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

In the Matter of the Accusation Against:

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, DBA SANTA MONICA – UCLA MEDICAL CENTER & ORTHOPEDIC HOSPITAL, Hospital Pharmacy Permit No. HPE 41170;

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, DBA SANTA MONICA – UCLA MEDICAL CENTER AND ORTHOPEDIC HOSPITAL IVAS,

Sterile Compounding Permit No. LSE 99994 (now 101545);

# MATTHEW KAZUNORI SASAKI, Registered Pharmacist License No. RPH 68915;

and

# MARINE MARTA ALTUNYAN, Registered Pharmacist License No. RPH 75760;

**Respondents.** 

Agency Case No. 6987

# **DECISION AND ORDER**

DECISION AND ORDER AS TO SANTA MONICA -UCLA MEDICAL CENTER & ORTHOPEDIC HOSPITAL AND SANTA MONICA UCLA MEDICAL CENTER & ORTHOPEDIC HOSPITAL IVAS ONLY (CASE NO. 6987) 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 November 10, 2021.

It is so ORDERED on October 11, 2021.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

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Ву

Seung W. Oh, Pharm.D. Board President

1	ROB BONTA Attorney General of California SHAWN P. COOK		
3	Supervising Deputy Attorney General ELAINE YAN		
4	Deputy Attorney General State Bar No. 277961		
5	300 So. Spring Street, Suite 1702 Los Angeles, CA 90013		
6 7	Telephone: (213) 269-6683 Facsimile: (916) 731-2126 E-mail: Elaine.Yan@doj.ca.gov Attorneys for Complainant		
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9	BEFORE THE BOARD OF PHARMACY		
10	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
11			
12			
13	In the Matter of the Accusation Against:	Case No. 6987	
14 15	THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, DBA SANTA MONICA - UCLA MEDICAL CENTER &	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO	
16	ORTHOPEDIC HOSPITAL 1250 16th Street	<b>RESPONDENTS THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,</b>	
17	Santa Monica, CA 90404 Hospital Pharmacy Permit No. HPE 41170	DBA SANTA MONICA - UCLA MEDICAL CENTER & ORTHOPEDIC HOSPITAL, THE REGENTS OF THE	
18	THE REGENTS OF THE UNIVERSITY	UNIVERSITY OF CALIFORNIA, DBA SANTA MONICA - UCLA MEDICAL	
19	OF CALIFORNIA, DBA SANTA MONICA – UCLA MEDICAL CENTER AND	<b>CENTER &amp; ORTHOPEDIC HOSPITAL</b> <b>IVAS, AND THE REGENTS OF THE</b>	
20 21	ORTHOPEDIC HOSPITAL IVAS 1250 16th Street Santa Monica, CA 90404	UNIVERSITY OF CALIFORNIA, DBA SANTA MONICA UCLA MEDICAL CENTER ONLY	
21	Sterile Compounding Permit No. LSE 99994,		
23	MATTHEW KAZUNORI SASAKI		
24	17528 Daphane Ave. Torrance, CA 90504		
25	Registered Pharmacist License No. RPH 68915,		
26	and		
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28			
		1 STIPULATED SETTLEMENT (6987)	

1	MARINE MARTA ALTUNYAN
2	1636 Sinaloa Ave. Pasadena, CA 91104
3	Registered Pharmacist License No. RPH 75760
4 5	Respondents.
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7	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
8	entitled proceedings that the following matters are true:
9	PARTIES
10	1. Anne Sodergren is the Executive Officer of the Board of Pharmacy. She brought this
11	action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney
12	General of the State of California, by Elaine Yan, Deputy Attorney General.
13	2. Respondents The Regents of the University of California, dba Santa Monica - UCLA
14	Medical Center & Orthopedic Hospital, The Regents of the University of California, dba Santa
15	Monica UCLA Medical Center, and The Regents of the University of California, dba Santa
16	Monica - UCLA Medical Center & Orthopedic Hospital IVAS are represented in this proceeding
17	by attorney Natalia Mazina, whose address is: 100 Pine Street, Suite 1250, San Francisco, CA
18	94111-5235.
19	3. On or about December 19, 1995, the board issued Hospital Pharmacy Permit Number
20	HPE 41170 to The Regents of the University of California, dba Santa Monica - UCLA Medical
21	Center & Orthopedic Hospital. The Hospital Pharmacy Permit was in full force and effect at all
22	times relevant to the charges brought herein and will expire on July 1, 2022, unless renewed.
23	4. On or about June 19, 2014, the board issued Sterile Compounding Permit Number
24	LSE 99994 to The Regents of the University of California, dba Santa Monica - UCLA Medical
25	Center & Orthopedic Hospital IVAS. The Sterile Compounding Permit was cancelled on April
26	20, 2020.
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	STIPULATED SETTLEMENT (6987)

1	5. On or about March 25, 2020, the board issued Sterile Compounding Permit Number		
2	LSE 101545 to The Regents of the University of California, dba Santa Monica UCLA Medical		
3	Center. The Sterile Compounding Permit will expire on July 1, 2022.		
4	JURISDICTION		
5	6. Accusation No. 6987 was filed before the board, and is currently pending against		
6	respondents. The Accusation and all other statutorily required documents were properly served		
7	on respondents on October 12, 2020. Respondents filed their Notices of Defense contesting the		
8	Accusation.		
9	7. A copy of Accusation No. 6987 is attached as exhibit A and incorporated herein by		
10	reference.		
11	8. Respondents cancelled Sterile Compounding Permit Number LSE 99994 upon the		
12	issuance of Sterile Compounding Permit Number LSE 101545. The parties stipulated that Sterile		
13	Compounding Permit Number LSE 101545 is subject to the same causes for discipline alleged in		
14	Accusation No. 6987 and that the board shall have continuing jurisdiction over Sterile		
15	Compounding Permit Number LSE 101545.		
16	ADVISEMENT AND WAIVERS		
17	9. Respondents have carefully read, fully discussed with counsel, and understand the		
18	charges and allegations in Accusation No. 6987. Respondents have also carefully read, fully		
19	discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary		
20	Order.		
21	10. Respondents are fully aware of their legal rights in this matter, including the right to a		
22	hearing on the charges and allegations in the Accusation; the right to confront and cross-examine		
23	the witnesses against them; the right to present evidence and to testify on their own behalf; the		
24	right to the issuance of subpoenas to compel the attendance of witnesses and the production of		
25	documents; the right to reconsideration and court review of an adverse decision; and all other		
26	rights accorded by the California Administrative Procedure Act and other applicable laws.		
27	11. Respondents voluntarily, knowingly, and intelligently waive and give up each and		
28	every right set forth above.		
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	STIPULATED SETTLEMENT (6987)		

1	<u>CULPABILITY</u>
2	12. Respondents understand and agree that the charges and allegations in Accusation No.
3	6987, if proven at a hearing, constitute cause for imposing discipline upon their Hospital
4	Pharmacy Permit and their Sterile Compounding Permits.
5	13. For the purpose of resolving the Accusation without the expense and uncertainty of
6	further proceedings, respondents agree that, at a hearing, complainant could establish a factual
7	basis for the charges in the Accusation, and that respondents hereby give up their right to contest
8	those charges.
9	14. Respondents agree that Hospital Pharmacy Permit No. HPE 41170, Sterile
10	Compounding Permit No. LSE 99994, and Sterile Compounding Permit No. LSE 101545 are
11	subject to discipline and they agree to be bound by the board's terms and conditions as set forth in
12	the Disciplinary Order below.
13	RESERVATION
14	15. The admissions made by respondents herein are only for the purposes of this
15	proceeding, or any other proceedings in which the Board of Pharmacy or other professional
16	licensing agency is involved, and shall not be admissible in any other criminal or civil
17	proceeding.
18	<u>CONTINGENCY</u>
19	16. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents
20	understand and agree that counsel for complainant and the staff of the Board of Pharmacy may
21	communicate directly with the board regarding this stipulation and settlement, without notice to
22	or participation by respondents or their counsel. By signing the stipulation, respondents
23	understand and agree that they may not withdraw their agreement or seek to rescind the
24	stipulation prior to the time the board considers and acts upon it. If the board fails to adopt this
25	stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of
26	no force or effect, except for this paragraph, it shall be inadmissible in any legal action between
27	the parties, and the board shall not be disqualified from further action by having considered this
28	matter.

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

18. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an
integrated writing representing the complete, final, and exclusive embodiment of their agreement.
It supersedes any and all prior or contemporaneous agreements, understandings, discussions,
negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary
Order may not be altered, amended, modified, supplemented, or otherwise changed except by a
writing executed by an authorized representative of each of the parties.

10 19. In consideration of the foregoing admissions and stipulations, the parties agree that
11 the Board may, without further notice or formal proceeding, issue and enter the following
12 Disciplinary Order:

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### **DISCIPLINARY ORDER**

IT IS HEREBY ORDERED that Hospital Pharmacy Permit No. HPE 41170 issued to
respondent The Regents of the University of California, dba Santa Monica - UCLA Medical
Center & Orthopedic Hospital and Sterile Compounding Permit No. LSE 101545 issued to
respondent The Regents of the University of California, dba Santa Monica UCLA Medical Center
are each and all revoked. However, the revocations are stayed and respondents are placed on
probation for five (5) years on the following terms and conditions:

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### 1. **Definition: Respondents**

21 For the purposes of these terms and conditions, "respondents" shall refer to The Regents of the University of California, dba Santa Monica - UCLA Medical Center & Orthopedic Hospital 22 and The Regents of the University of California, dba Santa Monica UCLA Medical Center. All 23 terms and conditions stated herein shall bind and be applicable to the licensed premises and to all 24 owners, managers, officers, administrators, members, directors, trustees, associates, or partners 25 thereof. For purposes of compliance with any term or condition, any report, submission, filing, 26 payment, or appearance required to be made by respondents to or before the board or its designee 27 shall be made by an owner or executive officer with authority to act on behalf of and legally bind 28

 $1 \parallel$  the licensed entity.

1	the licensed entity.	
2	2. Obey All Laws	
3	Respondents shall obey all state and federal laws and regulations.	
4	Respondents shall report any of the following occurrences to the board, in writing, within	
5	seventy- two (72) hours of such occurrence:	
6	• an arrest or issuance of a criminal complaint for violation of any provision of the	
7	Pharmacy Law, state and federal food and drug laws, or state and federal controlled	
8	substances laws;	
9	• a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal	
10	criminal proceeding to any criminal complaint, information or indictment;	
11	• a conviction of any crime; or	
12	• the filing of a disciplinary pleading, issuance of a citation, or initiation of another	
13	administrative action filed by any state or federal agency which involves	
14	respondents' Hospital Pharmacy Permit No. HPE 41170 or Sterile Compounding	
15	Permit No. LSE 101545 or which is related to the practice of pharmacy or the	
16	manufacturing, obtaining, handling, distributing, billing, or charging for any drug,	
17	device or controlled substance.	
18	Failure to timely report such occurrence shall be considered a violation of probation.	
19	3. <b>Report to the Board</b>	
20	Respondents shall report to the board quarterly, on a schedule as directed by the board or its	
21	designee. The report shall be made either in person or in writing, as directed. Among other	
22	requirements, respondents shall state in each report under penalty of perjury whether there has	
23	been compliance with all the terms and conditions of probation.	
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	STIPULATED SETTLEMENT (6987)	

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.

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### Interview with the Board

Upon receipt of reasonable prior notice, respondents 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.

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### Cooperate with Board Staff

Respondents shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondents' 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.

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### **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondents shall pay to the board its costs of investigation and prosecution in the amount of \$22,875.75. Respondents shall make said payment as follows: within thirty (30) days of the effective date of the Decision and Order. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

Respondents 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.

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#### **Probation Monitoring Costs**

Respondents 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 3 directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall 4 5 be considered a violation of probation.

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### **Status of License**

Respondents shall, at all times while on probation, maintain an active, current Hospital 7 Pharmacy Permit and an active, current Sterile Compounding Permit with the board, including 8 9 any period during which suspension or probation is tolled. Failure to maintain an active, current Hospital Pharmacy Permit and an active, current Sterile Compounding permit shall be considered 10 a violation of probation. 11

If respondents' Hospital Pharmacy Permit and/or Sterile Compounding Permit expire or are 12 cancelled by operation of law or otherwise at any time during the period of probation, including 13 any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondents' 14 license permit shall be subject to all terms and conditions of this probation not previously 15 satisfied. 16

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

Following the effective date of this decision, should respondents wish to discontinue 18 business, respondents may tender the premises license to the board for surrender. The board or its 19 designee shall have the discretion whether to grant the request for surrender or take any other 20action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the 21 license, respondents will no longer be subject to the terms and conditions of probation. 22

Respondents may not apply for any new license from the board for three (3) years from the 23 24 effective date of the surrender. Respondents shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board. 25

Respondents further stipulates that they shall reimburse the board for its costs of 26 investigation and prosecution prior to the acceptance of the surrender. 27

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#### 10. Sale or Discontinuance of Business

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

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#### 11. Notice to Employees

Respondents shall, upon or before the effective date of this decision, ensure that all 11 employees involved in permit operations are made aware of all the terms and conditions of 12 probation, either by posting a notice of the terms and conditions, circulating such notice, or both. 13 14 If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondents shall ensure that any employees 15 hired or used after the effective date of this decision are made aware of the terms and conditions 16 of probation by posting a notice, circulating a notice, or both. Additionally, respondent shall 17 submit written notification to the board, within fifteen (15) days of the effective date of this 18 decision, that this term has been satisfied. Failure to timely provide such notification to 19 employees, or to timely submit such notification to the board shall be considered a violation of 20probation. 21

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

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#### 12. Owners and Officers: Knowledge of the Law

Respondents shall provide, within thirty (30) days after the effective date of this decision,
signed and dated statements from its owners, including any owner or holder of ten percent (10%)
or more of the interest in respondents or respondents' stock, and all of their officer, stating under

penalty of perjury that said individuals have read and are familiar with state and federal laws and
 regulations governing the practice of pharmacy. The failure to timely provide said statements
 under penalty of perjury shall be considered a violation of probation.

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#### 13. Premises Open for Business

Respondents shall remain open and engaged in their ordinary business as a pharmacy in 5 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 8 extended by one month for each month during with this minimum is not met. During any such 9 period of tolling of probation, respondents must nonetheless comply with all terms and conditions of probation, unless respondents are informed otherwise in writing by the board or its designee. If 10 respondents are not open and engaged in their ordinary business as a pharmacy for a minimum of 11 120 hours in any calendar month, for any reason (including vacation), respondents shall notify the 12 board in writing within ten (10) days of the conclusion of that calendar month. This notification 13 14 shall include at minimum all of the following: the date(s) and hours respondents were open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on 15 which respondents will resume business as required. Respondents shall further notify the board 16 in writing with ten (10) days following the next calendar month during which respondents are 17 open and engaged in its ordinary business as a 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

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#### 14. Posted Notice of Probation

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

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

licensed entity.

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#### 15. **Violation of Probation**

If respondents have not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondents, and the board shall provide notice to respondents that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

9 If respondent violates probation in any respect, the board, after giving respondents notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that 10 was stayed. If a petition to revoke probation or an accusation is filed against respondents during 11 probation, or the preparation of an accusation or petition to revoke probation is requested from 12 the Office of the Attorney General, the board shall have continuing jurisdiction and the period of 13 14 probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and the charges and allegations in Accusation No. 6987 shall be deemed true 15 and correct. 16

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#### 16. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of 18 19 probation, respondents' licenses will be fully restored.

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#### 17. **Consultant Review of Pharmacy Operations**

During the period of probation, respondents shall retain an independent consultant 21 (Independent Consultant) at their own expense who shall be responsible for conducting an 22 inspection to review the operations of respondents' pharmacies on a quarterly basis for 23 24 compliance by respondents with state and federal laws and regulations governing the practice of pharmacy and compounding. During the period of probation, the Board or its designee retains the 25 discretion to modify the frequency of the inspection of the Independent Consultant's review. 26

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The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) 28

- days of the effective date of this decision.
- Failure to timely retain, seek approval for, or ensure timely reporting by the Independent
  Consultant shall be considered a violation of probation.
  - This provision shall apply throughout the entire period of probation.
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#### 18. Response Plan to High Dose Medication Alerts

Within sixty (60) days of the effective date of the decision, respondents shall submit their 6 response plan to alerts triggered by respondents' High Alert Medication Policy (Response Plan) 7 to the Independent Consultant for written assessment. Within thirty (30) days of the Independent 8 Consultant's completion of the written assessment, respondents shall submit the Response Plan 9 and the written assessment to the board for approval. Respondents' Response Plan shall be 10 subject to approval by the board or its designee. The period of probation will be automatically 11 extended until respondents' Response Plan is approved by the board. Failure to timely submit the 12 Response Plan to the Independent Consultant or to the board shall be considered a violation of 13 probation. 14

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#### 19. Remedial Education - Compounding

Within thirty (30) days of the effective of this decision, respondents shall submit to the 16 board or its designee, for prior approval, an appropriate program of remedial education related to 17 compounding for each and every pharmacist and pharmacy technician employed by respondents 18 whose job duties relate to compounding. The program of remedial education shall require 19 respondents' pharmacists and pharmacy technicians to complete at least 10 hours of remedial 20education per year at respondents' own expense during the entire period of probation. All 21 remedial education shall be in addition to, and shall not be credited toward, continuing education 22 courses used for license renewal purposes for pharmacists and pharmacy technicians. 23

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

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#### 20. **Remedial Education – Corrective Action**

Within thirty (30) days of the effective of this decision, respondents shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to 3 any and all corrective action respondents have taken in response to the incident that gave rise to 4 the charges and allegations in Accusation No. 6987 for each and every pharmacist, pharmacy 5 technician, and employee employed by respondents whose job duties relate to compounding. All 6 remedial education shall be in addition to, and shall not be credited toward, continuing education 7 8 courses used for license renewal purposes for pharmacists and pharmacy technicians.

9 Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until 10 such remedial education is successfully completed and written proof, in a form acceptable to the 11 board, is provided to the board or its designee. 12

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary 13 14 and relief employees and independent contractors employed or hired at any time during probation. 15

IT IS ALSO HEREBY ORDERED that Sterile Compounding Permit No. LSE 99994 16 issued to respondent The Regents of the University of California, dba Santa Monica - UCLA 17 Medical Center & Orthopedic Hospital IVAS (UCLA IVAS) is surrendered and accepted by the 18 board. 19

Respondent UCLA IVAS surrenders Sterile Compounding Permit No. LSE 99994 as 1. 20 of the effective date of this decision. Respondent UCLA IVAS shall relinquish the premises wall 21 license and renewal license to the board within ten (10) days of the effective date of this decision. 22

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2. The surrender of respondent UCLA IVAS' license and the acceptance of the 24 surrendered license by the board shall constitute the imposition of discipline against respondent UCLA IVAS. This decision constitutes a record of discipline and shall become a part of 25 respondent UCLA IVAS' license history with the board. 26

3. Respondent UCLA IVAS shall, within ten (10) days of the effective date, arrange for 27 the destruction of, the transfer to, sale of or storage in a facility licensed and approved by the 28

board of all controlled substances and dangerous drugs and/or dangerous devices. Respondent
 UCLA IVAS shall further arrange for the transfer of all records of acquisition and disposition of
 dangerous drugs to premises licensed and approved by the board. Respondent UCLA IVAS shall
 further provide written proof of such disposition and submit a completed Discontinuance of
 Business form according to board guidelines.

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4. Respondent UCLA IVAS may only seek a new or reinstated license from the board by way of a new application for licensure. Respondent UCLA IVAS shall not be eligible to petition for reinstatement of licensure.

9 5. Respondent UCLA IVAS may not reapply for any license from the board for three (3) years from the effective date of this decision. Respondent UCLA IVAS stipulates that should it 10 apply for any license from the board on or after the effective date of this decision, all allegations 11 set forth in the Accusation No. 6987 shall be deemed to be true, correct and admitted by 12 respondent UCLA IVAS when the board determines whether to grant or deny the application. 13 Respondent UCLA IVAS shall satisfy all requirements applicable to that license as of the date the 14 application is submitted to the board. Respondent UCLA IVAS is required to report this 15 surrender as disciplinary action. 16 17 /// /// 18 19 /// /// 20 /// 21 22 /// /// 23 24 /// /// 25 /// 26 27 /// 28 /// 14

1	ACCEPTANCE	
2	I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully	
3	discussed it with my attorney, Natalia Mazina. I understand the stipulation and the effect it will	
4	have on Hospital Pharmacy Permit Number HPE 41170, Sterile Compounding Permit Number	
5	LSE 101545, and Sterile Compounding Permit Number LSE 99994. I enter into this Stipulated	
6	Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be	
7	bound by the Decision and Order of the Board of Pharmacy.	
8		
9	DATED:	
10 11	JOHNESE SPISSO President, UCLA Health Chief Executive Officer, UCLA Hospital System Associate Vice Chancellor, UCLA Health Sciences	
12	The Regents of the University of California, dba Santa	
13	Monica – UCLA Medical Center & Orthopedic Hospital	
14	The Regents of the University of California, dba Santa Monica – UCLA Medical Center & Orthopedic	
15	Hospital IVAS The Regents of the University of California, dba Santa	
16	Monica UCLA Medical Center Respondents	
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18	I have read and fully discussed with The Regents of the University of California, dba Santa	
19	Monica - UCLA Medical Center & Orthopedic Hospital, The Regents of the University of	
20	California, dba Santa Monica UCLA Medical Center, and The Regents of the University of	
21	California, dba Santa Monica - UCLA Medical Center & Orthopedic Hospital IVAS the terms	
22	and conditions and other matters contained in the above Stipulated Settlement and Disciplinary	
23	Order. I approve its form and content.	
24	DATED:	
25	NATALIA MAZINA Attorney for Respondent	
26	Thiorney for Respondent	
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	15	
	STIPULATED SETTLEMENT (6987)	

1	ACCEPTANCE	
2	I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully	
3	discussed it with my attorney, Natalia Mazina. I understand the stipulation and the effect it will	
4	have on Hospital Pharmacy Permit Number HPE 41170, Sterile Compounding Permit Number	
5	LSE 101545, and Sterile Compounding Permit Number LSE 99994. I enter into this Stipulated	
6	Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be	
7	bound by the Decision and Order of the Board of Pharmacy.	
8		
9	DATED: 8/11/2021 (phuse pisso)	
10	JOHNESE SPISSO President, UCLA Health Chief Executive Officer, UCLA Hospital System	
11	Associate Vice Chancellor, UCLA Health Sciences The Regents of the University of California, dba Santa	
12	Monica – UCLA Medical Center & Orthopedic Hospital	
13	The Regents of the University of California, dba Santa Monica – UCLA Medical Center & Orthopedic	
14	Hospital IVAS	
15 16	The Regents of the University of California, dba Santa Monica UCLA Medical Center Respondents	
17		
18		
19	I have read and fully discussed with The Regents of the University of California, dba Santa	
20	Monica - UCLA Medical Center & Orthopedic Hospital, The Regents of the University of	
21	California, dba Santa Monica UCLA Medical Center, and The Regents of the University of	
22	California, dba Santa Monica - UCLA Medical Center & Orthopedic Hospital IVAS the terms	
23	and conditions and other matters contained in the above Stipulated Settlement and Disciplinary	
24	Order. I approve its form and content.	
25	DATED: Aug. 11, 2021	
26	Attorney for Respondent	
27		
28	///	
	15	
	STIPULATED SETTLEMENT (6987)	

1		<b>ENDORSEMENT</b>
2	The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully	
3	submitted for consideration by the B	board of Pharmacy.
4		
5	DATED:	
6		ROB BONTA Attorney General of California SHAWN P. COOK
7		Supervising Deputy Attorney General
8		
9 10		ELAINE YAN Deputy Attorney General Attorneys for Complainant
11		Attorneys for Complainant
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		16
		STIPULATED SETTLEMENT (6987)

1		ENDORSEMENT_
2	The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully	
3	submitted for consideration by the Boar	d of Pharmacy.
4		
5	DATED: <u>08/13/2021</u>	Respectfully submitted,
6 7		ROB BONTA Attorney General of California SHAWN P. COOK Supervising Deputy Attorney General
8		Supervising Dopin v Entornev seneral
0 9		
10		ELAINE YAN Deputy Attorney General Attorneys for Complainant
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		STIPULATED SETTLEMENT (6987)

## Exhibit A

Accusation No. 6987

1 2 3 4 5 6 7 8	XAVIER BECERRA Attorney General of California SHAWN P. COOK Supervising Deputy Attorney General ELAINE YAN Deputy Attorney General State Bar No. 277961 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 269-6683 Facsimile: (916) 731-2126 E-mail: Elaine.Yan@doj.ca.gov Attorneys for Complainant BEFORE	
9 10	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA	
11		
12	In the Matter of the Accusation Against:	Case No. 6987
13	THE REGENTS OF THE UNIVERSITY OF	
14 15	CALIFORNIA, DBA SANTA MONICA - UCLA MEDICAL CENTER & ORTHOPEDIC HOSPITAL	ACCUSATION
15	1250 16th Street Santa Monica, CA 90404	
17	Hospital Pharmacy Permit No. HPE 41170	
18	THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, DBA SANTA MONICA –	
19	UCLA MEDICAL CENTER AND ORTHOPEDIC HOSPITAL IVAS	
20	1250 16th Street Santa Monica, CA 90404	
21	Sterile Compounding Permit No. LSE 99994,	
22	MATTHEW KAZUNORI SASAKI	
23	17528 Daphane Ave. Torrance, CA 90504	
24	Registered Pharmacist License No. RPH 68915,	
25 26	and	
26 27		
27		
20	1	<u> </u>
	(THE REGENTS OF THE UNIVERSITY OF CALIFORNI	A, MATTHEW KAZUNORI SASAKI, and MARINE MARTA ALTUNYAN) ACCUSATION

1	MARINE MARTA ALTUNYAN 1636 Sinaloa Ave. Pasadena, CA 91104	
2	Registered Pharmacist License No. RPH 75760	
3	Respondents.	
4 5	 PARTIES	
6	1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity	
7	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.	
8	2. On or about December 19, 1995, the Board of Pharmacy (Board) issued Hospital	
9	Pharmacy Permit Number HPE 41170 to The Regents of the University of California, dba Santa	
10	Monica - UCLA Medical Center & Orthopedic Hospital (Respondent Hospital Pharmacy). The	
11	Hospital Pharmacy Permit was in full force and effect at all times relevant to the charges brought	
12	herein and will expire on July 1, 2021, unless renewed.	
13	3. On or about June 19, 2014, the Board issued Sterile Compounding Permit Number	
14	LSE 99994 to The Regents of the University of California, dba Santa Monica - UCLA Medical	
15	Center & Orthopedic Hospital IVAS (Respondent Main Pharmacy). The Sterile Compounding	
16	Permit was cancelled on April 20, 2020.	
17	4. On or about July 11, 2013, the Board issued Registered Pharmacist License Number	
18	RPH 68915 to Matthew Kazunori Sasaki (Respondent Sasaki). The Registered Pharmacist	
19	License was in full force and effect at all times relevant to the charges brought herein and will	
20	expire on April 30, 2021, unless renewed.	
21	5. On or about October 26, 2016, the Board issued Registered Pharmacist License	
22	Number RPH 75760 to Marine Marta Altunyan (Respondent Altunyan). The Registered	
23	Pharmacist License was in full force and effect at all times relevant to the charges brought herein	
24	and will expire on August 31, 2022, unless renewed.	
25	JURISDICTION	
26	6. This Accusation is brought before the Board of Pharmacy (Board), Department of	
27	Consumer Affairs, under the authority of the following laws. All section references are to the	
28	Business and Professions Code (Code) unless otherwise indicated.	
	2 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, MATTHEW KAZUNORI SASAKI, and MARINE	

1	7. Section 118, subdivision (b), of the Code provides that the suspension expiration,	
2	surrender, or cancellation of a license shall not deprive the Board/Registrar/Director of	
3	jurisdiction to proceed with a disciplinary action during the period within which the license may	
4	be renewed, restored, reissued or reinstated.	
5	8. Section 4300 of the Code states:	
6	(a) Every license issued may be suspended or revoked.	
7	(b) The board shall discipline the holder of any license issued by the board, whose default	
8	has been entered or whose case has been heard by the board and found guilty, by any of the	
9	following methods:	
10	(1) Suspending judgment.	
11	(2) Placing him or her upon probation.	
12	(3) Suspending his or her right to practice for a period not exceeding one year.	
13	(4) Revoking his or her license.	
14	(5) Taking any other action in relation to disciplining him or her as the board in its	
15	discretion may deem proper.	
16	(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The	
17	board may, in its sole discretion, issue a probationary license to any applicant for a license who is	
18	guilty of unprofessional conduct and who has met all other requirements for licensure. The board	
19	may issue the license subject to any terms or conditions not contrary to public policy, including,	
20	but not limited to, the following:	
21	(1) Medical or psychiatric evaluation.	
22	(2) Continuing medical or psychiatric treatment.	
23	(3) Restriction of type or circumstances of practice.	
24	(4) Continuing participation in a board-approved rehabilitation program.	
25	(5) Abstention from the use of alcohol or drugs.	
26	(6) Random fluid testing for alcohol or drugs.	
27	(7) Compliance with laws and regulations governing the practice of pharmacy.	
28	///	
	3 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, MATTHEW KAZUNORI SASAKI, and MARINE	
	(THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, MATTHEW KAZUNORI SASARI, and MARINE MARTA ALTUNYAN) ACCUSATION	

(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary 1 certificate of licensure for any violation of the terms and conditions of probation. Upon 2 satisfactory completion of probation, the board shall convert the probationary certificate to a 3 regular certificate, free of conditions. 4 (e) The proceedings under this article shall be conducted in accordance with Chapter 5 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board 6 shall have all the powers granted therein. The action shall be final, except that the propriety of the 7 action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil 8

9 Procedure.

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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.
Section 4402, subsection (a), of the Code provides that any license that is not renewed
within three years following its expiration may not be renewed, restored, or reinstated and shall

18 be cancelled by operation of law at the end of the three-year period.

## STATUTORY PROVISIONS

11. Section 4301 of the Code states:

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.

- (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.
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1	12. Section 4306.5, subsection (a), of the Code states:			
2	Unprofessional conduct for a pharmacist may include any of the following:			
3	(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or			
4	her education, training, or experience as a pharmacist, whether or not the act or omission arises in			
5	the course of the practice of pharmacy or the ownership, management, administration, or			
6	operation of a pharmacy or other entity licensed by the board.			
7	13. Section 4127.1, subsection (f), of the Code states:			
8	(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product			
9	shall be reported to the board within 12 hours and immediately reported to the MedWatch			
10	program of the federal Food and Drug Administration.			
11	14. Section 4081, subsection (a), of the Code states:			
12	(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of			
13	dangerous drugs or dangerous devices shall be at all times during business hours open to			
14	inspection by authorized officers of the law, and shall be preserved for at least three years from			
15	the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-			
16	party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility,			
17	physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in			
18	Section 4187, clinic, hospital, institution, or establishment holding a currently valid and			
19	unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing			
20	with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section			
21	16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous			
22	drugs or dangerous devices.			
23	15. Section 4307 of the Code states:			
24	(a) Any person who has been denied a license or whose license has been revoked or is			
25	under suspension, or who has failed to renew his or her license while it was under suspension, or			
26	who has been a manager, administrator, owner, member, officer, director, associate, partner, or			
27	any other person with management or control of any partnership, corporation, trust, firm, or			
28	association whose application for a license has been denied or revoked, is under suspension or has 5			
	(THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, MATTHEW KAZUNORI SASAKI, and MARINE MARTA ALTUNYAN) ACCUSATION			

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:

7 (1) Where a probationary license is issued or where an existing license is placed on
8 probation, this prohibition shall remain in effect for a period not to exceed five years.

9 (2) Where the license is denied or revoked, the prohibition shall continue until the license is
10 issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any 11 other person with management or control of a license" as used in this section and Section 4308, 12 may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee. 13 (c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to 14 Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. 15 However, no order may be issued in that case except as to a person who is named in the caption, 16 as to whom the pleading alleges the applicability of this section, and where the person has been 17 given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 18 19 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 20of law. 21

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#### **REGULATORY PROVISIONS**

16. California Code of Regulations, title 16, section 1707.3, states:
Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's
drug therapy and medication record before each prescription drug is delivered. The review shall
include screening for severe potential drug therapy problems.

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1	17. California Code of Regulations, title 16, section 1714, subsection (b), states:			
2	Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and			
3	equipment so that drugs are safely and properly prepared, maintained, secured and distributed.			
4	The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice			
5	of pharmacy.			
6	18. California Code of Regulations, title 16, section 1735.3, states:			
7	(a) For each compounded drug preparation, pharmacy records shall include:			
8	(1) The master formula document.			
9	(2) A compounding log consisting of a single document containing all of the following:			
10	(A) Name and Strength of the compounded drug preparation.			
11	(B) The date the drug preparation was compounded.			
12	(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.			
13	(D) The identity of the pharmacist reviewing the final drug preparation.			
14	(E) The quantity of each ingredient used in compounding the drug preparation.			
15	(F) The manufacturer, expiration date and lot number of each component. If the			
16	manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If			
17	the manufacturer does not supply an expiration date for any component, the records shall include			
18	the date of receipt of the component in the pharmacy, and the limitations of section 1735.2,			
19	subdivision (l) shall apply.			
20	(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile			
21	preparations compounded in a single lot for administration within seventy-two (72) hours to a			
22	patient in a health care facility licensed under section 1250 of the Health and Safety Code and			
23	stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United			
24	States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd Supplement (37th			
25	Revision, Effective December 1, 2014), hereby incorporated by reference.			
26	(G) A pharmacy-assigned unique reference or lot number for the compounded drug			
27	preparation.			
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(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

(I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug 8 9 Administration (FDA). All other chemicals, bulk drug substances, and drug products used to 10 compound drug preparations shall be obtained, whenever possible, from FDA- registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in 11 English or translated into English, for chemicals, bulk drug substances, and drug products used in 12 compounding. Certificates of purity or analysis are not required for drug products that are 13 14 approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received. 15

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy
in a readily retrievable form for at least three years from the date the record was last in effect. If
only recorded and stored electronically, on magnetic media, or in any other computerized form,
the records shall be maintained as specified by Business and Professions Code section 4070
subsection (c).

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19. California Code of Regulations, title 16, section 1761, subsection (a), states:

(a) No pharmacist shall compound or dispense any prescription which contains any
significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any
such prescription, the pharmacist shall contact the prescriber to obtain the information needed to
validate the prescription.

### **COST RECOVERY**

27 20. Section 125.3 of the Code states, in pertinent part, that the Board may request the
28 administrative law judge to direct a licentiate found to have committed a violation or violations of

1	the licensing act to pay a sum not to exceed the reasonable costs of the investigation and			
2	enforcement of the case.			
3	DEFINITIONS			
4	21. Sodium Chloride (NaCl) injectable is classified as a dangerous drug under California			
5	Business and Professions Code section 4022. It is for use as injectable electrolyte.			
6	22. mEq means milliequivalent. An equivalent is the amount of a substance that will			
7	react with a certain number of hydrogen ions. A milliequivalent is one-thousandth of an			
8	equivalent. mEq/L means milliequivalents per liter. mEq/kg means milliequivalents per			
9	kilogram.			
10	FACTUAL ALLEGATIONS			
11	23. At all times relevant herein, Respondent Hospital Pharmacy had two separate			
12	locations and possessed two Sterile Compounding Permits.			
13	24. Respondent Hospital Pharmacy had a main hospital pharmacy in the basement with			
14	Sterile Compounding Permit No. LSE 99994 (Respondent Main Pharmacy). Respondent Main			
15	Pharmacy did the hospital's sterile compounding from 23:00 to 06:00.			
16	25. Respondent Hospital Pharmacy had a satellite pharmacy on the second floor with			
17	Sterile Compounding Permit No. LSE 99995 (Satellite Pharmacy). The Satellite Pharmacy did			
18	the hospital's sterile compounding from 06:00 to 23:00.			
19	26. On or about November 13, 2018, NC was a 6-year-old male patient at Santa Monica –			
20	UCLA Medical Center and Orthopedic Hospital (UCLA Hospital). Patient NC's weight was 17.7			
21	kg.			
22	27. On November 13, 2018, at approximately 20:10, Patient NC's physician placed an			
23	order for 500 ml of IV fluids to be compounded at Respondent Hospital Pharmacy through UCLA			
24	Hospital's electronic health record program, CareConnect. The physician entered the order as			
25	Dextrose 12.5% with sodium chloride 26 mEq/kg and sodium acetate 111 mEq/L.			
26	28. The physician mistakenly selected mEq/kg as the dosage unit for sodium chloride			
27	using the dropdown menu in CareConnect. The intended dosage unit was mEq/L.			
28	///			
	9 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, MATTHEW KAZUNORI SASAKI, and MARINE			
	(THE RECENTS OF THE UNIVERSITT OF CALIFORNIA, MATTHEW RAZUNORI SASARI, and MARINE MARTA ALTUNYAN) ACCUSATION			

Respondent Altunyan received the order at Respondent Hospital Pharmacy's Satellite 29. 1 Pharmacy. 2 30. On November 13, 2018, at 23:06, Respondent Altunyan spoke with the physician but 3 never discussed the dosage of the sodium chloride. Respondent Altunyan then verified and 4 approved the order and generated two IV labels for the order. 5 31. On November 13, 2018, at 23:11, pharmacy technician RL regenerated the order label 6 at Respondent Main Pharmacy. RL subsequently compounded the IV fluids as ordered (Bag 1). 7 32. On November 13, 2018, at 23:16, Respondent Sasaki approved the order label and 8 Bag 1. 9 33. On November 14, 2018, at 00:29, Bag 1 was administered to Patient NC. Patient NC 10 received the entire 500 ml dose of Bag 1. 11 On November 14, 2018, at approximately 04:30, Respondent Hospital Pharmacy 34. 12 received another request for a 500 ml bag of IV fluids (Bag 2) that was identical to the earlier 13 order received for Patient NC. 14 On November 14, 2018, at approximately 04:39, pharmacy technician RL prepared 35. 15 and compounded Bag 2, and Respondent Sasaki approved it. 16 On November 14, 2018, at 05:10, Bag 2 was administered to Patient NC. During the 36. 17 administration of Bag 2, Patient NC began having seizures and was intubated. A Code Blue was 18 called, and Patient NC's blood was drawn for testing. 19 Respondent Sasaki responded to the Code Blue and observed that the dosage of 37. 20 21 sodium chloride on Bag 2 appeared abnormally high. The lab results showed that Patient NC's sodium level was elevated. Bag 2 was removed. At that time, 100 ml of the 500 ml Bag 2 had 22 been administered to Patient NC. 23 38. Bag 1 and Bag 2 each contained 554.7 mEq of sodium. The incorrect dosage unit 24 resulted in almost 20 times the intended amount of sodium chloride in Bag 1 and Bag 2. 25 39. American Society for Parenteral and Enteral Nutrition (ASPEN) is considered the 26 leading expert in the science and practice of clinical nutrition. In 2019, ASPEN published a 27 document titled "Appropriate Dosing for Parenteral Nutrition: ASPEN Recommendations." The 28 10 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, MATTHEW KAZUNORI SASAKI, and MARINE

1	document stated that the daily dose of sodium for a child should be between 2 to 5 mEq/kg. For			
2	Patient NC, whose weight was reported as 17.7 kg, the daily dose of sodium should have been			
3	between 35.4 to 88.5 mEq.			
4	40. Patient NC was given 665.64 mEq of sodium (554.7 mEq from Bag 1 + 110.94 mEq			
5	from Bag 2) in a 5-hour time period.			
6	41. Patient NC died as a result of the dosage error.			
7	FIRST CAUSE FOR DISCIPLINE			
8	(Failure to Comply with Pharmacy Law – All Respondents)			
9	42. Respondents are subject to disciplinary action under Section 4301, subsection (o), in			
10	that Respondents committed unprofessional conduct by failing to comply with Pharmacy Law			
11	and regulations, as follows:			
12	a. California Code of Regulations, title 16, section 1761, subsection (a):			
13	Respondents verified, approved for dispensing, compounded, or dispensed at least one erroneous			
14	prescription with dangerously high intravenous sodium chloride content, which led to Patient			
15	NC's death.			
16	b. California Code of Regulations, title 16, section 1707.3: Respondents failed to			
17	appropriately review and analyze patient NC's drug therapy. Respondents' failure led to the			
18	dispensing and administration of compounded intravenous fluid with dangerously high sodium			
19	chloride content, which led to Patient NC's death.			
20	Paragraphs 23 to 41 are re-alleged as if fully set forth herein.			
21	///			
22	///			
23	///			
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	11 (THE DECENTS OF THE UNIVERSITY OF CALLEODNIA, MATTHEW KAZUNODI SASAKI, and MADINE			
	(THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, MATTHEW KAZUNORI SASAKI, and MARINE MARTA ALTUNYAN) ACCUSATION			

1	SECOND CAUSE FOR DISCIPLINE		
2	(Failure to Report)		
3	(Respondent Hospital Pharmacy HPE 41170 and Respondent Main Pharmacy LSE 99994)		
4	43. Respondents Hospital Pharmacy and Main Pharmacy are subject to disciplinary		
5	action under Section 4301, subsection (o), in that they committed unprofessional conduct by		
6	failing to comply with California Business and Professions Code section 4127.1. Specifically, on		
7	November 14, 2018, patient NC had an adverse effect (death) attributable to Respondents' sterile		
8	drug product. Respondent Hospital Pharmacy and Respondent Main Pharmacy failed to report		
9	this adverse effect to the Board.		
10	Paragraphs 23 to 41 are re-alleged as if fully set forth herein.		
11	THIRD CAUSE FOR DISCIPLINE		
12	(Gross Negligence – Respondent Altunyan)		
13	44. Respondent Altunyan is subject to disciplinary action under Section 4301, subsection		
14	(c), in that Respondent Altunyan committed unprofessional conduct and gross negligence.		
15	Specifically, on or about November 13, 2018, Respondent Altunyan verified and approved for		
16	dispensing an erroneous prescription with dangerously high intravenous sodium chloride content,		
17	which led to Patient NC's death.		
18	Paragraphs 23 to 41 are re-alleged as if fully set forth herein.		
19	FOURTH CAUSE FOR DISCIPLINE		
20	(Unprofessional Conduct – Inappropriate Exercise of Education/Training/Experience)		
21	(Respondent Altunyan)		
22	45. Respondent Altunyan is subject to disciplinary action under Section 4301 and Section		
23	4306.5 in that Respondent Altunyan committed unprofessional conduct involving inappropriate		
24	exercise of her education, training, and experience as a pharmacist. Specifically, Respondent		
25	Altunyan verified and approved for dispensing an erroneous prescription with dangerously high		
26	intravenous sodium chloride content, which led to Patient NC's death.		
27	Paragraphs 23 to 41 are re-alleged as if fully set forth herein.		
28	///		
	12		
	(THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, MATTHEW KAZUNORI SASAKI, and MARINE MARTA ALTUNYAN) ACCUSATION		

1	FIFTH CAUSE FOR DISCIPLINE		
2	(Gross Negligence – Respondent Sasaki)		
3	46. Respondent Sasaki is subject to disciplinary action under Section 4301, subsection		
4	(c), in that Respondent Sasaki committed unprofessional conduct and gross negligence.		
5	Specifically, on or about November 14, 2018, Respondent Sasaki dispensed at least one erroneous		
6	prescription with dangerously high intravenous sodium chloride content, which led to Patient		
7	NC's death.		
8	Paragraphs 23 to 41 are re-alleged as if fully set forth herein.		
9	SIXTH CAUSE FOR DISCIPLINE		
10	(Unprofessional Conduct – Inappropriate Exercise of Education/Training/Experience)		
11	(Respondent Sasaki)		
12	47. Respondent Sasaki is subject to disciplinary action under Section 4301 and Section		
13	4306.5 in that Respondent Sasaki committed unprofessional conduct involving inappropriate		
14	exercise of his education, training, and experience as a pharmacist. Specifically, Respondent		
15	Sasaki dispensed at least one erroneous prescription with dangerously high intravenous sodium		
16	chloride content, which led to Patient NC's death.		
17	Paragraphs 23 to 41 are re-alleged as if fully set forth herein.		
18	DISCIPLINARY CONSIDERATIONS		
19	48. To determine the degree of discipline, if any, to be imposed on Respondent Hospital		
20	Pharmacy, HPE 41170, Complainant alleges that on April 6, 2016, the Board issued Citation No.		
21	CI 2015 69847 and ordered Respondent Hospital Pharmacy to pay a fine of \$1,500.00 for		
22	violating 1) California Code of Regulations, title 16, section 1714, subsection (b); 2) California		
23	Business and Professions Code section 4301, subsection (c); and 3) California Business and		
24	Professions Code section 4081, subsection (a).		
25	49. To determine the degree of discipline, if any, to be imposed on Respondent Main		
26	Pharmacy, LSE 99994, Complainant alleges that on April 6, 2016, the Board issued Citation No.		
27	CI 2015 69848 and ordered Respondent Main Pharmacy to pay a fine of \$1,000 for violating 1)		
28	California Code of Regulations, title 16, section 1714, subsection (b); 2) California Business and		
	13		
	(THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, MATTHEW KAZUNORI SASAKI, and MARINE MARTA ALTUNYAN) ACCUSATION		

Professions Code section 4301, subsection (c); 3) California Business and Professions Code section 4081, subsection (a); and 4) California Code of Regulations, title 16, section 1735.3.

#### **OTHER MATTERS**

50. Pursuant to Code section 4307, if discipline is imposed on Hospital Pharmacy Permit Number HPE 41170 issued to The Regents of the University of California, dba Santa Monica -5 UCLA Medical Center & Orthopedic Hospital, The Regents of the University of California, dba 6 7 Santa Monica – UCLA Medical Center & Orthopedic Hospital shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 8 five years if Hospital Pharmacy Permit Number HPE 41170 is placed on probation or until 9 Hospital Pharmacy Permit Number HPE 41170 is reinstated if it is revoked. 10

Pursuant to Code section 4307, if discipline is imposed on Hospital Pharmacy Permit 11 51. Number HPE 41170 issued to The Regents of the University of California, dba Santa Monica -12 UCLA Medical Center & Orthopedic Hospital while Johnese Spisso has been an officer and had 13 14 knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Johnese Spisso shall be prohibited from serving as a manager, administrator, owner, member, 15 officer, director, associate, or partner of a licensee for five years if Hospital Pharmacy Permit 16 Number HPE 41170 is placed on probation or until Hospital Pharmacy Permit Number HPE 17 41170 is reinstated if it is revoked. 18

52. Pursuant to Code section 4307, if discipline is imposed on Sterile Compounding 19 Permit Number LSE 99994 issued to The Regents of the University of California, dba Santa 20 21 Monica – UCLA Medical Center & Orthopedic Hospital IVAS, The Regents of the University of California, dba Santa Monica – UCLA Medical Center & Orthopedic Hospital IVAS shall be 22 prohibited from serving as a manager, administrator, owner, member, officer, director, associate, 23 24 or partner of a licensee for five years if Sterile Compounding Permit Number LSE 99994 is placed on probation or until Sterile Compounding Permit Number LSE 99994 is reinstated if it is 25 revoked. 26

53. Pursuant to Code section 4307, if discipline is imposed on Sterile Compounding 27 Permit Number LSE 99994 issued to The Regents of the University of California, dba Santa 28

1	Monica – UCLA Medical Center & Orthopedic Hospital IVAS while Johnese Spisso has been an				
2	officer and had knowledge of or knowingly participated in any conduct for which the licensee				
3	was disciplined, Johnese Spisso shall be prohibited from serving as a manager, administrator,				
4	owner, member, officer, director, associate, or partner of a licensee for five years if Sterile				
5	Compounding Permit Number LSE 99994 is placed on probation or until Sterile Compounding				
6	Permit Number LSE 99994 is reinstated if it is revoked.				
7	PRAYER				
8	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,				
9	and that following the hearing, the Board of Pharmacy issue a decision:				
10	1. Revoking or suspending Hospital Pharmacy Permit Number HPE 41170, issued to				
11	The Regents of the University of California, dba Santa Monica - UCLA Medical Center &				
12	Orthopedic Hospital;				
13	2. Revoking or suspending Sterile Compounding Permit Number LSE 99994, issued to				
14	The Regents of the University of California, dba Santa Monica - UCLA Medical Center &				
15	Orthopedic Hospital IVAS;				
16	3. Prohibiting Johnese Spisso from serving as a manager, administrator, owner, member,				
17	officer, director, associate, or partner of a licensee for five years if Hospital Pharmacy Permit				
18	Number HPE 41170 is placed on probation or until Hospital Pharmacy Permit Number HPE				
19	41170 is reinstated if Hospital Pharmacy Permit Number HPE 41170 issued to The Regents of the				
20	University of California, dba Santa Monica - UCLA Medical Center & Orthopedic Hospital is				
21	revoked;				
22	4. Prohibiting Johnese Spisso from serving as a manager, administrator, owner, member,				
23	officer, director, associate, or partner of a licensee for five years if Sterile Compounding Permit				
24	Number LSE 99994 is placed on probation or until Sterile Compounding Permit Number LSE				
25	99994 is reinstated if Sterile Compounding Permit Number LSE 99994 issued to The Regents of				
26	the University of California, dba Santa Monica - UCLA Medical Center & Orthopedic Hospital				
27	IVAS is revoked;				
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	15				
	(THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, MATTHEW KAZUNORI SASAKI, and MARINE MARTA ALTUNYAN) ACCUSATION				

1	5.	Revoking or suspending	ng Registered Pharmacist License Number RPH 68915, issued		
2	to Matthew Kazunori Sasaki;				
3	6.	6. Revoking or suspending Registered Pharmacist License Number RPH 75760, issued			
4	to Marine I	to Marine Marta Altunyan;			
5	7. Ordering The Regents of the University of California, dba Santa Monica - UCLA				
6	Medical Center & Orthopedic Hospital, The Regents of the University of California, dba Santa				
7	Monica - UCLA Medical Center & Orthopedic Hospital IVAS, Matthew Kazunori Sasaki, and				
8	Marine Marta Altunyan to pay the Board of Pharmacy the reasonable costs of the investigation				
9	and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,				
10	8.	Taking such other and	further action as deemed necessary and proper.		
11					
12	DATED:	9/23/2020	Signature on File ANNE SODERGREN		
13			Executive Officer Board of Pharmacy		
14			Department of Consumer Affairs State of California		
15			Complainant		
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	(THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, MATTHEW KAZUNORI SASAKI, and MARINE MARTA ALTUNYAN) ACCUSATION				