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

In the Matter of the Accusation Against:

SOUTHERN CALIFORNIA HEALTHCARE SYSTEMS, INC., DBA SOUTHERN CALIFORNIA HOSPITAL AT CULVER CITY,

Hospital Pharmacy Permit No. HSP 51172 and Sterile Compounding Permit No. LSC 100222;

JILL CHANG,
Pharmacist License No. RPH 66782;

AINSLIE HOI LI CHEUNG,
Pharmacist License No. RPH 64668; and

JACQUELINE HOANG VO,
Pharmacist License No. RPH 45816;

Respondents

Agency Case No. 6647; OAH No. 2020040205

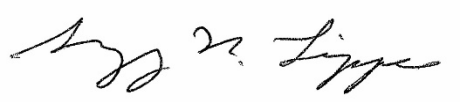
DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on March 19, 2021.

It is so ORDERED on February 17, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Greg Lippe
Board President

XAVIER BECERRA
Attorney General of California
ARMANDO ZAMBRANO
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NANCY A. KAISER
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Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **SOUTHERN CALIFORNIA HEALTHCARE SYSTEMS, INC., DBA SOUTHERN CALIFORNIA HOSPITAL AT CULVER CITY** **3828 Delmas Terrace** **Culver City, CA 90232** **Hospital Pharmacy Permit No. HSP 51172,** **SOUTHERN CALIFORNIA HEALTHCARE SYSTEMS, INC., DBA SOUTHERN CALIFORNIA HOSPITAL AT CULVER CITY** **3828 Delmas Terrace** **Culver City, CA 90232** **Sterile Compounding Permit No. LSC 100222,** **JILL CHANG** **778 Flicker Ct.** **Anaheim, CA 92807** **Pharmacist License No. RPH 66782,** **AINSLIE HOI LI CHEUNG** **12837 Palisades Ct.** **Poway, CA 92064** **Pharmacist License No. RPH 64668,** **and**	Case No. 6647 OAH No. 2020040205 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL AS TO JILL CHANG ONLY** **[Bus. & Prof. Code § 495]**

JACQUELINE HOANG VO
15757 McIntosh Ave.
Chino, CA 91708
Pharmacist License No. RPH 45816

Respondents.

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

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Nancy A. Kaiser, Deputy Attorney General.

2. Respondent Jill Chang (Respondent) is represented in this proceeding by attorney Luis Andre P. Vizcocho, whose address is: California Pharmacy Lawyers, 55 Cetus, 1st Floor, Irvine, CA 92618.

3. On or about December 28, 2011, the Board of Pharmacy issued Pharmacist License Number RPH 66782 to Jill Chang (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2021, unless renewed.

JURISDICTION

4. Accusation No. 6647 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on October 2, 2019. Respondent timely filed her Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 6647 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6647. Respondent has also carefully read, fully

discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

7. Respondent is fully aware of her legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on her 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.

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

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 6647, if proven at a hearing, constitute cause for imposing discipline upon her Pharmacist License.

10. For the purpose of resolving the Accusation 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 Accusation, and that Respondent hereby gives up her right to contest those charges.

11. Respondent agrees that her Pharmacist License is subject to discipline and she agrees to be bound by the Disciplinary Order below.

CONTINGENCY

12. 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 she may not withdraw her 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 for Public Reproval 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.

13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

14. This Stipulated Settlement and Disciplinary Order for Public Reproval 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 for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. 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 66782 issued to Respondent Jill Chang (Respondent) shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 6647, attached as exhibit A.

Coursework. No later than six months from the effective date of the public reproval, Respondent, at her own expense, shall enroll, successfully complete and submit verification of an appropriate program related to USP 797. The program of remedial education shall consist of at least twenty (20) hours, which shall be completed at Respondent's own expense. At least 50% of the total hours must be in person or live webinar. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists. Respondent shall obtain prior approval from the Board before enrolling in the course(s). Respondent shall submit to the Board the original transcripts or certificates of completion for the above-required course(s).

Cost Recovery. No later than one year from the effective date of the Decision, Respondent shall pay $4,043 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew her Pharmacist License until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 6647, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Pharmacy License No. RPH 66782.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Luis Andre P. Vizcocho. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 11/10/20

JILL CHANG
Respondent

I have read and fully discussed with Respondent Jill Chang the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: _____

LUIS ANDRE P. VIZCOCHO
Attorney for Respondent

Cost Recovery. No later than one year from the effective date of the Decision, Respondent shall pay $4,043 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew her Pharmacist License until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 6647, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Pharmacy License No. RPH 66782.

ACCEPTANCE

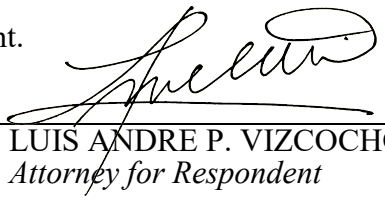
I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Luis Andre P. Vizcocho. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

JILL CHANG
Respondent

I have read and fully discussed with Respondent Jill Chang the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 11/12/2020



LUIS ANDRE P. VIZCOCHO
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 11/12/2020

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
ARMANDO ZAMBRANO
Supervising Deputy Attorney General

Nancy Kaiser

NANCY A. KAISER
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 6647

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Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **SOUTHERN CALIFORNIA HEALTHCARE SYSTEMS, INC., DBA SOUTHERN CALIFORNIA HOSPITAL AT CULVER CITY, DAVID TOPPER, C.E.O./DIRECTOR, SAMUEL LEE, PRES./DIRECTOR, WILLIAM MARC GORENSTEIN, TREAS./C.F.O., ELLEN SHIN, SECRETARY; JILL CHANG, PHARMACIST-IN-CHARGE (8/14/15-12/11/15, 3/2/16-8/31/17); AINSLIE HOI LI CHEUNG, PHARMACIST-IN-CHARGE (9/1/17-2/27/18) JACQUELINE HOANG VO, PHARMACIST-IN-CHARGE (since 8/14/18) 3828 Delmas Terrace Culver City, CA 90232 Hospital Pharmacy Permit No. HSP 51172,** **SOUTHERN CALIFORNIA HEALTHCARE SYSTEMS, INC., DBA SOUTHERN CALIFORNIA HOSPITAL AT CULVER CITY, DAVID TOPPER, C.E.O./DIR., SAMUEL LEE, PRES./DIR., WILLIAM MARC GORENSTEIN, TREAS./C.F.O., ELLEN SHIN, SECRETARY 3828 Delmas Terrace Culver City, CA 90232 Sterile Compounding Permit No. LSC 100222,**	Case No. 6647 **A C C U S A T I O N**

JILL CHANG
778 Flicker Ct.
Anaheim, CA 92807
Pharmacist License No. RPH 66782,

AINSLIE HOI LI CHEUNG
12837 Palisades Ct.
Poway, CA 92064
Pharmacist License No. RPH 64668,

and

JACQUELINE HOANG VO
15757 McIntosh Ave.
Chino, CA 91708
Pharmacist License No. RPH 45816

Respondents.

PARTIES

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

2. On or about December 31, 2012, the Board of Pharmacy issued Hospital Pharmacy Permit Number HSP 51172 to Southern California Healthcare Systems, Inc., dba Southern California Hospital at Culver City, located at 3828 Delmas Terrace, Culver City, CA 90232 (Respondent Pharmacy). The Hospital Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on December 1, 2019, unless renewed. Since December 31, 2012, David Topper has been the Chief Executive Officer and Director, Samuel Lee has been the President and Director, and Ellen Shin has been the Secretary. Since March 15, 2016, William Marc Gorenstein has been the Treasurer/Chief Financial Officer. From August 14, 2015 to December 11, 2015 and March 2, 2016 to August 31, 2017 Jill Chang, RPH 66782, was the pharmacist-in-charge. From September 1, 2017, to February 27, 2018, Ainslie Hoi Li Cheung, RPH 64668, was the pharmacist-in-charge. February 28, 2018, and July 26, 2018, Christina Cao RPH 57888 was the pharmacist-in-charge. Since August 14, 2018, Jacqueline Hoang Vo has been the pharmacist-in-charge.

3. On or about May 29, 2014, the Board of Pharmacy issued Sterile Compounding Permit Number LSC 100222 to Southern California Healthcare Systems, Inc., dba Southern California Hospital at Culver City, David (Respondent Pharmacy). The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on December 1, 2019, unless renewed.

4. On or about December 28, 2011, the Board of Pharmacy issued Pharmacist License Number RPH 66782 to Jill Chang (Respondent Chang). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2021, unless renewed.

5. On or about September 30, 2010, the Board of Pharmacy issued Pharmacist License Number RPH 64668 to Ainslie Hoi Li Cheung (Respondent Cheung). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on December 31, 2019, unless renewed.

6. On or about September 22, 1992, the Board of Pharmacy issued Pharmacist License Number RPH 45816 to Jacqueline Hoang Vo (Respondent Vo). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2020, unless renewed.

JURISDICTION

7. 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.

8. Section 4300 provides in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

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9. Section 4300.1 of the Code states:

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

10. Section 4113, subdivision (c), states that "[t]he 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."

11. Section 4022 of the Code states:

"'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self-use in humans or animals, and includes the following:
(a) Any drug that bears the legend: 'Caution: federal law prohibits dispensing without prescription,' 'Rx only,' or words of similar import.
"(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____,""Rx only,"or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
"(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

12. Section 4033 of the Code states, in part:

"(a)(1) 'Manufacturer' means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer."

13. Section 4301 of the Code states, in part:

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

14. Section 4306.5 of the Code states, in part:

"Unprofessional conduct for a pharmacist may include any of the following:
"(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.
"(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services."

15. Section 4307, subdivision (a), of the Code states:

"(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:
(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.
(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.
(b) Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.
(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law."

16. Section 4169 of the Code states, in part:

"(a) A person or entity shall not do any of the following:
. . .
(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code."

REGULATORY PROVISIONS

17. California Code of Regulations, title 16, section 1715 states in pertinent 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: . . .
(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy."

18. California Code of Regulations, title 16, section 1735.2, states, in pertinent part:

"(e)(3) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:… (3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.
. . .
"(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.
. . .
"(k) Prior to allowing any drug product preparation 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.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. 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 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 date of a new

pharmacist-in-charge or change of location, 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."

19. California Code of Regulations, title 16, section 1735.4(a)(5) states:

"(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least: . . . (5) The date compounded."

20. California Code of Regulations, title 16, section 1735.8(b) states:

"The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel."

21. California Code of Regulations, title 16, section 1751.3 states, in part:

"(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:
(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded."

22. California Code of Regulations, title 16, section 1751.4(a) states:

"No sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations."

23. California Code of Regulations, title 16, section 1751.8(e) states:

"Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (d), the sterile compounded drug preparation shall be labeled for "immediate use only"and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use"preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an

"immediate use"preparation. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. Such "immediate use"preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures."

HEALTH AND SAFETY CODE

24. Health & Safety Code section 111250 states: "Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance."

25. Health & Safety Code section 111295 states: "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

COST RECOVERY

26. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

FACTUAL SUMMARY

27. Respondent Pharmacy is an inpatient hospital pharmacy within Southern California Hospital at Culver City, a community hospital, located at 3828 Delmas Terrace, Culver City, California. The hospital is licensed for 450 general acute care beds by the California Department of Public Health (CDPH).

2017 Inspection

28. On or about November 21, 2017, a Board inspector performed a routine sterile compounding license renewal inspection of Respondent Pharmacy's facility, which revealed the following.

29. Respondent Pharmacy was performing sterile-to-sterile compounding and preparing low to medium risk compounded sterile preparations (CSPs), such as intravenous

antibiotics, electrolyte infusions, and total parenteral nutrition. The pharmacy prepared on average approximately 80 CSPs daily.

30. The pharmacy had one ISO Class 5 compounding aseptic isolator (CAI). CAIs are composed of two chambers: the main chamber, where sterile compounding takes place, and the purge/airlock chamber, where material transfer occurs. The purge/airlock chamber ensures that the main chamber remains at least ISO Class 5 during insertion and removal of items. Both chambers should maintain an ISO 5 or better environment for compounding sterile preparations. Respondent Pharmacy hired Clean Air Services (CAS), an outside company, to perform the environmental testing for its CAI every six months.

31. On February 25, 2017, CAS performed an environmental sampling test of Respondent Pharmacy's CAI. The CAI failed the test, in that the test results indicated that nine (9) CFUs of fungal air growth were inside the ISO 5 CAI airlock chamber. On March 10, 2017, the test results were reported to Respondent Pharmacy, yet the re-testing of the CAI for viable growth was not performed until May 4, 2017.

32. On May 4, 2017, Respondent Pharmacy's CAI failed the environmental sampling test again, as it continued to show fungal air growth inside the CAI. Specifically, the test results indicated that three (3) CFUs of fungal air growth were inside the ISO 5 CAI airlock chamber. On May 22, 2017, these results were reported to Respondent Pharmacy, yet the re-testing of the CAI for viable growth was not performed until August 15, 2017.

33. On August 15, 2017, Respondent Pharmacy's CAI failed the environmental sampling test again, in that five (5) CFUs (fungal organisms) were identified on the air samples inside the purge/airlock chamber of the ISO 5 CAI and three (3) CFUs (fungal organisms) were identified on the air samples inside the main chamber of the ISO 5 CAI. In addition, six (6) CFUs (bacterial organisms) were identified on the air samples inside the purge/airlock chamber of the ISO 5 CAI, and two (2) CFUs (bacterial organisms) were identified on the air samples inside the main chamber of the ISO 5 CAI.

34. On September 18, 2017, Respondent Pharmacy's CAI was retested and failed the environmental sampling test again. The report, dated September 26, 2017, showed that

two (2) CFUs were found in viable air samples inside the airlock chamber of the ISO 5 CAI. The result was listed as "Fail" and the reason for fail result stated, "Total CFU result exceeds action level concentration and actionable microorganism/s detected." Actionable microorganisms were identified in the report as "Gram-negative bacteria, coagulase-positive Staphylococcus, molds and yeasts."

35. From at least February 25, 2017, until at least November 22, 2017, Respondent Pharmacy prepared CSPs inside the ISO 5 CAI, without first assuring the CAI was free from microbial contamination. Since the pharmacy prepared on average about 80 CSPs daily, it means an estimated number of 21,000 possibly contaminated CSP units were prepared and dispensed to patients of Southern California Hospital at Culver City in this time frame.

36. Respondent Pharmacy's policies and procedures state, in part:

"Viable air sampling shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) inside of CAI and shall be done at least once every six months. It shall be performed by qualified individual who is familiar with the methods and procedures. When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operation and facility management".

37. Respondent Pharmacy's policies and procedures do not address action levels for CFUs detected during viable surface and air sampling and actions to take when the levels are exceeded.

38. Respondent Pharmacy's policies and procedures also state:

"A batched-produced low to medium risk CSP shall be subject to documented end product quantitative analysis once a year. The analysis will be conducted by a laboratory." One CSP prepared at the pharmacy was tested for potency on September 14, 2016, by an outside lab. On October 10, 2017, another CSP was sent out for testing. October 10, 2017, is more than one year after its CSP potency testing performed on September 14, 2016.

39. During the Board's inspection on November 21, 2017, several CSP labels and master formulas for compounded sterile preparations were reviewed. None of the CSP labels reviewed contained the date the CSP was compounded, and none of the master formula documents reviewed included the rationale or reference source justifying their determination of the maximum allowable beyond-use-date (expiration date) for CSPs.

40. The 2017 USP 797[1] guidelines state, in part:

"Any CFU[2] count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed. . . .Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and must be immediately remedied, regardless of CFU count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist."

41. For ISO Class 5, the 2017 USP 797 guidelines' recommended action level for microbial contamination is more than one (1) CFU.

2018 Inspection

42. On or about October 11, 2018, a Board inspector performed a routine sterile compounding license renewal inspection of Respondent Pharmacy's facility, which revealed the following.

[1] USP 797 refers to chapter 797 "Pharmaceutical Compounding – Sterile Preparations,"in the USP National Formulary. It is the first set of enforceable sterile compounding standards issued by the United States Pharmacopeia (USP).

[2] In microbiology, a colony-forming unit (CFU) is a unit used to measure the number of viable bacteria or fungal cells in a sample. Viable is defined as the ability to multiply.

43. On July 28, 2018, Respondent Pharmacy implemented its decision to decommission the use of the compounding aseptic isolator (CAI) and begin making the compounded sterile drug preparations (CSPs), previously made in the CAI, on the counter located in the segregated compounding area, as immediate-use CSPs with a beyond use date (BUD) of one (1) hour.

44. Between July 28, 2018, and October 9, 2018, Respondent Pharmacy compounded at least 200 banana bags each of which contained at least 3 additives, as immediate-use preparations, where there was no need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could not result in loss of life or intense suffering, and did not document the circumstance causing the need. Between August 14, 2018, and October 9, 2018, while Respondent Vo was the pharmacist-in-charge and responsible for pharmacy operations, Respondent Pharmacy compounded at least 150 of these banana bags.

FIRST CAUSE FOR DISCIPLINE

(Failure to Comply with Required Sterile Compounding Policies and Procedures)

45. Respondents Pharmacy, Chang, and Cheung are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1751.3(a)(1). Specifically, while Respondents Chang and Cheung served as the pharmacist-in-charge, respectively, Respondent Pharmacy did not maintain written policies and procedures that addressed action levels for CFUs detected during viable surface and air sampling and actions to be taken when the CFU levels are exceeded. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 28 through 41, above, as though set forth fully herein.

SECOND CAUSE FOR DISCIPLINE

(Failure to Comply with Facility and Equipment Standards for Sterile Compounding)

46. Respondents Pharmacy, Chang, and Cheung are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they

failed to comply with California Code of Regulations, title 16, section 1751.4(a). Specifically, while Respondents Chang and Cheung served as the pharmacist-in-charge, respectively, Respondent Pharmacy's policy and procedures stated, "When the environmental monitoring action levels are exceeded; the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operation and facility management." The pharmacy failed to conduct an immediate investigation, as described in their policy, when the environmental monitoring action levels were exceeded on viable testing on May 4, 2017, and September 18, 2017. The pharmacy, therefore, compounded sterile drug preparations in the compounding environment that failed to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 28 through 41, above, as though set forth fully herein.

THIRD CAUSE FOR DISCIPLINE

(Delivering Adulterated Medications)

47. Respondents Pharmacy, Chang, and Cheung are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with section 4169(a)(2) of the Code and Health and Safety Code sections 111250 and 111295. Specifically, from at least February 25, 2017, until at least November 22, 2017, the pharmacy delivered approximately 21,000 units of adulterated dangerous drugs to patients of Southern California Hospital at Culver City. From at least February 25, 2017, until at least August 31, 2017, while Respondent Chang served as the pharmacist-in-charge, the pharmacy delivered approximately 15,000 units of adulterated dangerous drugs to patients of Southern California Hospital at Culver City. From at least September 1, 2017, until at least November 22, 2017, while Respondent Cheung served as the pharmacist-in-charge, Respondent Pharmacy delivered approximately 6,000 units of adulterated dangerous drugs to patients of Southern California Hospital at Culver City. Complainant refers to, and

by this reference incorporates, the allegations set forth in paragraphs 28 through 41, above, as though set forth fully herein.

FOURTH CAUSE FOR DISCIPLINE

(Gross Negligence)

48. Respondent Pharmacy is subject to disciplinary action under section 4301, subdivision (c), in that it committed gross negligence. Specifically, from at least February 25, 2017, until at least November 22, 2017, Respondent Pharmacy was grossly negligent in properly addressing repetitive microbial air contamination of the ISO 5 CAI, where sterile compounding took place. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 28 through 41, above, as though set forth fully herein.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Comply with Compounding Quality Assurance Requirements)

49. Respondents Pharmacy and Cheung are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1735.8(b). Specifically, while Respondent Cheung was serving as the pharmacist-in-charge, Respondent Pharmacy's CSP potency testing performed on October 10, 2017, was more than one year after CSP potency testing performed on September 14, 2016, and, therefore, was not conducted on at least an annual basis. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 28 through 41, above, as though set forth fully herein.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Comply with Labeling Requirements)

50. Respondents Pharmacy and Cheung are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1735.4(a)(5). Specifically, while Respondent Cheung was serving as the pharmacist-in-charge, CSP labels reviewed on the Board's November 21, 2017, inspection did not contain the date compounded.

Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 28 through 41, above, as though set forth fully herein.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Comply with Compounding Limitations and Requirements)

51. Respondents Pharmacy and Cheung are subject to disciplinary action under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1735.2(e)(3). Specifically, while Respondent Cheung was serving as the pharmacist-in-charge, master formula documents for CSPs reviewed during the Board's November 21, 2017, inspection did not include the rationale or reference sources justifying the maximum allowable beyond use date for the preparations. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 28 through 41, above, as though set forth fully herein.

EIGHTH CAUSE FOR DISCIPLINE

(Inappropriate Exercise of Education,

Training, or Experience as a Pharmacist)

52. Respondents Cheung and Chang are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), on the grounds of unprofessional conduct, as defined in Code section 4306.5, subdivision (a), in that they inappropriately exercised their respective education, training, and experience as a pharmacist in the course of the practice of pharmacy and operation of a pharmacy. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 28 through 41, above, as though set forth fully herein.

NINTH CAUSE FOR DISCIPLINE

(Failure to Exercise Professional Judgment)

53. Respondents Cheung and Chang are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), on the grounds of unprofessional conduct, as defined in Code section 4306.5, subdivision (b), in that they failed to exercise and implement their best professional judgment when dispensing dangerous drugs. Complainant refers to, and by

this reference incorporates, the allegations set forth in paragraphs 28 through 41, above, as though set forth fully herein.

TENTH CAUSE FOR DISCIPLINE

(Failure to comply with Self-Assessment of a Pharmacy Requirement)

54. Respondents Pharmacy and Vo are subject to disciplinary action under Code section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1715(a) and (b)(2). Respondents Pharmacy and Vo failed to promote compliance through self-examination and education when Respondent Vo associated as the pharmacist-in-charge, effective August 14, 2018, and failed to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law until October 12, 2018. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 42 through 44, above, as though set forth fully herein.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Complete Compounding Self-Assessment)

55. Respondents Pharmacy and Vo are subject to disciplinary action under Code section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1735.2(k). Specifically, between September 15, 2018, and October 9, 2018, while Respondent Vo served as the pharmacist-in-charge, Respondent Pharmacy compounded at least 900 compounded drug preparations without Respondent Vo having completed a self-assessment for compounding pharmacies within 30 days of associating as the pharmacist-in-charge. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 42 to 44, above, as though set forth fully herein.

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Comply with Immediate Use Compounding Requirements)

56. Respondents Pharmacy and Vo are subject to disciplinary action under Code section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed

to comply with California Code of Regulations, title 16, section 1735.2(g). Specifically, between July 28, 2018, and October 9, 2018, Respondent Pharmacy compounded at least 200 banana bags, each of which contained at least 3 additives, as immediate-use preparations, where there was no need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could not result in loss of life or intense suffering, and did not document the circumstance causing the need. Between August 14, 2018, and October 9, 2018, while Respondent Vo served as the pharmacist-in-charge and was responsible for pharmacy operations, Respondent Pharmacy compounded at least 150 of these banana bags. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 42 to 44, above, as though set forth fully herein.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Follow Pharmacy's Policies and Procedures)

57. Respondents Pharmacy and Vo are subject to disciplinary action under Code section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed to comply with California Code of Regulations, title 16, section 1751.3 subdivision (a). Specifically, between July 28, 2018, and October 9, 2018, Respondent Pharmacy failed to follow its written policies and procedures, which stated "Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate-use CSPs", by compounding at least 200 medium-risk CSPs as immediate use. Between August 14, 2018, and October 9, 2018, while Respondent Vo served as the pharmacist-in-charge and was responsible for pharmacy operations, Respondent Pharmacy failed to follow its written policies and procedures, which stated "Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate-use CSPs", by compounding at least 150 of these banana bags. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 42 to 44, above, as though set forth fully herein.

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FOURTEENTH CAUSE FOR DISCIPLINE

(Inappropriate Exercise of Education,

Training, or Experience as a Pharmacist)

58. Respondent Vo is subject to disciplinary action under Code section 4301, subdivision (o), on the grounds of unprofessional conduct, for violating section 4306.5 subdivision (a). Specifically, between August 14, 2018, and October 9, 2018, while Respondent Vo served as the pharmacist-in-charge and was responsible for pharmacy operations for Respondent Pharmacy, she failed to exercise her education, training, experience and best professional judgment when Respondent Pharmacy dispensed at least 150 medium-risk level CSPs as "immediate-use". Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 42 to 44, above, as though set forth fully herein.

FIFTEENTH CAUSE FOR DISCIPLINE

(Failure to Exercise Professional Judgment)

51. Respondent Vo is subject to disciplinary action under Code section 4301, subdivisions (j) and (o), on the grounds of unprofessional conduct, as defined in Code section 4306.5, subdivision (b). Specifically, while serving as the pharmacist-in-charge, Respondent Vo failed to exercise and implement her best professional judgment when Respondent Pharmacy dispensed at least 150 medium-risk level CSPs as "immediate-use". Complainant refers to, and by this reference incorporates, the allegations set forth in paragraphs 42 to 44, above, as though set forth fully herein.

OTHER MATTERS

59. Pursuant to Code section 4307, if discipline is imposed on Hospital Pharmacy Permit Number HSP 51172 issued to Southern California Healthcare Systems, Inc., dba Southern California Hospital at Culver City, Southern California Healthcare Systems, Inc. shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Hospital Pharmacy

Permit Number HSP 51172 is placed on probation or until Hospital Pharmacy Permit Number HSP 51172 is reinstated if it is revoked.

60. Pursuant to Code section 4307, if discipline is imposed on Hospital Pharmacy Permit Number HSP 51172 issued to Southern California Healthcare Systems, Inc., dba Southern California Hospital at Culver City while David Topper, C.E.O./Director, Samuel Lee, Pres./Director, William Marc Gorenstein, Treas./C.F.O., and/or Ellen Shin, Secretary, as applicable, has been an officer and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, David Topper, C.E.O./Director, Samuel Lee, Pres./Director, William Marc Gorenstein, Treas./C.F.O., or Ellen Shin, Secretary, as applicable, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Hospital Pharmacy Permit Number HSP 51172 is placed on probation or until Hospital Pharmacy Permit Number HSP 51172 is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Hospital Pharmacy Permit Number HSP 51172, issued to Southern California Healthcare Systems, Inc., dba Southern California Hospital at Culver City, David;

2. Revoking or suspending Sterile Compounding Permit Number LSC 100222, issued to Southern California Healthcare Systems, Inc., dba Southern California Hospital at Culver City, David;

3. Revoking or suspending Pharmacist License Number RPH 66782, issued to Jill Chang;

4. Revoking or suspending Pharmacist License Number RPH 64668, issued to Ainslie Hoi Li Cheung;

5. Revoking or suspending Pharmacist License Number RPH 45816, issued to Jacqueline Hoang Vo;

6. Prohibiting Southern California Healthcare Systems, Inc., from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Hospital Pharmacy Permit Number HSP 51172 is placed on probation or until Hospital Pharmacy Permit Number HSP 51172 is reinstated if Hospital Pharmacy Permit No. HSP 51172 issued to Southern California Healthcare Systems, Inc., dba Southern California Hospital at Culver City is revoked;

7. Prohibiting David Topper, C.E.O./Director, Samuel Lee, Pres./Director, William Marc Gorenstein, Treas./C.F.O., and/or Ellen Shin, Secretary, as applicable, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Hospital Pharmacy Permit Number HSP 51172 is placed on probation or until Hospital Pharmacy Permit Number HSP 51172 is reinstated if Hospital Pharmacy Permit Number HSP 51172 issued to Southern California Healthcare Systems, Inc., dba Southern California Hospital at Culver City is revoked;

8. Ordering Southern California Healthcare Systems, Inc., dba Southern California Hospital at Culver City, Jill Chang, Ainslie Hoi Li Cheung, and Jacqueline Hoang Vo to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: September 10, 2019

ANNE SODERGREN
Interim Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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