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

In the Matter of the Accusation Against:

LIHUE PHARMACY INC., dba LIHUE PHARMACY INC.

KEVIN CRAIG GLICK, PRESIDENT, VICE-PRESIDENT, SECRETARY,

DIRECTOR, PHARMACIST-IN-CHARGE,

ENNY ROHSA GLICK, TREASURER/CHIEF FINANCIAL OFFICER,

Nonresident Pharmacy Permit No. NRP 2040

Nonresident Sterile Compounding Permit No NSC 101126; and

KEVIN CRAIG GLICK,

Pharmacist License No. RPH 38132,

Respondents.

Agency Case No. 7843

OAH No. 2024110106

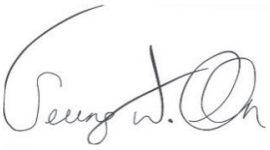
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval and Stipulated Settlement for Surrender are 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 June 27, 2025.

It is so ORDERED on May 28, 2025.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
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KAREN R. DENVIR
Supervising Deputy Attorney General
KATELYN E. DOCHERTY
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Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **LIHUE PHARMACY INC.,** **DBA LIHUE PHARMACY INC.** **KEVIN CRAIG GLICK, PRESIDENT, VICE-PRESIDENT, SECRETARY, DIRECTOR, PHARMACIST-IN-CHARGE,** **ENNY ROHSA GLICK, TREASURER/CHIEF FINANCIAL OFFICER** **4491 A Kolopa St.,** **Room A, Room B** **Lihue, HI 96766** **Nonresident Pharmacy Permit No. NRP 2040** **Nonresident Sterile Compounding Permit No. NSC 101126** **KEVIN CRAIG GLICK** **4490 Kolopa St.,** **Room B** **Lihue, HI 96766** **Pharmacist License Number 38132** Respondents.	Case No. 7843 OAH No. 2024110106 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL OF NRP 2040** **STIPULATED SETTLEMENT FOR SURRENDER OF NSC 101126** **(STIPULATED SETTLEMENT AS TO RESPONDENT LIHUE PHARMACY INC. ONLY)** **[Bus. & Prof. Code § 495]**

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

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Katelyn E. Docherty, Deputy Attorney General.

2. Respondent Lihue Pharmacy Inc., Lihue Pharmacy Inc. (Respondent Lihue) is represented in this proceeding by attorney Tony J. Park, whose address is: 9090 Irvine Center Drive, Irvine, CA 92618-4658.

JURISDICTION

3. On or about October 11, 2018, the Board of Pharmacy issued Nonresident Permit Number NRP 2040 to Respondent Lihue; with Kevin Craig Glick, President, 100% Shareholder, Vice-President, Secretary, Director, and Pharmacist-in-charge, Enny Rohsa Glick, Treasurer/Chief Financial Officer. The Nonresident Pharmacy Permit will expire on October 1, 2025, unless renewed.

4. On or about October 11, 2018, the Board of Pharmacy issued Nonresident Sterile Compounding Permit Number NSC 101126 to Respondent Lihue. The Nonresident Sterile Compounding Permit expired on October 1, 2023, and was cancelled on February 9, 2024.

5. On or about September 20, 1983, the Board of Pharmacy issued Pharmacist License number RPH 38132 to Kevin Craig Glick (Respondent Glick). The pharmacist license will expire on December 31, 2026, unless renewed.

6. Accusation No. 7843 was filed before the Board of Pharmacy (Board), for the Department of Consumer Affairs and is currently pending against Respondents. The Accusation and all other statutorily required documents were properly served on Respondent on October 7, 2024. Respondents timely filed their Notice of Defense contesting the Accusation. A copy of Accusation No. 7843 is attached as exhibit A and incorporated herein by reference.

///

ADVISEMENT AND WAIVERS

7. Respondent Lihue has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7843. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval and Surrender.

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

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

CULPABILITY

10. Respondent Lihue admits the truth of each and every charge and allegation in Accusation No. 7843.

11. Respondent Lihue agrees that its Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit are subject to discipline and agrees to be bound by the Disciplinary Order below.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent Lihue understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent Lihue or its counsel. By signing the stipulation, Respondent Lihue understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order

for Public Reproval and Surrender shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

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

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

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Nonresident Sterile Compounding Permit No. NRP 2040 issued to Respondent L Lihue Pharmacy Inc. doing business as (dba) Lihue Pharmacy Inc, shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 7843, attached as exhibit A.

Cost Recovery. Respondent Lihue and Respondent Glick shall be jointly and severally liable to reimburse the Board investigation and enforcement costs in the amount of $22,511.25. No later than one (1) year from the effective date of the Decision, Respondents shall pay a total of $22,511.25 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondents fail to pay the Board costs as ordered, Respondent Lihue shall not be allowed to renew its Nonresident

Pharmacy Permit until the costs are paid in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 7843, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Nonresident Pharmacy Permit No. NRP 2040.

IT IS FURTHER ORDERED that Nonresident Sterile Compounding Permit No. NSC 101126, issued to Respondent Lihue Pharmacy Inc. doing business as (dba) Lihue Pharmacy Inc, is surrendered and accepted by the Board.

1. The surrender of Respondent Lihue's Nonresident Sterile Compounding Permit (NSC) and the acceptance of the surrendered license by the Board shall constitute the imposition of discipline against Respondent Lihue. This decision constitutes a record of discipline and shall become a part of Respondent Lihue's license history with the Board. Respondent Lihue understands and agrees that for purposes of Business and Professions Code section 4307, this surrender shall be treated as if their license was revoked.

2. Respondent Lihue may only seek a new or reinstated NSC license from the Board by way of a new application for licensure. Respondent Lihue shall not be eligible to petition for reinstatement of licensure.

3. Respondent Lihue may not reapply for any license from the Board for three (3) years from the effective date of this decision. Respondent Lihue stipulates that should they apply for any license from the Board on or after the effective date of this decision, all allegations set forth in the accusation shall be deemed to be true, correct and admitted by respondent when the Board determines whether to grant or deny the application. Respondent Lihue shall satisfy all requirements applicable to that license as of the date the application is submitted to the Board. Respondent Lihue is required to report this surrender as disciplinary action.

4. As stated in the cost recovery paragraph above, Respondent Lihue and Respondent Glick shall be jointly and severally liable to reimburse the Board investigation and enforcement costs in the amount of $22,511.25.

ACCEPTANCE

I, Kevin Craig Glick, am President, Vice-President, Secretary, Director, and Pharmacist-in-charge for Lihue Pharmacy Inc., dba Lihue Pharmacy Inc., and I am authorized to sign this Stipulated Settlement and Disciplinary Order on behalf of Lihue Pharmacy Inc., dba Lihue Pharmacy Inc. I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and Surrender and have fully discussed it with our attorney, Tony J. Park. I understand the stipulation and the effect it will have on our Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval of the Nonresident Pharmacy Permit and Surrender of the Nonresident Sterile Compounding Permit voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

Kevin Craig Glick
LIHUE PHARMACY INC., DBA LIHUE PHARMACY INC.
Respondent

I have read and fully discussed with Respondent Lihue Pharmacy Inc., dba Lihue Pharmacy Inc. the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval and Surrender. I approve its form and content.

DATED: _____

TONY J. PARK
Attorney for Respondent

4. As stated in the cost recovery paragraph above, Respondent Lihue and Respondent Glick shall be jointly and severally liable to reimburse the Board investigation and enforcement costs in the amount of $22,511.25.

ACCEPTANCE

I, Kevin Craig Glick, am President, Vice-President, Secretary, Director, and Pharmacist-in-charge for Lihue Pharmacy Inc., dba Lihue Pharmacy Inc., and I am authorized to sign this Stipulated Settlement and Disciplinary Order on behalf of Lihue Pharmacy Inc., dba Lihue Pharmacy Inc. I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and Surrender and have fully discussed it with our attorney, Tony J. Park. I understand the stipulation and the effect it will have on our Nonresident Pharmacy Permit and Nonresident Sterile Compounding Permit. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval of the Nonresident Pharmacy Permit and Surrender of the Nonresident Sterile Compounding Permit voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 4/16/2025

Signed by: Kevin Glick E775FFA662B64F7...

Kevin Craig Glick
LIHUE PHARMACY INC., DBA LIHUE PHARMACY INC.
Respondent

I have read and fully discussed with Respondent Lihue Pharmacy Inc., dba Lihue Pharmacy Inc. the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval and Surrender. I approve its form and content.

DATED: 4/16/2025

Signed by: Tony Park BBF9CC7A091B410...

TONY J. PARK
Attorney for Respondent

ENDORSEMENT

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

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
KAREN R. DENVIR
Supervising Deputy Attorney General

KATELYN E. DOCHERTY
Deputy Attorney General
Attorneys for Complainant

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ENDORSEMENT

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

DATED: 04/17/2025

Respectfully submitted,

ROB BONTA
Attorney General of California
KAREN R. DENVIR
Supervising Deputy Attorney General

KATELYN E. DOCHERTY
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 7843

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Supervising Deputy Attorney General
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Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **LIHUE PHARMACY INC.,** **DBA LIHUE PHARMACY INC.** **KEVIN CRAIG GLICK, PRESIDENT, VICE-PRESIDENT, SECRETARY, DIRECTOR, PHARMACIST-IN-CHARGE;** **ENNY ROHSA GLICK, TREASURER/CHIEF FINANCIAL OFFICER** **4491 A Kolopa St.,** **Room A, Room B** **Lihue, HI 96766** **Nonresident Pharmacy Permit No. NRP 2040** **Nonresident Sterile Compounding Permit No. NSC 101126** **KEVIN CRAIG GLICK** **4490 Kolopa St.,** **Room B** **Lihue, HI 96766** **Pharmacist License Number 38132** Respondents.	Case No. 7843 **ACCUSATION**

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PARTIES

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

2. On or about October 11, 2018, the Board of Pharmacy issued Nonresident Permit Number NRP 2040 to Lihue Pharmacy Inc. doing business as (dba) Lihue Pharmacy Inc (Respondent Lihue); with Kevin Craig Glick, President, 100% Shareholder, Vice-President, Secretary, Director, and Pharmacist-in-charge; Enny Rohsa Glick, Treasurer/Chief Financial Officer. The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and expire on October 1, 2024, unless renewed.

3. On or about October 11, 2018, the Board of Pharmacy issued Nonresident Sterile Compounding Permit Number NSC 101126 to Respondent Lihue. The Nonresident Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and expired on October 1, 2023, and was cancelled on February 9, 2024.

4. On or about September 20, 1983, the Board of Pharmacy issued Pharmacist License number RPH 38132 to Kevin Craig Glick (Respondent Glick). The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on December 31, 2024, unless renewed.

JURISDICTION

5. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

6. Section 4011 of the Code states:

The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).

7. 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.

8. Section 4302 of the Code states:

> The board may deny, suspend, or revoke any license where conditions exist in relation to any person holding 10 percent or more of the ownership interest or where conditions exist in relation to any officer, director, or other person with management or control of the license that would constitute grounds for disciplinary action against a licensee.

9. Section 4303 of the Code states, in pertinent part:

(b) The board may cancel, deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy, provided that the grounds for the action are also grounds for action in the state in which the nonresident pharmacy is permanently located.

10. Section 4342 of the Code states, in pertinent part:

> (a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with section 109875) of Division 104 of the Health & Safety Code).

STATUTORY PROVISIONS

11. Section 4113 of the Code states in pertinent part:

…

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

…

12. Section 4169 of the Code states in pertinent part:

(a) A person or entity shall not do any of the following:

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

(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…

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

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

…

(b) Incompetence.

(c) Gross negligence.

…

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

…

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

14. Section 4306.5 of the Code states in pertinent 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.

…

15. Section 4307 of the Code states in pertinent part:

(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.

…

HEALTH AND SAFETY CODE

16. Health and Safety Code section 111250 states:

Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

17. Health and Safety Code section 111255 states:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

18. Health and Safety Code section 111295 states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

19. Health and Safety Code section 111330 states:

Any drug or device is misbranded if its labeling is false or misleading in any particular.

20. Health and Safety Code section 111335 states:

Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

21. Health and Safety Code section 111440 states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

22. Health and Safety Code section 111445 states:

It is unlawful for any person to misbrand any drug or device.

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REGULATORY PROVISIONS

23. California Code of Regulations, title 16, (Regulations) section 1707.5 states in pertinent part:

> (a) Labels on drug containers dispensed to patients in California shall conform to the following format:
>
> (1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:
>
> (A) Name of the patient
>
> (B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the statement "generic for " where the brand name is inserted and the name of the manufacturer. In the professional judgment of the pharmacist:
>
> (i) If the brand name is no longer widely used, the label may list only the generic name of the drug, and
>
> (ii) The manufacturer's name may be listed outside of the patient-centered area.
>
> (C) The directions for the use of the drug.
>
> (D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.
>
> (2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).
>
> (3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.
>
> (4) When applicable, directions for use shall use one of the following phrases:
>
> (A) Take 1 [insert appropriate dosage form] at bedtime
>
> (B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and l [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take ___ [insert appropriate dosage form] at a time. Wait at least ___ hours before taking again. Do not take more than ___ [appropriate dosage form] in one day

24. Regulations section 1717 states in pertinent part:

…

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart orders as defined in section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.…

25. Regulations section 1735.2 states, in pertinent part:

…

(d) No pharmacy or pharmacist shall compound a drug preparation that:

…

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

…

(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.

…

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

…

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

…

26. Regulations section 1751.3 states, in pertinent part:

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

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

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable)

(9) Facility management including certification and maintenance of controlled environments and related equipment.

(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

(11) Hand hygiene and garbing.

(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

(14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

(16) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(18) Proper use of equipment and supplies.

(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

(20) Record keeping requirements.

(21) Temperature monitoring in compounding and controlled storage areas.

(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

(23) Use of automated compounding devices (if applicable).

(24) Visual inspection and other final quality checks of sterile drug preparations.

27. Regulations section 1751.4 states:

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

…

(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section of Title 161751.8 of Title 16, Division 17, of the California Code of Regulations.

…

28. Regulations section 1751.7 states in pertinent part:

…

(b)

(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.

HAWAII ADMINISTRATIVE RULES

29. Hawaii Administrative Rules (HAR), chapter 95, subchapter 13, section 16-95-110 states in pertinent part:

(a) In addition to any other acts or conditions provided by law, the board may revoke, suspend, refuse to renew or restore, deny, or condition a license or permit for any one or more of the following acts or omissions:

…

(12) Violation of any state or federal law, including violation of a drug, controlled substance, or poison law;

…

(17) Failure to comply with the pharmaceutical compounding requirements found in chapters 795 (nonsterile preparations) and 797 (sterile preparations) of the United States Pharmacopeia National Formulary, as amended;

…

COST RECOVERY

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

INTRODUCTION

31. This case is about the compounding of prescription drugs, including those designated for sterile administration, in a pharmacy. Pharmacy compounding is when a licensed pharmacist combines, mixes, or alters drug ingredients to create a medication tailored to the needs of an individual patient. (See e.g., Cal. Code Regs., tit. 16, § 1735.)

32. Compounding is a form of drug manufacturing subject to the drug manufacturing requirements of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 301 et seq.]. Compounding in a pharmacy as a form of drug manufacturing is permitted under federal law by section 503A of the FDCA [21 U.S.C. § 353a].

33. The Food and Drug Administration (FDA) oversees drug manufacturing, but does not license pharmacies or pharmacists, nor control when or how their licenses permit compounding. The states issue these licenses and have primary jurisdiction. The states also set compounding standards that complement FDA standards for compounding as a form of drug manufacturing.

34. California law authorizes the Board to treat violations of federal statutes regulating controlled substances and dangerous drugs, as well as federal laws and regulations governing pharmacy practice, as grounds for discipline. (Bus. & Prof. Code §§ 4301, subds. (j), (o); 4342.)

35. Among the federal law requirements for pharmacy compounding is that bulk drug substances used for compounding: (1) must comply with the standards of an applicable United

States Pharmacopeia (USP)[1] or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, must be components of drugs already otherwise approved by the Secretary; or (3) if such a monograph does not exist and the substance is not a component of a drug approved by the Secretary, must appear on a list promulgated in regulation by the Secretary. (21 U.S.C. § 353a(b)(1)(A)(i).) Each bulk drug substance must also be manufactured by an FDA registrant, and be accompanied by a valid certificate of analysis from the manufacturer. (21 U.S.C. § 353a(b)(1)(A)(ii) and (iii).)

36. Under both federal and California law, *any* manufactured drug, including a pharmacy compound, must be deemed to be "misbranded" if its "labeling or packaging does not conform to the requirements of Chapter 4" *or* its "labeling is false or misleading in any particular." (21 U.S.C. § 352(a)(1) and (b) [definitions of "misbranded"]; Health & Saf. Code, §§ 111330, 111335 [definitions of "misbranded"]; Health & Saf. Code, § 111445 [misbranded drug prohibition].)

37. Compounds may be either "non-sterile" or "sterile," depending on the intended route of drug administration. Sterile drugs are those intended for parenteral administration (i.e., other than through the digestive system), including injectables and ophthalmic or inhalation drugs in aqueous format. It is important that these drugs be sterile and uncontaminated, because they bypass some of the body's natural defenses against pathogens and impurities.

38. California law allows all licensed pharmacists to compound *non-sterile* drug products in licensed pharmacies. (See e.g., Bus. & Prof. Code, §§ 4037, 4051, 4110.)

39. An additional specialty license is required before any licensed pharmacy is allowed to compound *sterile* drug products. (Bus. & Prof. Code, § 4127 *et seq*.) And particular regulatory requirements apply to preparation, maintenance, and distribution of sterile drug products. (Cal. Code Regs., tit. 16, § 1751 *et seq.*; see also Cal. Code Regs., tit. 16, § 1735 *et seq*.)

40. All compounding, whether sterile or non-sterile, must be consistent with standards

[1] The USP was recently updated, so there is a 2008 version and a 2023 version. All references in this document are to the 2008 version.

in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary (USP-NF), including relevant testing and quality assurance standards. (Bus. & Prof. Code, § 4126.8.) The Pharmacy Law also contains additional standards that supplement the USP-NF standards. (*Id.*; see, e.g., Bus. & Prof. Code, §§ 4126.10, 4127 *et seq*., 4128 *et seq*., 4129 *et seq*., Cal. Code Regs., tit. 16, §§ 1735 *et seq*., 1751 *et seq*.)

41. Each sterile compounding pharmacy must be inspected prior to each annual renewal of a sterile compounding license to ensure compliance with all compounding and sterile compounding requirements. (Bus. & Prof. Code, § 4127.1, subd. (c).) Out-of-state sterile compounding pharmacies must also have this specialty license, and are also annually inspected. (Bus. & Prof. Code, § 4127.2, subd. (c).) All of this demonstrates the attention and resources devoted to sterile drug compounding. This is because of the unique risks posed by sterile drug products. In 2012, for instance, a contaminated sterile drug compound was widely distributed, and caused a nationwide fungal meningitis outbreak, killing 64 people and causing infections in almost 800 others who received the drug.

FACTUAL ALLEGATIONS

42. Respondent Lihue owns and operates a pharmacy in the State of Hawaii, which is licensed as a nonresident pharmacy by the Board. A nonresident pharmacy license allows Respondent Lihue to ship non-sterile drug preparations into California for use by California consumers. Respondent Lihue also applied for and was granted a nonresident sterile compounding pharmacy permit which allowed them to ship sterile compounded drug products into California for use by California consumers. Respondent Glick is the pharmacist-in-charge for Respondent Lihue.

43. On or around May 15, 2023, Board Inspector AP, started the nonresident sterile compounding license renewal inspection for Respondent Lihue. During the Board's inspection process Inspector AP discovered the following:

44. On or around March 22, 2023, Advance Testing and Certification Controlled Environment Specialists (ATCCES) performed a certification of Respondent Lihue's cleanroom. However, a HEPA filter leak test was not performed by ATCCES at the time of certification. The

last time the HEPA filters passed a leak test was on or around March of 2021.

45. Inspector AP reviewed Respondent Lihue's dispense logs for the period of April 1, 2021 through June 19, 2023, and discovered that 2,628 non-sterile to sterile preparations were compounded without a compliant cleanroom due to failure to perform the required leak testing on HEPA filters and were furnished to California patients.

46. Respondent Lihue dispensed 42 prescriptions which equaled 630 mls of misbranded atropine 0.01%, lot #ATR-01-111122, to California patients on and between November 14, 2022, through January 9, 2023. Below is a table of all the misbranded atropine 0.01% that was furnished to California patients between November 11, 2022, to January 9, 2023:

DATE DISPENSED	PRESCRIPTION NUMBER	QUANTITY (ML)	BEYOND USE DATE
11/14/22	14610150-00	15	5/10/23
11/14/22	1461091-00	15	5/10/23
11/14/22	1461286-00	15	5/10/23
11/14/22	1461126-00	15	5/10/23
11/15/22	1451402-01	15	5/9/23
11/15/22	1460190-00	15	5/9/23
11/21/22	1449903-2	15	5/9/23
11/21/22	1453012-01	15	5/9/23
11/21/22	1460752-00	15	5/9/23
11/21/22	1461549-00	15	5/9/23
11/24/22	1462030-00	15	5/9/23
11/28/22	1450638-01	15	5/9/23
11/28/22	1453462-01	15	5/9/23
11/28/22	1456810-01	15	5/9/23
11/28/22	1462098-00	15	5/9/23
11/30/22	1454716-01	15	5/9/23
12/5/22	1450999-02	15	5/9/23
12/5/22	1451746-03	15	5/9/23
12/5/22	1462537-00	15	5/9/23
12/5/22	1462538-00	15	5/9/23
12/5/22	1462539-00	15	5/9/23
12/5/22	1462540-00	15	5/9/23
12/12/22	1450639-02	15	5/9/23
12/12/22	1463272-00	15	5/9/23
12/19/22	1450642-00	15	5/9/23
12/19/22	1450643-02	15	5/9/23
12/19/22	1451423-01	15	5/9/23
12/19/22	1451590-02	15	5/9/23
12/19/22	1453952-02	15	5/9/23
12/19/22	1462638-00	15	5/9/23
12/19/22	1463823-00	15	5/9/23
12/26/22	1451886-01	15	5/9/23
12/26/22	1456146-00	15	5/9/23

12/26/22	1457014-01	15	5/9/23
12/26/22	1461443-00	15	5/9/23
12/28/22	1451423-03	15	5/9/23
12/28/22	1451423-02	15	3/27/23
12/28/22	1454716-02	15	5/9/23
1/3/23	1464647-00	15	5/9/23
1/9/23	1450942-02	15	5/9/23
1/9/23	1450640-02	15	5/9/23
1/9/23	1456457-01	15	5/9/23
TOTAL	**42 PRESCRIPTIONS**	**630 MLS**	

47. The records for "C-Cyclosporin 0.03% Emulsion," lot #CYC-03-040423-PL, compounded on April 4, 2023 revealed that Respondent Lihue pharmacy had assigned a beyond use date of May 19, 2023. However, the compounded drug contained the ingredient "C-Cyclosporin 0.5% Stock Soln," lot #CYC05-110722AH, with an expiration date of December 22, 2022. Upon further review the records for "C-Cyclosporin 0.5% Stock Soln," showed that it was compounded on November 7, 2022 and contained "S-CASTOR OIL USP LIQD," lot #C200338, which had an expiration date of December 31, 2022. The BUD of the cyclosporine stock solution prepared on November 7, 2022, and used as an ingredient in the cyclosporine 0.03% emulsion, exceeded the BUD of the finished preparation. In addition, one ingredient of the cyclosporine stock solution, castor oil, also exceeded the BUD of the finished preparation.

48. Prescription records for RX#1464984-02 for patient PL written on December 30, 2022, for "C-Cyclosporine 0.03% E" contained no identification/initials of the pharmacist who received the prescription order, and the prescription label included a dispense date of April 4, 2023, and stated to "Discard After: 05/19/2023."

49. In a review of the prescription labels provided by Respondent Lihue pharmacy it was discovered that the below prescriptions did not contain the patient name, name and strength of the drug and directions for use in the proper order.

a) RX #1454716-03, C-Atropine 0.01% BUD 1000, dispensed on 5/22/23

b) RX #1478509-00, C-Atropine 0.05% BUD 1000, dispensed on 5/15/23

c) RX #1464984-02, C-Cyclosporin 0.03% Emulsion, dispensed on 4/4/23

d) RX #1472082-00, C-Gabapentin 0.5% Opth Soln, LPG dispensed on 3/17/23

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Respondent Lihue

FIRST CAUSE FOR DISCIPLINE

(Assignment of Unsupported Extended Beyond Use Dates)

50. Respondent Lihue is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondent Lihue violated Regulations section 1735.2, subdivision (i). The circumstances are as follows:

a. On or about November 11, 2022, Respondent Lihue compounded and on and between November 11, 2022 to January 9, 2023, and shipped at least forty-two prescriptions to California, of atropine 0.01% ophthalmic solution (lot # ATR-01-111122), and assigned a beyond use date which exceeded the expiration date or beyond used date of any ingredient in the compounded drug preparation, as set forth in paragraph 46, above.

b. On or about April 4, 2023, Respondent Lihue compounded, and shipped to California, C-Cyclosporin 0.03% Emulsion (lot #CYC-03-040423-PL) that Respondent Lihue had assigned a beyond use date which exceeded the expiration date or beyond used date of any ingredient in the compounded drug preparation, as set forth in paragraph 47, above.

SECOND CAUSE FOR DISCIPLINE

(Failure to have a Compliant Compounding Environment)

51. Respondent Lihue is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs by violating Regulations section 1751.4, subdivision (a) and (f) by compounding, selling, and dispensing drugs without certification and testing of primary and secondary engineering controls no less than every six months, and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed. The circumstances are that Respondent Lihue compounded, dispensed and sold at least 2,628 non-sterile to sterile compounded preparations to California patients which were compounded without a compliant compounding environment, as required leak testing of

HEPA filters in the cleanroom had not been performed since March of 2021, as set forth in paragraphs 42-49, above.

THIRD CAUSE FOR DISCIPLINE

(Misbranded Drugs)

52. Respondent Lihue is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs by violating Code section 4169, subdivision (a), and Health and Safety Code sections 111330, 11335, 111440, 111445 by compounding, selling, and dispensing misbranded drugs. The circumstances are that Respondent Lihue compounded, dispensed and sold cyclosporine 0.03% ophthalmic emulsion and atropine 0.01% ophthalmic solution, sterile compounded drugs to California patients which were compounded with at least one component that expired before the assigned beyond use date and therefore were or could have been misbranded as set forth in paragraph 42-49, above.

FORTH CAUSE FOR DISCIPLINE

(Failure to Follow Policies and Procedures)

53. Respondent Lihue is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs by violating Regulations section 1751.3, subdivision (a) by Respondent Lihue failing to follow its own policies and procedures. The circumstances are follows:

a) Respondent Lihue violated their Policy 53 (Compounding Room Environment), when they failed to perform leak testing of the HEPA filters during biannual certification. On or around May of 2023, Respondent Lihue informed Board Inspector AP, that the last testing of the HEPA filters occurred in March of 2021.

b.) Respondent Lihue violated Standard Operating Procedure ("SOP') number 1028 (Air Quality Checks), when Respondent Lihue failed to perform "air quality checks" as required. The SOP stated that "air quality checks" were to be performed monthly for compounding areas used for low-risk and medium-risk preparations, and weekly for areas used for high-risk preparations.

c.) Respondent Lihue violated SOP number 1006 (Work-Surface Sampling), when Respondent Lihue failed to perform surface sampling of pass-thru every six months. On or about December 21, 2023, Respondent Lihue provided Board inspector AP with the results for their last sampling which occurred on March 3, 2023.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Initial Orally Transmitted Prescription)

54. Respondent Lihue is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs by violating Regulations section 1717, subdivision (c), by failing to have the receiving pharmacist initial an orally transmitted prescription for a patient, as set forth in paragraph 48, above.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Conform to Label Requirements)

55. Respondent Lihue is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs by violating Regulations section 1707.5, subdivision (a), by dispensing at least four prescriptions to California patients in drug containers which were affixed with noncompliant labels, as set forth in paragraph 49, above.

SEVENTH CAUSE FOR DISCIPLINE

(Incompetence)

56. Respondent Lihue is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (b), (j) and (o), in that Respondent Lihue committed incompetence when it assigned beyond use dates to sterile preparations which exceeded the expiration date of non-sterile components of those preparations as set forth in paragraphs 42-55, above.

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EIGHTH CAUSE FOR DISCIPLINE

(Gross Negligence)

57. Respondent Lihue is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (c), (j) and (o), in that Respondent Lihue committed gross negligence when it uses a non-compliant clean room for over two years to compound high risk sterile preparations, and assigned beyond use dates to sterile preparations which exceeded the expiration date of non-sterile components of those preparations as set forth in paragraphs 42-55, above.

Respondent Glick

Respondent Glick was pharmacist-in-charge of Respondent Lihue at all relevant times. Respondent Glick is therefore responsible under Code section 4113(c) for Respondent Lihue's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

NINTH CAUSE FOR DISCIPLINE

(Assignment of Unsupported Extended Beyond Use Dates)

58. Respondent Glick is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), as a pharmacist-in-charge, for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs in that Respondent Glick violated Regulations section 1735.2, subdivision (i). The circumstances are as follows:

a. On or about November 11, 2022, Respondent Lihue compounded and on and between November 11, 2022 to January 9, 2023, and shipped at least forty-two prescriptions to California, of atropine 0.01% ophthalmic solution (lot # ATR-01-111122), and assigned a beyond use date which exceeded the expiration date or beyond used date of any ingredient in the compounded drug preparation, as set forth in paragraph 46, above.

b. On or about April 4, 2023, Respondent Lihue compounded, and shipped to California, C-Cyclosporin 0.03% Emulsion (lot #CYC-03-040423-PL) that Respondent Lihue had assigned a beyond use date which exceeded the expiration date or beyond used date of any ingredient in the compounded drug preparation, as set forth in paragraph 47, above.

TENTH CAUSE FOR DISCIPLINE

(Failure to have a Compliant Compounding Environment)

59. Respondent Glick is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), as a pharmacist-in-charge, for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs by violating Regulations section 1751.4, subdivision (a) and (f) by compounding, selling, and dispensing drugs without certification and testing of primary and secondary engineering controls no less than every six months, and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed. The circumstances are that while Respondent Glick was pharmacist-in-charge for Respondent Lihue, he allowed Respondent Lihue to compound, dispense and sell at least 2,628 non-sterile to sterile compounded preparations to California patients which were compounded without a compliant compounding environment, as required leak testing of HEPA filters in the cleanroom had not been performed since March of 2021, as set forth in paragraphs 42-49, above.

ELEVENTH CAUSE FOR DISCIPLINE

(Misbranded Drugs)

60. Respondent Glick is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), as pharmacist-in-charge, for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs by violating Code section 4169, subdivision (a), and Health and Safety Code sections 111330, 11335, 111440, 111445 by compounding, selling, and dispensing misbranded drugs. The circumstances are that Respondent Lihue compounded, dispensed and sold cyclosporine 0.03% ophthalmic emulsion and atropine 0.01% ophthalmic solution, sterile compounded drugs to California patients which were compounded with at least one component that expired before the assigned beyond use date and therefore were or could have been misbranded, while Respondent Glick was pharmacist-in-charge, as set forth in paragraph 42-49, above.

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TWELFTH CAUSE FOR DISCIPLINE

(Failure to Follow Policies and Procedures)

61. Respondent Glick is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), as a pharmacist-in-charge, for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs by violating Regulations section 1751.3, subdivision (a) by Respondent Glick failing to follow Respondent Lihue's policies and procedures. The circumstances are follows:

a) Respondent Glick violated their Policy 53 (Compounding Room Environment), when Respondent Glick failed to ensure that Respondent Lihue preformed leak testing of the HEPA filters during biannual certification. On or around May of 2023, Respondent Lihue informed Board Inspector AP, that the last testing of the HEPA filters occurred in March of 2021.

b.) Respondent Glick violated Standard Operating Procedure ("SOP') number 1028 (Air Quality Checks), when Respondent Glick failed to ensure Respondent Lihue preformed "air quality checks" as required. The SOP stated that "air quality checks" were to be performed monthly for compounding areas used for low-risk and medium-risk preparations, and weekly for areas used for high-risk preparations.

c.) Respondent Glick violated SOP number 1006 (Work-Surface Sampling), when Respondent Glick failed to ensure Respondent Lihue performed surface sampling of pass-thru every six months. On or about December 21, 2023, Respondent Lihue provided Board inspector AP with the results for their last sampling which occurred on March 3, 2023.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Initial Orally transmitted prescription)

62. Respondent Glick is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), as a pharmacist-in-charge, for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs by violating Regulations section 1717, subdivision (c), by failing to have the receiving pharmacist initial an orally transmitted prescription for a patient, as set forth in paragraph 48, above.

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FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Conform to Label Requirements)

63. Respondent Glick is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), as a pharmacist-in-charge, for failing to follow laws and regulations governing pharmacy and regulating dangerous drugs by violating Regulations section 1707.5, subdivision (a), by allowing Respondent Lihue to dispense at least four prescriptions to California patients in drug containers which were affixed with noncompliant labels, as set forth in paragraph 49, above.

FIFTEENTH CAUSE FOR DISCIPLINE

(Incompetence)

64. Respondent Glick is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (b), (j) and (o), as a pharmacist-in-charge, in that Respondent Glick committed incompetence when he allowed Respondent Lihue to assign beyond use dates to sterile preparations which exceeded the expiration date of non-sterile components of those preparations as set forth in paragraphs 42-63, above.

SIXTEENTH CAUSE FOR DISCIPLINE

(Gross Negligence)

65. Respondent Glick is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (c), (j) and (o), as a pharmacist-in-charge, in that Respondent Glick committed gross negligence when he allowed Respondent Lihue to use a non-compliant clean room for over two years to compound high risk sterile preparations, and assigned beyond use dates to sterile preparations which exceeded the expiration date of non-sterile components of those preparations as set forth in paragraphs 42-63, above.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Inappropriate Use of Education, Training, and Experience)

66. Respondent Glick is subject to disciplinary action for unprofessional conduct pursuant to Code sections 4301, subdivision (o), and 4306.5, subdivision (a), as a pharmacist-in-charge, in that Respondent Glick inappropriately exercised his education, training, and experience

as a pharmacist when he allowed Respondent Lihue to use a non-compliant clean room for over two years to compound high risk sterile preparations, when he failed to follow policies and procedures related to certification and environmental monitoring of the cleanroom, when he allowed Respondent Lihue assigned beyond use dates to sterile preparations which exceeded the expiration date of non-sterile components of those preparations, and when he delegated management of sterile compounding without proper oversight, as set forth in paragraphs 42-65, above.

OTHER MATTERS

67. Pursuant to Code section 4307, if discipline is imposed on Nonresident Pharmacy Permit Number NRP 2040 or on Nonresident Sterile Compounding Pharmacy Permit Number NSC 101126 issued to Lihue Pharmacy Inc; Kevin Craig Glick, president, vice-president, secretary, director, pharmacist-in-charge, and Enny Rohsa Glick, treasurer/chief financial officer, then Lihue Pharmacy Inc, Kevin Craig Glick, and Enny Rohsa Glick, shall each be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five years if either or both of the pharmacy permits are placed on probation; or, 2) if either or both of the pharmacy permits are revoked, the prohibition shall continue until either of the permits are reinstated.

68. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 38132 Kevin Craig Glick, then Lihue Pharmacy Inc, Kevin Craig Glick, and Enny Rohsa Glick, shall each be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five years if either or both of the pharmacy permits are placed on probation; or, 2) if either or both of the pharmacy permits are revoked, the prohibition shall continue until the license is reinstated.

PRAYER

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

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1. Revoking or suspending Nonresident Pharmacy Permit Number NRP 2040, issued to Lihue Pharmacy Inc; Kevin Craig Glick, president, vice-president, secretary, director, pharmacist-in-charge, and Enny Rohsa Glick, treasurer/chief financial officer;

2. Revoking or suspending Nonresident Sterile Compounding Permit Number NSC 101126, issued to Lihue Pharmacy Inc; Kevin Craig Glick, president, vice-president, secretary, director, pharmacist-in-charge, and Enny Rohsa Glick, treasurer/chief financial officer;

3. Revoking or suspending Pharmacist License Number RPH 38132, issued to Kevin Craig Glick;

4. Prohibiting Lihue Pharmacy Inc, from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

5. Prohibiting Kevin Craig Glick, from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

6. Prohibiting Enny Rosha Glick, from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any pharmacy licensee;

7. Ordering Lihue Pharmacy Inc. to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and, if placed on probation, the costs of probation monitoring;

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8. Ordering Kevin Craig Glick to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and, if placed on probation, the costs of probation monitoring; and,

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

DATED: 10/6/2024

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2024.10.06 15:07:26 -07'00'

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

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