

**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 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

A handwritten signature in black ink, appearing to read "Greg M. Lippe", written in a cursive style.

By

Greg Lippe  
Board President

XAVIER BECERRA  
Attorney General of California  
ARMANDO ZAMBRANO  
Supervising Deputy Attorney General  
NANCY A. KAISER  
Deputy Attorney General  
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Facsimile: (916) 731-2126  
*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**

Case No. 6647

OAH No. 2020040205

**STIPULATED SETTLEMENT AND  
DISCIPLINARY ORDER AS TO  
SOUTHERN CALIFORNIA  
HEALTHCARE SYSTEMS, INC., DBA  
SOUTHERN CALIFORNIA HOSPITAL  
AT CULVER CITY ONLY**

1 Culver City, CA 90232  
2 Sterile Compounding Permit No. LSC  
3 100222,

4 JILL CHANG  
5 778 Flicker Ct.  
6 Anaheim, CA 92807  
7 Pharmacist License No. RPH 66782,

8 AINSLIE HOI LI CHEUNG  
9 12837 Palisades Ct.  
10 Poway, CA 92064  
11 Pharmacist License No. RPH 64668,

12 and

13 JACQUELINE HOANG VO  
14 15757 McIntosh Ave.  
15 Chino, CA 91708  
16 Pharmacist License No. RPH 45816

17 Respondents.

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

20 **PARTIES**

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

25 2. Respondent Southern California Healthcare Systems, Inc., dba Southern California  
26 Hospital at Culver City (Respondent) is represented in this proceeding by attorney Joseph R.  
27 LaMagna, whose address is: Hooper, Lundy & Bookman, P.C., 101 W. Broadway, Suite 1200,  
28 San Diego, CA 92101-3890.

3. On or about December 31, 2012, the Board 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). Since  
December 31, 2012, David Topper has been the Chief Executive Officer and Director, Samuel

1 Lee has been the President and Director, and Ellen Shin has been the Secretary. Since March 15,  
2 2016, William Marc Gorenstein has been the Treasurer/Chief Financial Officer.

3 4. On or about May 29, 2014, the Board issued Sterile Compounding Permit Number  
4 LSC 100222 to Southern California Healthcare Systems, Inc., dba Southern California Hospital at  
5 Culver City (Respondent). The Sterile Compounding Permit was in full force and effect at all  
6 times relevant to the charges brought herein and will expire on December 1, 2020, unless  
7 renewed.

### 8 **JURISDICTION**

9 5. Accusation No. 6647 was filed before the Board, and is currently pending against  
10 Respondent. The Accusation and all other statutorily required documents were properly served  
11 on Respondent on October 2, 2019. Respondent timely filed its Notice of Defense contesting the  
12 Accusation.

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

### 15 **ADVISEMENT AND WAIVERS**

16 7. Respondent has carefully read, fully discussed with counsel, and understands the  
17 charges and allegations in Accusation No. 6647. Respondent has also carefully read, fully  
18 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary  
19 Order.

20 8. Respondent is fully aware of its legal rights in this matter, including the right to a  
21 hearing on the charges and allegations in the Accusation; the right to confront and cross-examine  
22 the witnesses against them; the right to present evidence and to testify on its own behalf; the right  
23 to the issuance of subpoenas to compel the attendance of witnesses and the production of  
24 documents; the right to reconsideration and court review of an adverse decision; and all other  
25 rights accorded by the California Administrative Procedure Act and other applicable laws.

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

28 ///

1 **CULPABILITY**

2 10. Respondent understands and agrees that the charges and allegations in Accusation  
3 No. 6647, if proven at a hearing, constitute cause for imposing discipline upon its Hospital  
4 Pharmacy Permit and Sterile Compounding Permit.

5 11. For the purpose of resolving the Accusation without the expense and uncertainty of  
6 further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual  
7 basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest  
8 those charges.

9 12. Respondent agrees that its Hospital Pharmacy Permit and Sterile Compounding  
10 Permit are subject to discipline, and they agree to be bound by the Board's probationary terms as  
11 set forth in the Disciplinary Order below.

12 **CONTINGENCY**

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

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

25 15. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an  
26 integrated writing representing the complete, final, and exclusive embodiment of their agreement.  
27 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,  
28 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.

16. 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 Hospital Pharmacy Permit No. HSP 51172 and Sterile Compounding Permit No. LSC 100222 issued to Respondent Southern California Healthcare Systems, Inc., dba Southern California Hospital at Culver City are revoked. However, the revocations are stayed and Respondent is placed on probation for two (2) years on the following terms and conditions:

For the purposes of these terms and conditions, "Respondent" shall refer to Southern California Healthcare Systems, Inc., dba Southern California Hospital at Culver City, and includes both Hospital Pharmacy Permit No. HSP 51172 and Sterile Compounding Permit No. LSC 100222. All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by Respondent to or before the Board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

**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 (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 contendere, no contest, or similar, in any state or federal criminal

proceeding to any criminal complaint, information or indictment;

- a conviction of any crime; or
- discipline, citation, or other administrative action filed by any state or federal agency which involves either 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 dangerous drug, and/or dangerous device or controlled substance.

Failure to timely report any 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 (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 shall timely 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 the probation, including but not limited to: timely responses to requests for information by Board staff; timely compliance with directives from Board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or



condition of probation. Failure to timely cooperate shall be considered a violation of probation.

#### **5. 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 \$28,302. Respondent may pay those costs pursuant to a payment plan. There shall be no deviation from that plan 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.

Respondent shall be permitted to pay these costs in a payment plan approved by the Board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

#### **6. 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.

#### **7. Status of License**

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

If Respondent'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's license shall be subject to all terms and conditions of this probation not previously satisfied.

#### **8. License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent wish to discontinue business, Respondent may tender the premises license to the Board for surrender. The Board or its

1 designee shall have the discretion whether to grant the request for surrender or take any other  
2 action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the  
3 license, Respondent will no longer be subject to the terms and conditions of probation.

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

7 Respondent further stipulates that it shall reimburse the Board for its costs of investigation  
8 and prosecution prior to the acceptance of the surrender.

9 Upon acceptance of the surrender, Respondent shall relinquish the premises wall and  
10 renewal license to the Board within ten (10) days of notification by the Board that the surrender is  
11 accepted. Respondent shall further submit a completed Discontinuance of Business form  
12 according to Board guidelines and shall notify the Board of the records inventory transfer within  
13 five (5) days. Respondent shall further arrange for the transfer of all records of acquisition and  
14 disposition of dangerous drugs and/or devices to premises licensed and approved by the Board.

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

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

27 Respondent further stipulates that it shall reimburse the Board for its costs of investigation  
28 and prosecution prior to the acceptance of the surrender.

1           **9. Sale or Discontinuance of Business**

2           During the period of probation, should Respondent sell, trade or transfer all or part of the  
3 ownership of the licensed entity, discontinue doing business under the license issued to  
4 Respondent, or should practice at that location be assumed by another full or partial owner,  
5 person, firm, business, or entity, under the same or a different premises license number, the Board  
6 or its designee shall have the sole discretion to determine whether to exercise continuing  
7 jurisdiction over the licensed location, under the current or new premises license number, and/or  
8 carry the remaining period of probation forward to be applicable to the current or new premises  
9 license number of the new owner.

10           **10. Notice to Employees**

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

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

24           **11. Owners and Officers: Knowledge of the Law**

25           Respondent shall provide, within thirty (30) days after the effective date of this decision,  
26 signed and dated statements from its owners, including any owner or holder of ten percent (10%)  
27 or more of the interest in Respondent or Respondent's stock, and all of its officer, stating under  
28 penalty of perjury that said individuals have read and are familiar with state and federal laws and

1 regulations governing the practice of pharmacy. The failure to timely provide said statements  
2 under penalty of perjury shall be considered a violation of probation.

3 **12. Premises Open for Business**

4 Respondent shall remain open and engaged in its ordinary business as a licensed pharmacy  
5 in California for a minimum of 120 hours per calendar month. Any month during which this  
6 minimum is not met shall toll the period of probation, i.e., the period of probation shall be  
7 extended by one month for each month during with this minimum is not met. During any such  
8 period of tolling of probation, Respondent must nonetheless comply with all terms and conditions  
9 of probation, unless Respondent is informed otherwise in writing by the Board or its designee. If  
10 Respondent is not open and engaged in its ordinary business as a pharmacy for a minimum of 120  
11 hours in any calendar month, for any reason (including vacation), Respondent shall notify the  
12 Board in writing within ten (10) days of the conclusion of that calendar month. This notification  
13 shall include at minimum all of the following: the date(s) and hours Respondent was open; the  
14 reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on  
15 which Respondent will resume business as required. Respondent shall further notify the Board in  
16 writing with ten (10) days following the next calendar month during which Respondent is open  
17 and engaged in its ordinary business as a licensed pharmacy in California for a minimum of 120  
18 hours. Any failure to timely provide such notification(s) shall be considered a violation of  
19 probation.

20 **13. Posted Notice of Probation**

21 Respondent shall prominently post a probation notice provided by the Board or its designee  
22 in a place conspicuous to and readable by the public within two (2) days of receipt thereof from  
23 the Board or its designee. Failure to timely post such notice, or to maintain the posting during the  
24 entire period of probation, shall be considered a violation of probation.

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

1           **14. Violation of Probation**

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

7           If Respondent violates probation in any respect, the Board, after giving Respondent notice  
8 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that  
9 was stayed. If a petition to revoke probation or an accusation is filed against Respondent during  
10 probation, the Board shall have continuing jurisdiction and the period of probation shall be  
11 automatically extended until the petition to revoke probation or accusation is heard and decided,  
12 and the charges and allegations in Accusation No. 6647 shall be deemed true and correct.

13           **15. Completion of Probation**

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

16           **16. Independent Consultant**

17           During the period of probation, Respondent shall retain an independent consultant at its  
18 own expense who shall be responsible for reviewing sterile compounding operations on a  
19 monthly basis for compliance by Respondent with state and federal laws and regulations  
20 governing the practice of pharmacy and for compliance by Respondent. The consultant shall  
21 be a pharmacist licensed by and not on probation with the Board and whose name shall be  
22 submitted to the Board or its designee, for prior approval, within thirty (30) days of the  
23 effective date of this decision. During the period of probation, the Board or its designee,  
24 retains the discretion to reduce the frequency of the pharmacist consultant's review of  
25 Respondent's operations.

26           Failure to timely retain, seek approval of, or ensure timely reporting by the consultant  
27 shall be considered a violation of probation.

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1 I have read and fully discussed with Respondent Southern California Healthcare Systems,  
2 Inc., dba Southern California Hospital at Culver City the terms and conditions and other matters  
3 contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and  
4 content.

5 DATED: \_\_\_\_\_ *SIGNATURE ATTACHED*

6 SANSAN LIN  
7 *Attorney for Respondent*  
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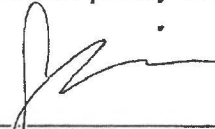
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I have read and fully discussed with Respondent Southern California Healthcare Systems, Inc., dba Southern California Hospital at Culver City the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: November 13, 2020

  
\_\_\_\_\_  
SANSAN LIN  
*Attorney for Respondent*

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**ENDORSEMENT**

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

DATED: 11/13/2020

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**

XAVIER BECERRA  
Attorney General of California  
ARMANDO ZAMBRANO  
Supervising Deputy Attorney General  
NANCY A. KAISER  
Deputy Attorney General  
State Bar No. 192083  
300 So. Spring Street, Suite 1702  
Los Angeles, CA 90013  
Telephone: (213) 269-6320  
Facsimile: (213) 897-2804  
*Attorneys for Complainant*

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PHARMACIST-IN-CHARGE (since 8/14/18)  
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Culver City, CA 90232  
Hospital Pharmacy Permit No. HSP 51172,**

**A C C U S A T I O N**

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**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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1           9.     Section 4300.1 of the Code states:

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

8           10.    Section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be  
9           responsible for a pharmacy's compliance with all state and federal laws and regulations  
10          pertaining to the practice of pharmacy."

11          11.    Section 4022 of the Code states:

12          "‘Dangerous drug’ or ‘dangerous device’ means any drug or device unsafe for  
13          self-use in humans or animals, and includes the following:

14          (a) Any drug that bears the legend: ‘Caution: federal law prohibits dispensing without  
15          prescription,’ ‘Rx only,’ or words of similar import.

16          (b) Any device that bears the statement: "Caution: federal law restricts this device to  
17          sale by or on the order of a \_\_\_\_\_," "Rx only," or words of similar import, the  
18          blank to be filled in with the designation of the practitioner licensed to use or order use  
19          of the device.

20          (c) Any other drug or device that by federal or state law can be lawfully dispensed  
21          only on prescription or furnished pursuant to Section 4006."

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

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

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

28          "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:

· · ·  
29          "(c) Gross negligence.

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

· · ·  
32          "(o) Violating or attempting to violate, directly or indirectly, or assisting in or  
33          abetting the violation of or conspiring to violate any provision or term of this  
34          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

1 pharmacist-in-charge or change of location, and within 30 days of the issuance of a  
2 new pharmacy license. The primary purpose of the self-assessment is to promote  
compliance through self-examination and education.”

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

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

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

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

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

11 “(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain  
12 written policies and procedures for compounding. Any material failure to follow the  
13 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:

14 (1) Action levels for colony-forming units (CFUs) detected during viable surface  
15 sampling, glove fingertip, and viable air sampling and actions to be taken when the  
levels are exceeded.”

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

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

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

21 “Where any sterile compounded drug preparation was compounded either outside of  
22 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  
23 labeled for "immediate use only" and administration shall begin no later than one hour  
24 following the start of the compounding process. Unless the "immediate  
use" preparation is immediately and completely administered by the person who  
25 prepared it or immediate and complete administration is witnessed by the preparer,  
the preparation shall bear a label listing patient identification information, the names  
26 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  
27 administration has not begun within one hour following the start of the compounding  
process, the compounded sterile preparation shall be promptly, properly, entirely, and  
28 safely discarded. This provision does not preclude the use of a PEC to compound an

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

#### 10 **HEALTH AND SAFETY CODE**

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

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

#### 15 **COST RECOVERY**

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

#### 22 **FACTUAL SUMMARY**

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

#### 27 **2017 Inspection**

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

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

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

10 31. On February 25, 2017, CAS performed an environmental sampling test of  
11 Respondent Pharmacy's CAI. The CAI failed the test, in that the test results indicated that  
12 nine (9) CFUs of fungal air growth were inside the ISO 5 CAI airlock chamber. On March  
13 10, 2017, the test results were reported to Respondent Pharmacy, yet the re-testing of the  
14 CAI for viable growth was not performed until May 4, 2017.

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

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

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

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

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

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

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

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

23 38. Respondent Pharmacy’s policies and procedures also state:

24 “A batched-produced low to medium risk CSP shall be subject to documented end  
25 product quantitative analysis once a year. The analysis will be conducted by a laboratory.”  
26 One CSP prepared at the pharmacy was tested for potency on September 14, 2016, by an  
27 outside lab. On October 10, 2017, another CSP was sent out for testing. October 10, 2017,  
28 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<sup>1</sup> guidelines state, in part:

“Any CFU<sup>2</sup> 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.

<sup>1</sup> 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).

<sup>2</sup> 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.

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

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

#### 14                                   **FIRST CAUSE FOR DISCIPLINE**

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

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

#### 25                                   **SECOND CAUSE FOR DISCIPLINE**

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

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

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

### 15 **THIRD CAUSE FOR DISCIPLINE**

#### 16 **(Delivering Adulterated Medications)**

17 47. Respondents Pharmacy, Chang, and Cheung are subject to disciplinary action  
18 under section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they  
19 failed to comply with section 4169(a)(2) of the Code and Health and Safety Code sections  
20 111250 and 111295. Specifically, from at least February 25, 2017, until at least November  
21 22, 2017, the pharmacy delivered approximately 21,000 units of adulterated dangerous  
22 drugs to patients of Southern California Hospital at Culver City. From at least February 25,  
23 2017, until at least August 31, 2017, while Respondent Chang served as the pharmacist-in-  
24 charge, the pharmacy delivered approximately 15,000 units of adulterated dangerous drugs  
25 to patients of Southern California Hospital at Culver City. From at least September 1, 2017,  
26 until at least November 22, 2017, while Respondent Cheung served as the pharmacist-in-  
27 charge, Respondent Pharmacy delivered approximately 6,000 units of adulterated dangerous  
28 drugs to patients of Southern California Hospital at Culver City. Complainant refers to, and



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

3 **FOURTH CAUSE FOR DISCIPLINE**

4 **(Gross Negligence)**

5 48. Respondent Pharmacy is subject to disciplinary action under section 4301,  
6 subdivision (c), in that it committed gross negligence. Specifically, from at least February  
7 25, 2017, until at least November 22, 2017, Respondent Pharmacy was grossly negligent in  
8 properly addressing repetitive microbial air contamination of the ISO 5 CAI, where sterile  
9 compounding took place. Complainant refers to, and by this reference incorporates, the  
10 allegations set forth in paragraphs 28 through 41, above, as though set forth fully herein.

11 **FIFTH CAUSE FOR DISCIPLINE**

12 **(Failure to Comply with Compounding Quality Assurance Requirements)**

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

21 **SIXTH CAUSE FOR DISCIPLINE**

22 **(Failure to Comply with Labeling Requirements)**

23 50. Respondents Pharmacy and Cheung are subject to disciplinary action under  
24 section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed  
25 to comply with California Code of Regulations, title 16, section 1735.4(a)(5). Specifically,  
26 while Respondent Cheung was serving as the pharmacist-in-charge, CSP labels reviewed on  
27 the Board's November 21, 2017, inspection did not contain the date compounded.  
28

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

3 **SEVENTH CAUSE FOR DISCIPLINE**

4 **(Failure to Comply with Compounding Limitations and Requirements)**

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

13 **EIGHTH CAUSE FOR DISCIPLINE**

14 **(Inappropriate Exercise of Education,**  
15 **Training, or Experience as a Pharmacist)**

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

23 **NINTH CAUSE FOR DISCIPLINE**

24 **(Failure to Exercise Professional Judgment)**

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

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

3 **TENTH CAUSE FOR DISCIPLINE**

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

5 54. Respondents Pharmacy and Vo are subject to disciplinary action under Code  
6 section 4301, subdivision (o), on the grounds of unprofessional conduct, in that they failed  
7 to comply with California Code of Regulations, title 16, section 1715(a) and (b)(2).  
8 Respondents Pharmacy and Vo failed to promote compliance through self-examination and  
9 education when Respondent Vo associated as the pharmacist-in-charge, effective August 14,  
10 2018, and failed to complete a self-assessment of the pharmacy's compliance with federal  
11 and state pharmacy law until October 12, 2018. Complainant refers to, and by this reference  
12 incorporates, the allegations set forth in paragraphs 42 through 44, above, as though set  
13 forth fully herein.

14 **ELEVENTH CAUSE FOR DISCIPLINE**

15 **(Failure to Complete Compounding Self-Assessment)**

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

25 **TWELFTH CAUSE FOR DISCIPLINE**

26 **(Failure to Comply with Immediate Use Compounding Requirements)**

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

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

### 12 **THIRTEENTH CAUSE FOR DISCIPLINE**

#### 13 **(Failure to Follow Pharmacy's Policies and Procedures)**

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

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1 **FOURTEENTH CAUSE FOR DISCIPLINE**

2 **(Inappropriate Exercise of Education,**  
3 **Training, or Experience as a Pharmacist)**

4 58. Respondent Vo is subject to disciplinary action under Code section 4301,  
5 subdivision (o), on the grounds of unprofessional conduct, for violating section 4306.5  
6 subdivision (a). Specifically, between August 14, 2018, and October 9, 2018, while  
7 Respondent Vo served as the pharmacist-in-charge and was responsible for pharmacy  
8 operations for Respondent Pharmacy, she failed to exercise her education, training,  
9 experience and best professional judgment when Respondent Pharmacy dispensed at least  
10 150 medium-risk level CSPs as “immediate-use”. Complainant refers to, and by this  
11 reference incorporates, the allegations set forth in paragraphs 42 to 44, above, as though set  
12 forth fully herein.

13 **FIFTEENTH CAUSE FOR DISCIPLINE**

14 **(Failure to Exercise Professional Judgment)**

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

22 **OTHER MATTERS**

23 59. Pursuant to Code section 4307, if discipline is imposed on Hospital  
24 Pharmacy Permit Number HSP 51172 issued to Southern California Healthcare Systems,  
25 Inc., dba Southern California Hospital at Culver City, Southern California Healthcare  
26 Systems, Inc. shall be prohibited from serving as a manager, administrator, owner, member,  
27 officer, director, associate, or partner of a licensee for five years if Hospital Pharmacy  
28

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

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

14 **PRAYER**

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

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

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

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

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

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

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

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

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

18           9.     Taking such other and further action as deemed necessary and proper.  
19  
20

21           DATED:     September 10, 2019  
22



23           ANNE SODERGREN  
24           Interim Executive Officer  
25           Board of Pharmacy  
26           Department of Consumer Affairs  
27           State of California  
28           Complainant

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