

**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 Repeval 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 June 27, 2025.

It is so ORDERED on May 28, 2025.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

A handwritten signature in black ink, appearing to read "Seung W. Oh". The signature is written in a cursive style with a large initial "S" and "O".

Seung W. Oh, Pharm.D.
Board President

1 ROB BONTA
Attorney General of California
2 KAREN R. DENVER
Supervising Deputy Attorney General
3 KATELYN E. DOCHERTY
Deputy Attorney General
4 State Bar No. 322028
1300 I Street, Suite 125
5 P.O. Box 944255
Sacramento, CA 94244-2550
6 Telephone: (916) 210-6277
Facsimile: (916) 327-8643
7 E-mail: Katelyn.Docherty@doj.ca.gov
Attorneys for Complainant

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9 **BEFORE THE
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10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

12 In the Matter of the Accusation Against:

13 **LIHUE PHARMACY INC.,**
14 **DBA LIHUE PHARMACY INC.**
15 **KEVIN CRAIG GLICK, PRESIDENT,**
16 **VICE-PRESIDENT, SECRETARY,**
17 **DIRECTOR, PHARMACIST-IN-**
18 **CHARGE,**
19 **ENNY ROHSA GLICK,**
20 **TREASURER/CHIEF FINANCIAL**
21 **OFFICER**
22 **4491 A Kolopa St.,**
23 **Room A, Room B**
24 **Lihue, HI 96766**

25 **Nonresident Pharmacy Permit No. NRP**
26 **2040**
27 **Nonresident Sterile Compounding Permit**
28 **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 (AS TO RESPONDENT
KEVIN CRAIG GLICK ONLY)**

[Bus. & Prof. Code § 495]

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

3 **PARTIES**

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

8 2. Respondent Kevin Craig Glick (Respondent Glick) is represented in this proceeding
9 by attorney Tony J. Park, whose address is: 9090 Irvine Center Drive, Irvine, CA 92618-4658

10 **JURISDICTION**

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

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

19 5. On or about September 20, 1983, the Board of Pharmacy issued Pharmacist License
20 number RPH 38132 to Respondent Glick. The pharmacist license will expire on December 31,
21 2026, unless renewed.

22 6. Accusation No. 7843 was filed before the Board of Pharmacy (Board), for the
23 Department of Consumer Affairs and is currently pending against Respondents. The Accusation
24 and all other statutorily required documents were properly served on Respondents on October 7,
25 2024. Respondents timely filed their Notice of Defense contesting the Accusation. A copy of
26 Accusation No. 7843 is attached as exhibit A and incorporated herein by reference.

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1 **ADVISEMENT AND WAIVERS**

2 7. Respondent Glick has carefully read, fully discussed with counsel, and understands
3 the charges and allegations in Accusation No. 7843. Respondent Glick has also carefully read,
4 fully discussed with counsel, and understands the effects of this Stipulated Settlement and
5 Disciplinary Order for Public Repeval.

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

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

15 **CULPABILITY**

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

18 11. Respondent Glick agrees that his Pharmacist License is subject to discipline and
19 agrees to be bound by the Disciplinary Order below.

20 **CONTINGENCY**

21 12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent
22 Glick understands and agrees that counsel for Complainant and the staff of the Board of
23 Pharmacy may communicate directly with the Board regarding this stipulation and settlement,
24 without notice to or participation by Respondent Glick or his counsel. By signing the stipulation,
25 Respondent Glick understands and agrees that he may not withdraw his agreement or seek to
26 rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to
27 adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order
28 for Public Repeval shall be of no force or effect, except for this paragraph, it shall be

1 inadmissible in any legal action between the parties, and the Board shall not be disqualified from
2 further action by having considered this matter.

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

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

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

16 **DISCIPLINARY ORDER**

17 IT IS HEREBY ORDERED that Pharmacist License Number 38132 issued to Respondent
18 Kevin Graig Glick (Respondent Glick) shall be publicly reprovved by the Board of Pharmacy
19 under Business and Professions Code section 495 in resolution of Accusation No. 7843, attached
20 as exhibit A.

21 **Cost Recovery.** Respondent Glick and Respondent Lihue shall be jointly and severally
22 liable to reimburse the Board investigation and enforcement costs in the amount of \$22,511.25.
23 No later than one (1) year from the effective date of the Decision, Respondents shall pay a total of
24 \$22,511.25 to the Board for its costs associated with the investigation and enforcement of this
25 matter pursuant to Business and Professions Code Section 125.3. If Respondents fail to pay the
26 Board costs as ordered, Respondent Glick shall not be allowed to renew his Pharmacist License
27 until Respondents pay costs in full. In addition, the Board may enforce this order for payment of
28 its costs in any appropriate court, in addition to any other rights the Board may have.

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reapproval 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 Reapproval 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

1 ROB BONTA
Attorney General of California
2 KAREN R. DENVER
Supervising Deputy Attorney General
3 KATELYN E. DOCHERTY
Deputy Attorney General
4 State Bar No. 322028
1300 I Street, Suite 125
5 P.O. Box 944255
Sacramento, CA 94244-2550
6 Telephone: (916) 210-6277
Facsimile: (916) 327-8643
7 *Attorneys for Complainant*

8
9 **BEFORE THE**
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11 **STATE OF CALIFORNIA**

12 In the Matter of the Accusation Against:

Case No. 7843

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DBA LIHUE PHARMACY INC.
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15 **DIRECTOR, PHARMACIST-IN-**
CHARGE;
16 **ENNY ROHSA GLICK,**
TREASURER/CHIEF FINANCIAL
17 **OFFICER**
4491 A Kolopa St.,
18 **Room A, Room B**
Lihue, HI 96766

ACCUSATION

19 **Nonresident Pharmacy Permit No. NRP**
20 **2040**
Nonresident Sterile Compounding Permit
21 **No. NSC 101126**

22 **KEVIN CRAIG GLICK**
4490 Kolopa St.,
23 **Room B**
Lihue, HI 96766

24 **Pharmacist License Number 38132**

25 Respondents.

26
27 ///

28 ///

1 **PARTIES**

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

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

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

14 4. On or about September 20, 1983, the Board of Pharmacy issued Pharmacist License
15 number RPH 38132 to Kevin Craig Glick (Respondent Glick). The pharmacist license was in full
16 force and effect at all times relevant to the charges brought herein and will expire on December
17 31, 2024, unless renewed.

18 **JURISDICTION**

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

22 6. Section 4011 of the Code states:

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

25 7. Section 4300.1 of the Code states:

26 The expiration, cancellation, forfeiture, or suspension of a board-issued license
27 by operation of law or by order or decision of the board or a court of law, the
28 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

1 with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety
Code...

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

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

5 ...

6 (b) Incompetence.

7 (c) Gross negligence.

8 ...

9 (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.

10 ...

11 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
12 abetting the violation of or conspiring to violate any provision or term of this chapter
13 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 14. Section 4306.5 of the Code states in pertinent part:

15 Unprofessional conduct for a pharmacist may include any of the following:

16 (a) Acts or omissions that involve, in whole or in part, the inappropriate exercise
17 of his or her education, training, or experience as a pharmacist, whether or not the
18 act or omission arises in the course of the practice of pharmacy or the ownership,
19 management, administration, or operation of a pharmacy or other entity licensed
by the board.

20 ...

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

22 (a) Any person who has been denied a license or whose license has been revoked or is
23 under suspension, or who has failed to renew his or her license while it was under
24 suspension, or who has been a manager, administrator, owner, member, officer,
25 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
26 been denied or revoked, is under suspension or has been placed on probation, and
while acting as the manager, administrator, owner, member, officer, director,
27 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,
28 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

1 placed on probation, this prohibition shall remain in effect for a period not to
2 exceed five years.

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

5 ...

6 **HEALTH AND SAFETY CODE**

7 16. Health and Safety Code section 111250 states:

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

10 17. Health and Safety Code section 111255 states:

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

14 18. Health and Safety Code section 111295 states:

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

17 19. Health and Safety Code section 111330 states:

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

19 20. Health and Safety Code section 111335 states:

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

22 21. Health and Safety Code section 111440 states:

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

25 22. Health and Safety Code section 111445 states:

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

27 ///

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1 **REGULATORY PROVISIONS**

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

4 (a) Labels on drug containers dispensed to patients in California shall
conform to the following format:

5 (1) Each of the following items, and only these four items, shall be clustered
6 into one area of the label that comprises at least 50 percent of the label. Each item
7 shall be printed in at least a 12-point sans serif typeface, and listed in the following
order:

8 (A) Name of the patient

9 (B) Name of the drug and strength of the drug. For the purposes of this
10 section, "name of the drug" means either the manufacturer's trade name of the
11 drug, or the generic name and the statement "generic for " where the brand name is
12 inserted and the name of the manufacturer. In the professional judgment of the
pharmacist:

13 (i) If the brand name is no longer widely used, the label may list only the
generic name of the drug, and

14 (ii) The manufacturer's name may be listed outside of the patient-centered
15 area.

16 (C) The directions for the use of the drug.

17 (D) The condition or purpose for which the drug was prescribed if the
18 condition or purpose is indicated on the prescription.

19 (2) For added emphasis, the label shall also highlight in bold typeface or
20 color, or use blank space to set off the items listed in subdivision (a)(1).

21 (3) The remaining required elements for the label specified in section 4076
22 of the Business and Professions Code, as well as any other items of information
23 appearing on the label or the container, shall be printed so as not to interfere with
24 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.

25 (4) When applicable, directions for use shall use one of the following
26 phrases:

27 (A) Take 1 [insert appropriate dosage form] at bedtime

28 (B) Take 2 [insert appropriate dosage form] at bedtime

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(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 1 [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:

...

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

9
10 25. Regulations section 1735.2 states, in pertinent part:

11 ...

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

13 ...

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

22 ...

23 (g) The pharmacist performing or supervising compounding is responsible for
24 the integrity, potency, quality, and labeled strength of a compounded drug preparation
25 until the beyond use date indicated on the label, so long as label instructions for
26 storage and handling are followed after the preparation is dispensed.

27 ...

28 (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

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

5 ...

6 26. Regulations section 1751.3 states, in pertinent part:

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

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

15 (2) Airflow considerations and pressure differential monitoring.

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

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

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

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

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

24 (8) Depyrogenation of glassware (if applicable)

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

27 (10) For compounding aseptic isolators and compounding aseptic
28 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.

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

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

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

11 (18) Proper use of equipment and supplies.

12 (19) Quality assurance program compliant with sections 1711, 1735.8 and
13 1751.7.

14 (20) Record keeping requirements.

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

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

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

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

21 27. Regulations section 1751.4 states:

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

26 ...

27 (f) Pharmacies preparing sterile compounded preparations require the use of a
28 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.

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

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

9 ...

10 28. Regulations section 1751.7 states in pertinent part:

11 ...

12 (b)

13 (1) The pharmacy and each individual involved in the compounding of
14 sterile drug preparations must successfully demonstrate competency on aseptic
15 technique and aseptic area practices before being allowed to prepare sterile drug
16 preparations. The validation process shall be carried out in the same manner as
17 normal production, except that an appropriate microbiological growth medium is
18 used in place of the actual product used during sterile preparation. The validation
19 process shall be representative of the types of manipulations, products and batch
20 sizes the individual is expected to prepare and include a media-fill test. The
21 validation process shall be as complicated as the most complex manipulations
22 performed by staff and contain the same amount or greater amount of volume
23 transferred during the compounding process. The same personnel, procedures,
24 equipment, and materials must be used in the testing. Media used must have
25 demonstrated the ability to support and promote growth. Completed medium
26 samples must be incubated in a manner consistent with the manufacturer's
27 recommendations. If microbial growth is detected, then each individual's sterile
28 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;

1 ...
2 (17) Failure to comply with the pharmaceutical compounding requirements
3 found in chapters 795 (nonsterile preparations) and 797 (sterile preparations) of the
4 United States Pharmacopeia National Formulary, as amended;

5 **COST RECOVERY**

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

10 **INTRODUCTION**

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

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

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

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

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

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

8 36. Under both federal and California law, *any* manufactured drug, including a
9 pharmacy compound, must be deemed to be “misbranded” if its “labeling or packaging does not
10 conform to the requirements of Chapter 4” *or* its “labeling is false or misleading in any
11 particular.” (21 U.S.C. § 352(a)(1) and (b) [definitions of “misbranded”]; Health & Saf. Code, §§
12 111330, 111335 [definitions of “misbranded”]; Health & Saf. Code, § 111445 [misbranded drug
13 prohibition].)

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

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

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

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

27 _____
28 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.

1 in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-
2 National Formulary (USP-NF), including relevant testing and quality assurance standards. (Bus.
3 & Prof. Code, § 4126.8.) The Pharmacy Law also contains additional standards that supplement
4 the USP-NF standards. (*Id.*; see, e.g., Bus. & Prof. Code, §§ 4126.10, 4127 *et seq.*, 4128 *et seq.*,
5 4129 *et seq.*, Cal. Code Regs., tit. 16, §§ 1735 *et seq.*, 1751 *et seq.*)

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

15 **FACTUAL ALLEGATIONS**

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

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

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

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

2 45. Inspector AP reviewed Respondent Lihue's dispense logs for the period of April 1,
3 2021 through June 19, 2023, and discovered that 2,628 non-sterile to sterile preparations were
4 compounded without a compliant cleanroom due to failure to perform the required leak testing on
5 HEPA filters and were furnished to California patients.

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

10	DATE DISPENSED	PRESCRIPTION NUMBER	QUANTITY (ML)	BEYOND USE DATE
11	11/14/22	14610150-00	15	5/10/23
12	11/14/22	1461091-00	15	5/10/23
13	11/14/22	1461286-00	15	5/10/23
14	11/14/22	1461126-00	15	5/10/23
15	11/15/22	1451402-01	15	5/9/23
16	11/15/22	1460190-00	15	5/9/23
17	11/21/22	1449903-2	15	5/9/23
18	11/21/22	1453012-01	15	5/9/23
19	11/21/22	1460752-00	15	5/9/23
20	11/21/22	1461549-00	15	5/9/23
21	11/24/22	1462030-00	15	5/9/23
22	11/28/22	1450638-01	15	5/9/23
23	11/28/22	1453462-01	15	5/9/23
24	11/28/22	1456810-01	15	5/9/23
25	11/28/22	1462098-00	15	5/9/23
26	11/30/22	1454716-01	15	5/9/23
27	12/5/22	1450999-02	15	5/9/23
28	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

///

1 **Respondent Lihue**

2 **FIRST CAUSE FOR DISCIPLINE**

3 **(Assignment of Unsupported Extended Beyond Use Dates)**

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

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

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

17 **SECOND CAUSE FOR DISCIPLINE**

18 **(Failure to have a Compliant Compounding Environment)**

19 51. Respondent Lihue is subject to disciplinary action for unprofessional conduct
20 pursuant to Code section 4301, subdivisions (j) and (o), for failing to follow laws and regulations
21 governing pharmacy and regulating dangerous drugs by violating Regulations section 1751.4,
22 subdivision (a) and (f) by compounding, selling, and dispensing drugs without certification and
23 testing of primary and secondary engineering controls no less than every six months, and
24 whenever the device or area designated for compounding is relocated, altered or a service to the
25 facility is performed. The circumstances are that Respondent Lihue compounded, dispensed and
26 sold at least 2,628 non-sterile to sterile compounded preparations to California patients which
27 were compounded without a compliant compounding environment, as required leak testing of
28

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

3 **THIRD CAUSE FOR DISCIPLINE**

4 **(Misbranded Drugs)**

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

14 **FORTH CAUSE FOR DISCIPLINE**

15 **(Failure to Follow Policies and Procedures)**

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

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

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

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

5 **FIFTH CAUSE FOR DISCIPLINE**

6 **(Failure to Initial Orally Transmitted Prescription)**

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

12 **SIXTH CAUSE FOR DISCIPLINE**

13 **(Failure to Conform to Label Requirements)**

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

19 **SEVENTH CAUSE FOR DISCIPLINE**

20 **(Incompetence)**

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

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27 ///

28 ///

1 **EIGHTH CAUSE FOR DISCIPLINE**

2 **(Gross Negligence)**

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

9 **Respondent Glick**

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

13 **NINTH CAUSE FOR DISCIPLINE**

14 **(Assignment of Unsupported Extended Beyond Use Dates)**

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

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

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

1 **TENTH CAUSE FOR DISCIPLINE**

2 **(Failure to have a Compliant Compounding Environment)**

3 59. Respondent Glick is subject to disciplinary action for unprofessional conduct
4 pursuant to Code section 4301, subdivisions (j) and (o), as a pharmacist-in-charge, for failing to
5 follow laws and regulations governing pharmacy and regulating dangerous drugs by violating
6 Regulations section 1751.4, subdivision (a) and (f) by compounding, selling, and dispensing
7 drugs without certification and testing of primary and secondary engineering controls no less than
8 every six months, and whenever the device or area designated for compounding is relocated,
9 altered or a service to the facility is performed. The circumstances are that while Respondent
10 Glick was pharmacist-in-charge for Respondent Lihue, he allowed Respondent Lihue to
11 compound, dispense and sell at least 2,628 non-sterile to sterile compounded preparations to
12 California patients which were compounded without a compliant compounding environment, as
13 required leak testing of HEPA filters in the cleanroom had not been performed since March of
14 2021, as set forth in paragraphs 42-49, above.

15 **ELEVENTH CAUSE FOR DISCIPLINE**

16 **(Misbranded Drugs)**

17 60. Respondent Glick is subject to disciplinary action for unprofessional conduct
18 pursuant to Code section 4301, subdivisions (j) and (o), as pharmacist-in-charge, for failing to
19 follow laws and regulations governing pharmacy and regulating dangerous drugs by violating
20 Code section 4169, subdivision (a), and Health and Safety Code sections 111330, 11335, 111440,
21 111445 by compounding, selling, and dispensing misbranded drugs. The circumstances are that
22 Respondent Lihue compounded, dispensed and sold cyclosporine 0.03% ophthalmic emulsion
23 and atropine 0.01% ophthalmic solution, sterile compounded drugs to California patients which
24 were compounded with at least one component that expired before the assigned beyond use date
25 and therefore were or could have been misbranded, while Respondent Glick was pharmacist-in-
26 charge, as set forth in paragraph 42-49, above.

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1 **TWELFTH CAUSE FOR DISCIPLINE**

2 **(Failure to Follow Policies and Procedures)**

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

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

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

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

21 **THIRTEENTH CAUSE FOR DISCIPLINE**

22 **(Failure to Initial Orally transmitted prescription)**

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

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1 **FOURTEENTH CAUSE FOR DISCIPLINE**

2 **(Failure to Conform to Label Requirements)**

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

9 **FIFTEENTH CAUSE FOR DISCIPLINE**

10 **(Incompetence)**

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

16 **SIXTEENTH CAUSE FOR DISCIPLINE**

17 **(Gross Negligence)**

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

24 **SEVENTEENTH CAUSE FOR DISCIPLINE**

25 **(Inappropriate Use of Education, Training, and Experience)**

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

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

8 **OTHER MATTERS**

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

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

24 **PRAYER**

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

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

4 2. Revoking or suspending Nonresident Sterile Compounding Permit Number NSC
5 101126, issued to Lihue Pharmacy Inc; Kevin Craig Glick, president, vice-president, secretary,
6 director, pharmacist-in-charge, and Enny Rohsa Glick, treasurer/chief financial officer;

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

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

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

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

18 7. Ordering Lihue Pharmacy Inc. to pay the Board of Pharmacy the reasonable costs of
19 the investigation and enforcement of this case, pursuant to Business and Professions Code section
20 125.3; and, if placed on probation, the costs of probation monitoring;

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1 8. Ordering Kevin Craig Glick to pay the Board of Pharmacy the reasonable costs of the
2 investigation and enforcement of this case, pursuant to Business and Professions Code section
3 125.3; and, if placed on probation, the costs of probation monitoring; and,

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

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DATED: 10/6/2024

Sodergren, Digitally signed by
Anne@DCA 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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