt is revoked. However, the revocation is stayed and Respondent Brodt is placed on probation for four (4) years on the following terms and conditions.

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#### 1. Suspension

As part of probation, Respondent Brodt is suspended from working as a pharmacist for 30 days beginning the effective date of this decision.

During suspension, Respondent Brodt shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs licensed by the board, or any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent Brodt shall not perform any of the duties of a pharmacist, nor do any act involving drug selection, selection of stock, manufacturing, dispensing; nor shall Respondent Brodt manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices and controlled substances.

Respondent Brodt shall not direct, control or perform any aspect involving the distribution of dangerous drugs and devices and controlled substances. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed entity in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

#### 2. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent Brodt shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the

  Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- an arrest or issuance of a criminal complaint for violation of any state or federal law
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- □ a conviction of any crime

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discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's Pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

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

#### 3. Report to the Board

Respondent Brodt 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 Brodt 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.

#### 4. Interview with the Board

Upon receipt of reasonable prior notice, Respondent Brodt shall appear in person for interviews with the Board or its designee, upon request 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.

#### 5. Cooperate with Board Staff

Respondent Brodt shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent Brodt's compliance with the terms and conditions of his probation. Failure to cooperate shall be considered a violation of probation.

#### 6. Notice to Employers

During the period of probation, Respondent Brodt shall notify all present and prospective employers of the decision in case number 3797 and the terms, conditions and restrictions imposed on Respondent Brodt by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his direct supervisor, designated representative-in-charge (including each new designated representative-in-charge employed during respondent's tenure of employment), and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 3797 and terms and conditions imposed thereby. It shall be Respondent Brodt's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.

If Respondent Brodt works for or is employed by or through a pharmacy employment service, respondent must notify his direct supervisor, designated representative-in-charge and owner at each entity licensed by the Board of the terms and conditions of the decision in case number 3797 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he has read the decision in case number 3797 and the terms and conditions imposed thereby. It shall be the respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a designated representative or in any position for which a designated representative

license is a requirement or criterion for employment, whether the respondent is considered an employee or independent contractor or volunteer.

#### 7. No Being Designated Representative-in-Charge

During the period of probation, Respondent Brodt shall not be the designated representative-in-charge of any entity licensed by the Board unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

#### 8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondent Brodt shall pay to the Board its costs of investigation and prosecution in the amount of \$3,000. Respondent Brodt shall make the payments on a payment plan approved by the Board. There shall be no deviation from this schedule absent prior written approval by the 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 Brodt shall not relieve Respondent Brodt of his responsibility to reimburse the Board its costs of investigation and prosecution.

#### 9. Probation Monitoring Costs

Respondent Brodt 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.

#### 10. Status of License

Respondent Brodt shall, at all times while on probation, maintain an active, current pharmacist license with the Board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

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

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#### 11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should Respondent Brodt cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent Brodt may tender his designated representative 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 Brodt will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of Respondent Brodt's license history with the board.

Upon acceptance of the surrender, Respondent Brodt shall relinquish his pharmacist license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license, permit, or registration from the board for three (3) years from the effective date of the surrender. Respondent Brodt shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board.

### 12. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent Brodt shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving and the address of the new employer, supervisor and owner and work schedule, if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address and mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

#### 13. Tolling of Probation

Except during periods of suspension, Respondent Brodt shall, at all times while on probation, be employed as a designated representative in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of

probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, Respondent Brodt must nonetheless comply with all terms and conditions of probation.

Should Respondent Brodt, regardless of residency, for any reason (including vacation) cease working as a designated representative for a minimum of 40 hours in California, Respondent Brodt must notify the board in writing within ten (10) days of cessation of work and must further notify the Board in writing within ten (10) days of the resumption of work. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of work" means any calendar month during which respondent is not working as a designated representative for at least 40 hours as a designated representative as defined by Business and Professions Code section 4053. "Resumption of work" means any calendar month during which respondent is working as a designated representative for at least 40 hours as a designated representative as defined by Business and Professions Code section 4053.

#### 14. Violation of Probation

If a Respondent Brodt has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent Brodt, and probation shall automatically be 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 Brodt violates probation in any respect, the Board, after giving Respondent Brodt notice and an opportunity to be heard, may revoke probation and carry out the disciplinary 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 Brodt

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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.

#### 15. Completion of Probation

Upon written notice by the Board indicating successful completion of probation, Respondent Brodt's Pharmacist License will be fully restored.

#### 16. No Ownership of Licensed Premises

Respondent Brodt shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent Brodt shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

#### 17. Community Services Program

Within sixty (60) days of the effective date of this decision, Respondent Brodt shall submit to the Board or its designee, for prior approval, a community service program in which Respondent Brodt shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least 30 hours per year while on probation. Within thirty (30) days of board approval thereof, Respondent Brodt shall submit documentation to the board demonstrating commencement of the community service program. A record of this notification must be provided to the board upon request. Respondent Brodt shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

#### 18. Remedial Education

Within sixty (60) days of the effective date of this decision, Respondent Brodt shall submit to the Board or its designee, for prior approval, an appropriate program of remedial education related to compounding and record keeping. The program of remedial education shall consist of at least 10 hours each year for the first three years of Respondent Brodt's probation. The

education classes shall be at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the Board, is provided to the board or its designee.

Following the completion of each course, the Board or its designee may require the respondent, at his or her own expense, to take an approved examination to test the Respondent Brodt's knowledge of the course. If Respondent Brodt does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require Respondent Brodt to take another course approved by the Board in the same subject area.

#### 19. Consultant for Owner or Pharmacist-In-Charge

During the period of probation, Respondent Brodt shall not supervise any intern pharmacist, or serve as a consultant to any entity licensed by the board. In the event that the Respondent Brodt is currently the pharmacist-in-charge of a pharmacy, the pharmacy shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by Respondent Brodt with state and federal laws and regulations governing the practice of pharmacy and for compliance by Respondent Brodt with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the Board or its designee, for prior approval. Within thirty (30) days of the effective date of this decision. Respondent Brodt shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he is not the current PIC. The Board may, in case of an employment change by respondent or for other reasons as deemed appropriate by the board or its designee, preclude Respondent Brodt from acting as a pharmacist-in-charge. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

#### 20. Tolling of Suspension

During the period of suspension, Respondent Brodt shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of the (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days Respondent Brodt is absent from California. During any such period of tolling of suspension, Respondent Brodt must nonetheless comply with all terms and conditions of probation.

Respondent Brodt must notify the Board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume the practice of pharmacy until notified by the board that the period of suspension has been satisfactorily completed.

#### 21. Ethics Course

Within sixty (60) calendar days of the effective date of this decision, Respondent Brodt shall enroll in a course in ethics, at respondent's expense, approved in advance by the Board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent Brodt shall submit a certificate of completion to the Board or its designee within five days after completing the course.

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Sent by: TREP	EL MCGRANE GREENFIELD LLP 4089950308; 12/06/12 4:53PM; JetFox #711; Page 2/3
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*	TO "SANDRA MCINTOSH
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1	ACCEPTAN .
2	I have carefully read the above appliated Settle and Disciplinary Order and have fully
3	discussed it with my attorney, Sandra - Matosh. I will a stipulation and the effect it will
4	have on my Pharmacist License. I enter into this Stipe wed Scutteriont and Disciplinary Order
. 5	voluntarily, knowingly, and intelligently, and agreed to bound by the Decision and Order of the
6	Board of Pharmacy.
7 \	11/0-2 1 01
8	DATED: 12/6/12 /2000 (Scott)
9	MANDON 1 A LAT Respondent
10	I have carefully read the above Stipulated Spiritement and Disciplinary Order and have fully
11	discussed it with my attorney, Sandra regintosh. The mend the effect it will
12	have on my Pharmacy. Tenter into the Stipulated States and Desciplinary Order voluntarily,
13	knowingly, and intelligently, and against be bound in the Decision and Order of the Board of
. 14	Pharmacy.
15	
16	DATED: 12/6/12. Clarae
17	FEAR FIFE LITER PILARMACY—ELAINE CHAN OWN
18	kesponaeni
19	I have carefully rough the above and attention of the and large fully
. 20	discussed it with my alternay, Sandra ( lettech, and a least discussed it with my alternay, Sandra ( lettech, and the effect it will
21	have on my Pharmacy Technician Liberary. Tenter at a drie Stipoland Settlement voluntarily,
22	knowingly, and intelligently, and agree to be bounded the Decision and Order of the Board of
23	Pharmacy.
. 24	DATED: 12/6/12 Elavai Q
25	DATED: 12/6/12 Clarai (1)
26	i espondent
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1	I have read and fully discussed with Respondents Brandon Brodt, Respondent 450 Sutter
2	Pharmacy, and Respondent Elaine Chan the terms and conditions and other matters contained in
.3	the above Stipulated Settlement and Disciplinary Order. I approve its form and content.
4	DATED: 12/6/12 Sundra R Me Into
5	Sandra McIntosh Attorney for Respondents
6	
7	ENDORSEMENT
8	The foregoing Stipulated Settlement and Disciplinary Order are hereby respectfully
9	submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.
10	Dated: /2-7-/ Respectfully submitted,
11	
12	Kamala D. Harris Attorney General of California
13 -	DIANN SOKOLOFF Supervising Deputy Attorney General
14	5/.01
15	PIMOTHY J. McDonough
16	Deputy Attorney General Attorneys for Complainant
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- 1)	STIPULATED SETTLEMENT (3797)

Exhibit A

Accusation No. 3797

1	KAMALA D. HARRIS		
2	Attorney General of California DIANN SOKOLOFF		
3	Supervising Deputy Attorney General TIMOTHY J. McDonough		
4	Deputy Attorney General State Bar No. 235850		
5	1515 Clay Street, 20th Floor P.O. Box 70550		
6	Oakland, CA 94612-0550 Telephone: (510) 622-2134		
7	Facsimile: (510) 622-2270 Attorneys for Complainant		
8		RE THE	
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS		
10	STATE OF C	CALIFORNIA	
11	In the Matter of the Accusation Against:	Case No. 3797	
12	BRANDON BRODT		
13	450 Sutter Street, #712 7th Floor San Francisco, California 94108 Pharmacist No. RPH 43082,	ACCUSATION	
14	ELAINE CHAN		
15	Owner Four Fifty Sutter Pharmacy 875 Payne Street		
16	Sunnyvale, CA 94087		
17	Pharmacy Technician No. TCH 36761,	,	
18	and FOUR FIFTY SUTTER PHARMACY 450 SUTTER STREET, #710	·	
19	SAN FRANCISCO, CA 450 Sutter Street, #710		
20	San Francisco, CA 94108 Pharmacy License No. PHY45225		
21			
22	Respondents.		
23			
24	Complainant alleges:		
25	PAR	<u>TIES</u>	
26	Virginia Herold (Complainant) bring	s this Accusation solely in her official capacity	
27	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.		
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- 2. On or about March 1, 1990, the Board of Pharmacy issued Pharmacist License
  Number RPH 43082 to Brandon Brodt (Respondent Brodt). The Pharmacist License was in full
  force and effect at all times relevant to the charges alleged in this Accusation and will expire on
  January 31, 2012, unless renewed. Since approximately November 4, 2004, Respondent Brodt
  has been and/or has been reflected in Board records as the Pharmacist-in-Charge for Respondent
  Four Fifty Sutter Pharmacy.
- 3. On or about March 7, 2001, the Board of Pharmacy issued Pharmacy License Number PHY45225 to Four Fifty Sutter Pharmacy (Respondent FFSP). The Pharmacy License was in full force and effect at all times relevant to the charges alleged in this Accusation and will expire on March 1, 2012, unless renewed.
- 4. On or about January 2, 2002, the Board of Pharmacy issued Pharmacy Technician License Number TCH 36761 to Elaine Chan (Respondent Chan). The Pharmacist Technician License was in full force and effect at all times relevant to the charges alleged in this Accusation and will expire on July 31, 2011, unless renewed. Respondent Chan is the owner of Respondent Four Fifty Sutter Pharmacy (FFSP).

#### JURISDICTION |

- 5. 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.
- 6. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].
  - 7. Section 4300 of the Code states, in relevant part:
  - "(a) Every license issued may be suspended or revoked.
- "(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
  - "(1) Suspending judgment.

"(2) I	Placing	him	or	her	upon	probation.
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- "(3) Suspending his or her right to practice for a period not exceeding one year.
- "(4) Revoking his or her license.
- "(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

"(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

8. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

#### STATUTORY PROVISIONS

9. Section 4301 of the Code states, in relevant part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

Unprofessional conduct shall include, but is not limited to, any of the following:

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"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board.

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

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requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

- "(7) The equipment used in compounding the drug product.
- "(8) A pharmacy assigned reference or lot number for the compounded drug product.
- "(9) The expiration date of the final compounded drug product.
- "(10) The quantity or amount of drug product compounded.
- "(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.
- "(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.
- "(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created."
  - 15. California Code of Regulations, title 16, section 1735.2 states, in relevant part:
- "(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

#### COST RECOVERY

16. Section 125.3 of the Code states, in relevant part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

#### FACTUAL BACKGROUND

#### November 25, 2008 Inspection at FFSP.

- 17. On or about November 25, 2008, Board Investigator Nip conducted an inspection at Respondent Four Fifty Sutter Pharmacy (FFSP) after the Board received a tip that a technician at the pharmacy was acting as a pharmacist by checking off prescriptions and consulting with patients. The complaint also claimed that "root canal powder" was manufactured by Respondent Elaine Chan (Chan), a pharmacy technician and sole owner of FFSP, at her home without the supervision of a pharmacist. According to the complaint, the root canal powder was brought back into the pharmacy to be dispensed to dental offices. During the inspection, Investigator Nip asked Respondent Chan about the compounding of root canal powder. Respondent Chan said that the pharmacy had not compounded this product for a long time and denied that any of the product was made outside of the pharmacy.
- 18. At the conclusion of the inspection, Investigator Nip issued a written notice for non-compliance based on the following: 1) a prescription with an incorrect expiration date on its label was in the will call area<sup>2</sup> and ready for patient pick-up; 2) a coumpounded product was found in the pharmacy's inventory without a retrievable compounding record and formula during and after the inspection; 3) a compounded product labeled with a 12 month expiration date from the date of the preparation date was found in the will call area ready for patient pick-up; (4) numerous compounded products--with expiration dates beyond the allowable 180 days-- were located on the compounding shelves and inventory area; (5) lack of a Drug Enforcement Agency (DEA) power

<sup>&</sup>lt;sup>1</sup> The investigation in 2008 did not reveal sufficient evidence to substantiate these allegations.

allegations.

The will-call area of a pharmacy is the area where prescriptions are waiting to be picked up by patients.

of attorney for the pharmacist-in-charge, Respondent Brandon Brodt (Brodt), who was not present during the inspection; and (6) no Theft/Impairment of Licensed Employees policies and procedures were in place.

#### December 15, 2009 and March 16, 2010 Inspections at FFSP

- 19. On or about December 15, 2009, Board Inspector Barnard went to Respondent FFSP to conduct another inspection after receiving another complaint about the pharmacy. The inspectors noticed numerous violations of pharmacy laws. Among those noted was a lack of a Drug Enforcement Agency (DEA) power of attorney for the pharmacist-in-charge, Respondent Brandon Brodt (Brodt), who was not present during the inspection. Other violations included a cluttered and disorganized pharmacy, out-dated chemicals in stock which needed to be quarantined for destruction, prescriptions left in will-call for over 30 days, labeling errors on some prescriptions, lack of a DEA Biennial inventory, and a lack of Quality Assurance Review Reports and documentation. At the end of the inspection, the inspector asked that certain documents and photographs be sent to her within fourteen days showing corrections to the various violations of pharmacy laws.
- 20. On December 23, 2009, Respondent Brodt sent a fax to the Board investigator with a copy of a DEA power of attorney for himself-the pharmacist-in-charge-and a copy of a DEA bienniel inventory dated July 7, 2008. The fax indicated that other corrections would be addressed in another fax. On January 14, 2010, Inspector Barnard called Respondent Chan to discuss the missing documentation and on February 10, 2010, Inspector Barnard received some of the documentation in the mail that she had requested.
- 21. On March 16, 2010, Board Inspectors Barnard and Nip returned to FFSP to see if certain corrections had been made. Inspector Nip was also investigating an additional complaint received by the Board. Most of the pharmacy was still cluttered and disorganized and there was insufficient clear work space for the safe practice of pharmacy. Many mandatory documents could not be found such as a Community Pharmacy Self-Assessement. Complete compounding records were not available. Further, certain Quality Assurance Review Reports were missing.

Inspector Nip found four prescriptions in the will call area with incorrect expiration dates.<sup>3</sup> Specifically, prescriptions RX 6412288, RX6412289, RX 6412609, RX6412672 had expiration dates of March 2, 2011, March 2, 2011, March 11, 2011, and March 15, 2011, respectfully. However, the actual expiration dates for these prescriptions was November 2010, November 2010, July 2010, and December 2010, respectfully. The inspectors found return-to-stock prescription containers in inventory which were expired. The inspectors noted that the Pharmacy refridgerator contained expired drugs and chemicals. The backroom refridgerator contained food along with an H1N1 vaccine and the refridgerator did not contain a thermometer. Before leaving FFSP, the inspectors provided legal reference information regarding compliance with pharmacy laws. The inspectors requested missing documentation to be sent to them in three days. Respondent Brodt sent a facsimile to the inspectors with some of the requested information on March 17, 2010.

22. During the inspection, Inspectors found a handwritten telephone prescription document for medications (Testosterone injectable and Ambien 10 mg) ordered by Dr. Leonidas Priest for "office use." Respondent Chan did not know the location of Dr. Priest's office. She was also unable to provide a valid office phone number for Dr. Priest. When asked about compounding root canal powder, Respondent Chan indicated that the formula for the product was very old and that she had not made any for a long time. She admitted she probably did compound some in the past three years. The inspectors asked for compounding logs for the dental root canal powder for the last three years, the master formula, and the names of dentists to whom the compound was sold. The inspectors asked that the documents be sent to them in three days. The documents were not timely received.

#### April 29, 2010 Inspection at FFSP

23. On April 29, 2010, Inspector Nip returned to FFSP for a further inspection. Much of the pharmacy area had been cleared of debris. However, the compounding counter was still cluttered, contained expired chemicals, and provided insufficient work-space. Inspector Nip was

<sup>&</sup>lt;sup>3</sup> The prescription labels had dates on them which incorrectly extended the dating of the prescription beyond the manufacturer's expiration date for the product.

 unable to obtain many documents she requested because Respondent Chan was the only one who had access to the documentation and she was not present at the time. Some documents were reviewed. Documents showed that FFSP had dispensed a large amount of medications to Dr. Priest "for office use" by telephoned prescriptions or pharmacy-generated refill requests. Inpector Nip could not locate any hand-written prescription document and label from Dr. Priest. Further, a prescription document and label for root canal cement, dated April 9, 2010, for a dentist in Newark, CA was located in the will call/on order box of the pharmacy. At the end of the inspection, Inspector Nip asked that certain documents be forwarded to her. On May 10, 2010, Inspector Nip received some documents she requested from Respondent Chan. The documents received indicated that seventeen dentists obtained compounded root canal cement from FFSP within three years of March 16, 2010.

#### Causes of Discipline-Respondent Brodt as Pharmacist-in-Charge at FFSP.

# FIRST CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Maintain Premises -Safe Practice of Pharmacy) (Bus. & Prof. § 4301(o) and 16 CCR § 1714(b))

- 24. Respondent Brodt, as Pharmacist-in-Charge of FFSP, has subjected his Pharmacist License to disciplinary action under Code section 4301, subdivision (o), by violating California Code of Regulations, title 16, section 1714, subdivision (b), in that he failed to maintain the pharmacy in a manner suitable for the safe practice of pharmacy. The circumstances are as follows:
- 25. On December 15, 2009 and March 16, 2010 inspections at FFSP revealed that the pharmacy was disorganized, dirty and contained insufficient unobstructed space for the safe practice of pharmacy. The pharmacy sink was dirty and the compounding area was unsanitary. The work spaces were covered with boxes, paperwork, and trash. The pharmacy dispensing area was insufficient in size to accommodate two pharmacists and a technician working at the same time. Further, FFSP stored outdated compounded products, expired chemicals and drugs, and prescriptions which were 60 days old or older. Pharmacy paperwork was not located during the inspection due to disorganization.

### SECOND CAUSE FOR DISCIPLINE (Unprofessional Conduct- Missing Quality Assurance Review Reports) (Bus, & Prof. § 4301(0) and 16 CCR § 1711(f))

26. Respondent Brandon Brodt, as Pharmacist-in-Charge of FFSP, has subjected his Pharmacist License to disciplinary action under Code section 4301, subdivision (o), by violating California Code of Regulations, title 16, section 1711, subdivision (f), in that he failed to maintain a medication error Quality Assurance Review Report in the pharmacy for the present year. Specifically, on March 16, 2010, during an inspection at FFSP there were no Quality Assurance Review Reports on file and immediately retrievable pertaining to medication dispensing errors involving two prescriptions dated October 28, 2009. These reports were not on file even though they were requested before and not located during the December 15, 2009 inspection.

# THIRD CAUSE FOR DISCIPLINE (Unprofessional Conduct-Labeling Error) (Bus. & Prof. §§ 4031(o), 4076 (a)(9), & 4077(a))

27. Respondent Brodt, as Pharmacist-in-Charge of FFSP, has subjected his Pharmacist License to disciplinary action under Code section 4301, subdivision (o), by violating Code sections 4076, subdivision (a)(9), and 4077, subdivision (a), in that on March 16, 2010, during an inspection of the pharmacy, four prescriptions in the will call area which were ready for patient pick-up were labeled with incorrect expiration dates. Each prescription contained expiration dates which post-dated the actual expiration dates listed on the manufacturer's box containers. The circumstances of the incorrect expiration dates for the four prescriptions are explained in paragraph 21, above.

#### FOURTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Erroneous Prescriptions) (Bus. & Prof. § 4301(o) and 16 CCR § 1761(a))

28. Respondent Brodt, as Pharmacist-in-Charge of FFSP, has subjected his Pharmacist License to disciplinary action under Code section 4301, subdivision (o), by violating California Code of Regulations, title 16, section 1761, subdivision (a), in that FFSP dispensed numerous medications to a doctor for "office use" without obtaining important information such as the doctor's office address or phone number. The circumstances are as follows:

29. On or about August 10, 2007, to approximately March 12, 2010, FFSP dispensed numerous medications to Dr. Priest for "office use." The medications dispensed included Adipex, Ambien, Delatestryl, Nandrolone Decanoate, Phentermina, Testosterone, and Zolpidem Tartrate. Dr. Priest would pick up the medications himself and usually pay with cash. Respondent Chan claimed that Dr. Priest ran a diet clinic. However, during this period of time, Dr. Priest primarily worked in an emergency department in a medical center in Stockton without another known office location or office telephone number.

## FIFTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions) (Bus. & Prof. § 4301(o) and Health and Safety Code § 11153(a))

- 30. Respondent Brodt, as Pharmacist-in-Charge of FFSP, has subjected his Pharmacist License to disciplinary action under Code section 4301, subdivision (o), by violating Health and Safety Code sections 11153, subdivision (a), in that Respondent FFSP dispensed medications to Dr. Priest which were not for legitimate medical purposes in the usual course of his practice. The circumstances are as follows:
- 31. On or about August 10, 2007 to approximately March 12, 2010, FFSP dispensed numerous medications to Dr. Priest for "office use." Many of these medications were in large quantities not ordinarily needed for "office use." Dr. Priest would pick up the medications himself and often pay with cash. Respondent Chan claimed that the large quantities of medications for office use were needed because Dr. Priest ran a diet clinic. The medications provided to Dr. Priest are listed in a paragraph 29, above. However, during this period of time Dr. Priest primarily worked in an emergency department in a medical center in Stockton without another known office location or office telephone number.

# SIXTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Transmit Dispensing Data to CURES) (Bus. & Prof. § 4301(o) and Health and Safety Code § 11165(d))

32. Respondent Brodt, as Pharmacist-in-Charge of FFSP, has subjected his Pharmacist License to disciplinary action under Code section 4301, subdivision (o), by violating Health and Safety Code sections 11165, subdivision (d), in that from on or about December 16, 2009, until Approximately April 13, 2010, Respondent FFSP failed to transmit dispensing data on a weekly

basis for Schedule II, Schedule III, and Schedule IV controlled substances to Controlled Substances Utilization Review and Evaluation System (CURES).

#### SEVENTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Maintain Compounding Records) (Bus. & Prof. § 4301(0) and 16 CCR § 1735.3)

33. Respondent Brodt, as Pharmacist-in-Charge of FFSP, has subjected his Pharmacist License to disciplinary action under Code section 4301, subdivision (o), by violating California Code of Regulations, title 16, section 1735.3 in that, on or about March 16, 2007, to approximately April 29, 2010, Respondent FFSP dispensed root canal cement to seventeen different dentists in various quantities. However, Respondent FFSP did not maintain the complete compounding records for the root canal cement it dispensed. Any records that FFSP did have were not readily available.

#### EIGHTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Labeling Error) (Bus. & Prof. § 4301(o) and CCR § 1735.2(h))

- 34. Respondent Brodt, as Pharmacist-in-Charge of FFSP, has subjected his Pharmacist License to disciplinary action under Code section 4301, subdivision (o), by violating California Code of Regulations, title 16, section 1735.2, subdivision (h), in that Respondent FFSP dispensed prescriptions for compounded root canal cement with expiration dates over 180 days from the time it was prepared. The circumstances are as follows:
- 35. On or about July 17, 2009, Respondent FFSP dispensed to Dr. Le Claire prescription number RX6405783, compounded root canal cement, which had an assigned expiration date of July 17, 2010, on its label. Also, on or about August 20, 2009, Respondent FFSP dispensed to Dr. Louie prescription number RX6406838, compounded root canal cement, which had an assigned expiration date of August 20, 2010 on its label.

#### Causes of Discipline-Respondent FFSP.

#### FIRST CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Maintain Premises —Safe Practice of Pharmacy) (Bus. & Prof. § 4301(e) and 16 CCR § 1714(b))

36. Respondent FFSP's Pharmacy License is subject to disciplinary action under Code section 4301, subdivision (o), because of violations of California Code of Regulations, title 16,

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section 1714, subdivision (b), in that FFSP was not maintained in a manner suitable for the safe practice of pharmacy. The circumstances are explained in paragraph 25, above.

#### SECOND CAUSE FOR DISCIPLINE (Unprofessional Conduct-Missing Quality Assurance Review Report) (Bus. & Prof. § 4301(0) and 16 CCR § 1711(f))

37. Respondent FFSP's Pharmacy License is subject to disciplinary action under Code section 4301, subdivision (o), because of violations of California Code of Regulations, title 16, section 1711, subdivision (f), in that FFSP did not maintain a medication error Quality Assurance Review Report in the pharmacy for the present year. Specifically, on March 16, 2010, during an inspection at FFSP there were no Quality Assurance Review Reports on file and immediately retrievable pertaining to medication dispensing errors for two prescriptions dated October 23, 2009 and October 28, 2009. These reports were not on file even though they were requested before and not located during the December 15, 2009 inspection.

#### THIRD CAUSE FOR DISCIPLINE (Unprofessional Conduct-Labeling Error) (Bus. & Prof. §§ 4076 (a)(9) & 4077(a))

38. Respondent FFSP's Pharmacy License is subject to disciplinary action under Code section 4301, subdivision (o), because of violations of Code section 4076, subdivision (a)(9) and section 4077, subdivision (a), in that, on March 16, 2010, during an inspection of FFSP, four prescriptions in the will call area which were ready for patient pick-up were labeled with incorrect expiration dates. Each prescription contained expiration dates which were later than the actual expiration dates listed on the manufacturer's box containers. The circumstances of the four prescriptions are explained in paragraph 21, above.

#### FOURTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Erroneous Prescriptions) (Bus. & Prof. § 4301(o) and 16 CCR § 1761(a))

39. Respondent FFSP's Pharmacy License is subject to disciplinary action under Code section 4301, subdivision (o), because of violations of California Code of Regulations, title 16, section 1761, subdivision (a), in that Pharmacists and staff at FFSP dispensed numerous medications to a doctor for office use without obtaining important information such as the

doctor's office address or phone number. The circumstances are explained in paragraph 29, above.

## FIFTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Verify Legitimacy of Prescriptions) (Bus, & Prof. § 4301(o) and Health and Safety Code § 11153(a))

40. Respondent FFSP's Pharmacy License is subject to disciplinary action under Code section 4301, subdivision (o), because of violations of Health and Safety Code section 11153, subdivision (a), in that Pharmacists and staff at FFSP dispensed medications to Dr. Priest which were not for legitimate medical purposes in the usual course of his practice. The circumstances are explained in paragraph 29, above.

# SIXTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Transmit Dispensing Data to CURES) (Bus. & Prof. § 4301(o) and Health and Safety Code § 11165(d))

41. Respondent FFSP's Pharmacy License is subject to disciplinary action under Code section 4301, subdivision (o), because of violations of Health and Safety Code section 11165, subdivision (d), in that from on or about December 16, 2009, until approximately April 13, 2010, Respondent FFSP failed to transmit dispensing data for Schedule II, Schedule III, and Schedule IV controlled substances to Controlled Substances Utilization Review and Evaluation System (CURES) on a weekly basis.

# SEVENTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Failure to Maintain Compounding Records) (Bus. & Prof. § 4301(o) and CCR § 1735.3)

42. Respondent FFSP's Pharmacy License is subject to disciplinary action under Code section 4301, subdivision (o), because of violations of California Code of Regulations, title 16, section 1735.3, in that on or about March 16, 2007, to approximately April 29, 2010, Pharmacists and Staff at FFSP dispensed root canal cement to seventeen different dentists in various quantities. However, Respondent FFSP did not maintain complete compounding records for the root canal cement it dispensed.

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### EIGHTH CAUSE FOR DISCIPLINE (Unprofessional Conduct-Labeling Error) (Bus. & Prof. § 4301(e) and 16 CCR § 1735.2(h))

Respondent FFSP's Pharmacy License is subject to disciplinary action under Code section 4301, subdivision (o), because of violations of California Code of Regulations, title 16, section 1735.2, subdivision (h), in that Pharmacists and staff at FFSP dispensed prescriptions for compounded root canal cement with expiration dates over 180 days from the time it was prepared. The circumstances are explained in paragraph 35, above.

#### · Causes of Discipline-Respondent Chan.

#### FIRST CAUSE FOR DISCIPLINE (Unprofessional Conduct-Subversion of Board Investigation) (Bus. & Prof. 4301(q))

Respondent Chan has subjected her Pharmacy Technician License to disciplinary action under section 4301, subdivision (q), in that she acted unprofessionally when she engaged in conduct that attempted to deceive the Board's investigation into FFSP. Specifically, Respondent Chan informed Board inspectors that the pharmacy had not compounded or dispensed root canal powder for a long time while the pharmacy had continuously dispensed root canal powder to at least 17 different dentists within the last three years from March 2007, to April 2010. Further, Respondent Chan failed to submit requested dispensing records of the compounded root canal powder to Board investigators by March 21, 2010, as requested. The requested records were not submitted until May 10, 2010, after another inspection was conducted at FFSP on April 29, 2010.

#### DISCIPLINE CONSIDERATIONS

- To determine the degree of discipline, if any, to be imposed on Respondent Brodt, 45. Complainant alleges that on or about June 15, 2007, in a prior action, the Board of Pharmacy issued Citation Number CI 06 33851 and ordered Respondent to pay \$1,000 in fines. That Citation is now final and is incorporated by reference as if fully set forth.
- 46. To determine the degree of discipline, if any, to be imposed on Respondent Brodt, Complainant alleges that on or about July 8, 2009, in a prior action, the Board of Pharmacy issued

Accusation

1	4. Ordering Brandon Brodt, Elaine Chan, and Four Fifty Sutter Pharmacy to pay the			
2	Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, under			
3	Business and Professions Code section 125.3;			
4	5. Taking such other and further action as deemed necessary and proper.			
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6	7/14/11			
7	DATED: TITII Jusine Herde			
8	Executive Officer Board of Pharmacy			
9	Department of Consumer Affairs State of California			
10	Complainant			
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Accusation