

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

In the Matter of the Accusation Against:

**AHMC ANAHEIM REGIONAL MEDICAL CENTER,
Hospital Pharmacy Permit No. HSP 49999,
Sterile Compounding Permit No. LSC 101265; and**

**PEI-CHI TSAI,
Pharmacist License No. RPH 53801,**

Respondents.

Agency Case No. 7439

OAH No. 2023100527

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 July 11, 2024.

It is so ORDERED on June 11, 2024.

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".

Seung W. Oh, Pharm.D.
Board President

1 ROB BONTA
Attorney General of California
2 ERIN M. SUNSERI
Supervising Deputy Attorney General
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Attorneys for Complainant
8

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

13 In the Matter of the Accusation Against:

14 **AHMC ANAHEIM REGIONAL**
15 **MEDICAL CENTER**
16 **1111 W. La Palma Ave.**
17 **Anaheim, CA 92801**

18 **Hospital Pharmacy Permit No. HSP 49999,**
19 **Sterile Compounding Permit No. LSC**
20 **101265**

21 **and**

22 **PEI-CHI TSAI**
23 **1827 Fairford Drive**
24 **Fullerton, CA 92833**

25 **Pharmacist License No. RPH 53801**

26 Respondents.

Case No. 7439

OAH No. 2023100527

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER FOR PUBLIC
REPROVAL AS TO RESPONDENT PEI-
CHI TSAI ONLY

[Bus. & Prof. Code § 495]

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

1 **PARTIES**

2 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy
3 (Board). She brought this action solely in her official capacity and is represented in this matter by
4 Rob Bonta, Attorney General of the State of California, by Amie J. Flynn, Deputy Attorney
5 General.

6 2. Respondent Pei-Chi Tsai (Respondent Tsai) is represented in this proceeding by
7 attorney Hope Levy-Biehl, whose address is: 865 S. Figueroa Street, Suite 2400, Los Angeles,
8 California, 90017-2566.

9 3. On or about August 22, 2002, the Board of Pharmacy issued Pharmacist License
10 Number RPH 53801 to Respondent Tsai. Respondent Tsai has served and been listed in Board
11 records as Pharmacist-in-Charge of Respondent AHMC since February 1, 2019. The Pharmacist
12 License was in full force and effect at all times relevant to the charges brought herein and will
13 expire on June 30, 2024, unless renewed.

14 **JURISDICTION**

15 4. Accusation No. 7439 was filed before the Board, and is currently pending against
16 Respondent. The Accusation and all other statutorily required documents were properly served on
17 Respondent on August 18, 2023. Respondent timely filed her Notice of Defense contesting the
18 Accusation.

19 5. A copy of Accusation No. 7439 is attached as Exhibit A and incorporated herein by
20 reference.

21 **ADVISEMENT AND WAIVERS**

22 6. Respondent Tsai has carefully read, fully discussed with counsel, and understands the
23 charges and allegations in Accusation No. 7439. Respondent Tsai has also carefully read, fully
24 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
25 Order.

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

1 the right to the issuance of subpoenas to compel the attendance of witnesses and the production of
2 documents; the right to reconsideration and court review of an adverse decision; and all other
3 rights accorded by the California Administrative Procedure Act and other applicable laws.

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

6 **CULPABILITY**

7 9. Respondent Tsai admits the truth of each and every charge and allegation in
8 Accusation No. 7439.

9 10. Respondent Tsai agrees that her Pharmacist License is subject to discipline and she
10 agrees to be bound by the Board's Disciplinary Order below.

11 **CONTINGENCY**

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

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

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

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

6 **DISCIPLINARY ORDER**

7 IT IS HEREBY ORDERED that Pharmacist License Number RPH 53801 issued to
8 Respondent Pei-Chi Tsai shall be publicly reprovved by the Board of Pharmacy under Business
9 and Professions Code section 495 in resolution of Accusation No. 7430, attached as Exhibit A.

10 **Cost Recovery.** Respondent Tsai shall pay the amount of \$4,136.55 to the Board for its
11 costs of investigation and prosecution. Full payment shall be made within one year of the
12 effective date of the Disciplinary Order for Public Repraval.

13 If Respondent Tsai fails to pay the Board costs as ordered, Respondent Tsai shall not be
14 allowed to renew her Pharmacist License until Respondent Tsai pays costs in full. In addition,
15 the Board may enforce this order for payment of its costs in any appropriate court, in addition to
16 any other rights the Board may have.

17 **Remedial Education.** Within sixty (60) days of the effective date of this decision,
18 Respondent Tsai shall submit to the board or its designee, for prior approval, an appropriate
19 program of remedial education related to sterile compounding per USP 797 standards and shall
20 consist of at least 15 hours, which shall be completed within one year after the effective date of
21 this decision at Respondent's own expense. The remedial education must be 50% in person or live
22 webinar. All remedial education shall be in addition to, and shall not be credited toward,
23 continuing education (CE) courses used for license renewal purposes for pharmacists.

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ENDORSEMENT

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

DATED: _____

Respectfully submitted,
ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General

AMIE J. FLYNN
Deputy Attorney General
Attorneys for Complainant

SD2023800309/Stipulated Settlement for Public Repeval for Respondent Tsai in ADA Compliant Format.docx

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ENDORSEMENT

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

DATED: April 19, 2024

Respectfully submitted,

ROB BONTA
Attorney General of California
ERIN M. SUNSERI
Supervising Deputy Attorney General



AMIE J. FLYNN
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 7439

1 ROB BONTA
Attorney General of California
2 ERIN M. SUNSERI
Supervising Deputy Attorney General
3 AMIE J. FLYNN
Deputy Attorney General
4 State Bar No. 149600
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10 **BOARD OF PHARMACY**
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15 **MEDICAL CENTER**
16 **1111 W. La Palma Ave.**
17 **Anaheim, CA 92801**

ACCUSATION

18 **Hospital Pharmacy Permit No. HSP 49999,**
19 **Sterile Compounding Permit No. LSC**
20 **101265,**

21 **and**

22 **PEI-CHI TSAI**
23 **1827 Fairford Drive**
24 **Fullerton, CA 92833**

25 **Pharmacist License No. RPH 53801**

26 Respondents.

27 **PARTIES**

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

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1 9. Code section 4307, subdivision (a) states:

2 Any person who has been denied a license or whose license has been revoked
3 or is under suspension, or who has failed to renew his or her license while it was
4 under suspension, or who has been a manager, administrator, owner member, officer,
5 director, associate, or partner of any partnership, corporation, firm, or association
6 whose application for a license has been denied or revoked, is under suspension or
7 has been placed on probation, and while acting as the manger, administrator, owner,
8 member, officer, director, associate, or partner had knowledge or knowingly
9 participated in any conduct for which the license was denied, revoked, suspended, or
10 placed on probation, shall be prohibited from serving as a manger, administrator,
11 owner, member, officer, director, associate, or partner of a licensee as follows:

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

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

17 10. Code section 4342, subdivision (a) states:

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

25 INTRODUCTION

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

12 12. The Food and Drug Administration (FDA) oversees drug manufacturing, but does
13 not license pharmacies or pharmacists, nor control when or how their licenses permit
14 compounding. The states issue these licenses, and have primary jurisdiction. The states also set

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1 compounding standards that complement FDA standards for compounding as a form of drug
2 manufacturing.

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

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

11 15. California law allows all licensed pharmacists to compound *non-sterile* drug
12 products in licensed pharmacies. (e.g., Bus. & Prof. Code, §§ 4037, 4051, 4110.) All
13 compounding must be consistent with standards in the pharmacy compounding chapters of the
14 current version of the United States Pharmacopeia-National Formulary (USP-NF), including
15 relevant testing and quality assurance standards. (Bus. & Prof. Code, § 4126.8.) The Pharmacy
16 Law also contains additional standards that supplement the USP-NF standards. (*Id.*; see, e.g.,
17 Bus. & Prof. Code, §§ 4126.10, 4127 *et seq.*, 4128 *et seq.*, 4129 *et seq.*, Cal. Code Regs., tit. 16,
18 §§ 1735 *et seq.*, 1751 *et seq.*)

19 16. An additional specialty license is required before any licensed pharmacy is
20 allowed to compound *sterile* drug products, (Bus. & Prof. Code, § 4127 *et seq.*) and particular
21 regulatory requirements apply to preparation, maintenance, and distribution of sterile drug
22 products. (Cal. Code Regs., tit. 16, § 1751 *et seq.*; see also Cal. Code Regs., tit. 16, § 1735 *et*
23 *seq.*) Each sterile compounding pharmacy must be inspected prior to each annual renewal of a
24 sterile compounding license to ensure compliance with all compounding and sterile compounding
25 requirements. (Bus. & Prof. Code, § 4127.1, subd. (c).) All of this demonstrates the attention and
26 resources devoted to sterile drug compounding. This is because of the unique risks posed by
27 sterile drug products. In 2012, for instance, a contaminated sterile drug compound was widely

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1 distributed, and caused a nationwide fungal meningitis outbreak, killing 64 people and causing
2 infections in almost 800 others who received the drug.

3 17. In this case, Respondents have engaged in compounding of drug products intended
4 for sterile administration. Respondents' compounding area was in a location that was adjacent to
5 construction sites which failed to meet the definitional requirements of a segregated sterile
6 compounding area. Without meeting such requirements for its designated space, Respondents
7 assigned beyond use dates for its compounded sterile preparations (CSPs) which were not in
8 accordance with the established beyond use dating regulations for sterile compounded drug
9 preparations. Additionally, after noting positive growth of a highly pathogenic microorganism,
10 mold, (specifically Penicillium sp.), Respondent's facility did not contact a competent
11 microbiologist, infection control professional, nor industrial hygienist to provide remediation
12 assistance for the positive growth of a highly pathogenic microorganism (Penicillium sp.) in the
13 ISO Class 5 LAFW from the date of receipt of the viable sampling results, April 29, 2022 to the
14 date of inspection May 2, 2022. Further, Respondents did not have written policies and
15 procedures following detection of the colony-forming units (CFU).

16 **STATUTORY PROVISIONS**

17 18. Code section 4023.5 states:

18 For the purposes of this chapter, "direct supervision and control" means that a
19 pharmacist is on the premises at all times and is fully aware of all activities performed
20 by either a pharmacy technician or intern pharmacist.

21 19. Code section 4113 states in pertinent part:

22 (a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days
23 thereof, shall notify the board in writing of the identity and license number of that
24 pharmacist and the date he or she was designated.

25 (b) The proposed pharmacist-in-charge shall be subject to approval by the board. The
26 board shall not issue or renew a pharmacy license without identification of an approved
27 pharmacist-in-charge for the pharmacy.

28 (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.

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20. Code section 4126.8 states:

The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. The board may adopt regulations to impose additional standards for compounding drug preparations.

21. Code section 4169 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.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

...

22. Section 4301 of the Code states:

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

...

(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.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

...

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1 23. Code section 4306.5, subdivision (a), states, in pertinent part:

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

3 Acts or omissions that involve, in whole or in part, the inappropriate exercise
4 of his or her education, training, or experience as a pharmacist, whether or not the
5 act or omission arises in the course of the practice of pharmacy or the ownership,
6 management, administration, or operation of a pharmacy or other entity licensed by
7 the board.

8 ...

9 24. Health and Safety Code section 111250 states:

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

12 25. Health and Safety Code section 111255 states:

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

16 26. Health and Safety Code section 111295 states:

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

19 27. Section 501(a)(2)(A) of the Federal Food, Drug and Cosmetic Act (21 U.S.C.
20 351(a)(2)(A)) states:

21 A drug or device shall be deemed to be adulterated if it has been prepared,
22 packed, or held under insanitary conditions whereby it may have been contaminated
23 with filth, or whereby it may have been rendered injurious to health.

24 28. Section 501(a)(2)(A) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 353(a))
25 states:

26 The Secretary is directed to promulgate regulations exempting from any labeling or
27 packaging requirement of this chapter drugs and devices which are, in accordance with the
28 practice of the trade, to be processed, labeled, or repacked in substantial quantities at
establishments other than those where originally processed or packed, on condition that
such drugs and devices are not adulterated or misbranded under the provisions of this
chapter upon removal from such processing, labeling, or repacking establishment.

REGULATORY PROVISIONS

29 29. California Code of Regulations, title 16, section 1709 states:

30 (a) Each license issued by the board to operate a pharmacy shall reflect the name and
31 address of the pharmacy, the form of ownership, and the pharmacist-in-charge. Each
32 pharmacy shall, in its initial application and on the annual renewal form, report the name of

1 the pharmacist-in-charge, the names of all owners, and the names of the corporate officers
2 (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate
3 officers shall be reported to the board within 30 days of the change.

4 ...

5 30. California Code of Regulations, title 16, section 1735 states:

6 (a) "Compounding" means any of the following activities occurring in a licensed
7 pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

8 (1) Altering the dosage form or delivery system of a drug

9 (2) Altering the strength of a drug

10 (3) Combining components or active ingredients

11 (4) Preparing a compounded drug preparation from chemicals or bulk drug substances

12 ...

13 31. California Code of Regulations, title 16, section 1735.1, subdivision (af) states:

14 "Segregated sterile compounding area" means a designated space for sterile-to-
15 sterile compounding where a PEC [Primary Engineering Control] is located within
16 either a demarcated area (at least three foot perimeter) or in a separate room. Such
17 area or room shall not contain and shall be void of activities and materials that are
18 extraneous to sterile compounding. The segregated sterile compounding area shall not
19 be in a location that has unsealed windows or doors that connect to the outdoors, in a
20 location with high traffic flow, or in a location that is adjacent to construction sites,
21 warehouses, or food preparation. The segregated sterile compounding area shall not
22 have a sink, other than an emergency eye-washing station, located within three feet of
23 a PEC. The segregated sterile compounding area shall be restricted to preparation of
24 sterile-to-sterile compounded preparations.

25 32. California Code of Regulations, title 16, section 1751.3, subdivision (a) states:

26 Any pharmacy engaged in compounding sterile drug preparations shall
27 maintain written policies and procedures for compounding. Any material failure to
28 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.

- 1 (4) Cleaning and maintenance of ISO environments and segregated
compounding areas.
- 2 (5) Compounded sterile drug preparation stability and beyond use dating.
- 3 (6) Compounding, filling, and labeling of sterile drug preparations.
- 4 (7) Daily and monthly cleaning and disinfection schedule for the controlled
5 areas and any equipment in the controlled area as specified in section 1751.4.
- 6 (8) Depyrogenation of glassware (if applicable).
- 7 (9) Facility management including certification and maintenance of controlled
environments and related equipment.
- 8 (10) For compounding aseptic isolators and compounding aseptic containment
9 isolators, documentation of the manufacturer's recommended purge time.
- 10 (11) Hand hygiene and garbing.
- 11 (12) Labeling of the sterile compounded drug preparations based on the
intended route of administration and recommended rate of administration.
- 12 (13) Methods by which the supervising pharmacist will fulfill his or her
13 responsibility to ensure the quality of compounded drug preparations.
- 14 (14) Orientation, training, and competency evaluation of staff in all aspects of
the preparation of sterile drug preparations including didactic training and
15 knowledge/competency assessments that include at minimum: hand hygiene and
garbing; decontamination (where applicable); cleaning and disinfection of controlled
16 compounding areas; and proper aseptic technique, demonstrated through the use of a
media-fill test performed by applicable personnel; and aseptic area practices.
- 17 (15) Preparing sterile compounded drug preparations from non-sterile
18 components (if applicable). This shall include sterilization method suitability testing
for each master formula document.
- 19 (16) Procedures for handling, compounding and disposal of hazardous agents.
20 The written policies and procedures shall describe the pharmacy protocols for
cleanups and spills in conformity with local health jurisdiction standards.
- 21 (17) Procedures for handling, compounding and disposal of infectious
22 materials. The written policies and procedures shall describe the pharmacy protocols
for cleanups and spills in conformity with local health jurisdiction standards.
- 23 (18) Proper use of equipment and supplies.
- 24 (19) Quality assurance program compliant with sections 1711, 1735.8 and
25 1751.7.
- 26 (20) Record keeping requirements.
- 27 (21) Temperature monitoring in compounding and controlled storage areas.
- 28 (22) The determination and approval by a pharmacist of ingredients and the
compounding process for each preparation before compounding begins.

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

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

4 33. California Code of Regulations, title 16, section 1751.8 states in pertinent part:

5 ...

6 (d) The beyond use date shall specify that storage and exposure periods cannot
7 exceed 12 hours where the sterile compounded drug preparation is compounded solely with
8 aseptic manipulations and all of the following apply:

9 (1) The preparation was compounded entirely within an ISO Class 5 PEC that is
10 located in a segregated sterile compounding area and restricted to sterile compounding
11 activities, using only sterile ingredients, components, and devices, by personnel properly
12 cleansed and garbed; and

13 (e) Where any sterile compounded drug preparation was compounded either outside
14 of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any
15 of subdivisions (a) through (d), the sterile compounded drug preparation shall be labeled
16 "for immediate use only" and administration shall begin no later than one hour following
17 the start of the compounding process. Unless the "immediate use" preparation is
18 immediately and completely administered by the person who prepared it or immediate and
19 complete administration is witnessed by the preparer, the preparation shall bear a label
20 listing patient identification information, the names and amounts of all ingredients, the
21 name or initials of the person who prepared the compounded sterile preparation, and the
22 exact one-hour beyond use date and time. If administration has not begun within one hour
23 following the start of the compounding process, the compounded sterile preparation shall be
24 promptly, properly, entirely, and safely discarded. This provision does not preclude the use
25 of a PEC to compound an "immediate use" preparation. A PEC used solely to compound
26 'immediate use' preparations need not be placed within an ISO Class 7 cleanroom, with an
27 ante-area. Such "immediate use" preparations shall be compounded only in those limited
28 situations where there is a need for immediate administration of a sterile preparation
compounded outside of an ISO class 5 environment and where failure to administer could
result in loss of life or intense suffering. Any such compounding shall be only in such
quantity as is necessary to meet the immediate need and the circumstance causing the
immediate need shall be documented in accordance with policies and procedures.

34. United States Pharmacopeia Chapter 797 states that highly pathogenic
microorganisms (e.g. Gram-negative rods, coagulase positive staphylococcus, molds, and yeasts)
can be potentially fatal to patients receiving compounded sterile preparations and must be
immediately remedied, regardless of CFU (colony forming units) count, with the assistance of a
competent microbiologist, infection control professional, or industrial hygienist."

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1 **COST RECOVERY**

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

6 **FACTUAL ALLEGATIONS**

7 36. Respondent Pharmacy is a pharmacy located in Anaheim, California. It compounds
8 sterile to sterile preparations for administration to patients.

9 37. At all times mentioned herein, Respondent Tsai has been the Pharmacist-in-Charge
10 (PIC) at Respondent Pharmacy.

11 38. On May 2, 2022, a Board of Pharmacy inspector conducted an onsite sterile
12 compounding license inspection of Respondent Pharmacy. Prior to the inspection, the inspector
13 requested and received documents from the Pharmacist in Charge (PIC), Respondent Tsai,
14 relating to the upcoming inspection. Respondent Tsai emailed an April 28, 2022 Certification
15 Report from Clean Air Certification, showing a collection date of April 9, 2022. The
16 Certification Report noted the presence of a highly pathogenic microorganism, mold, identified as
17 *Penicillium* sp., collected from a viable surface sample within the primary engineering control
18 (horizontal laminar airflow bench, LAFW). The LAFW is an International Standards
19 Organization (ISO) Class 5 certified area.

20 39. During the May 2, 2022 inspection, the Board of Pharmacy inspector inspected a
21 single sterile compounding licensed area within the AHMC Anaheim Regional Medical Center
22 (Hospital) with Respondent Tsai. The Board inspector and Respondent Tsai discussed the results
23 of the Certification Report, specifically the viable surface sample inside the ISO Class 5 LAFW.
24 Respondent Tsai stated that upon receiving the Certification Report results, she contacted the
25 Hospital engineering department to discuss both the room's air handling system and potentially
26 contracting with a third party to provide air duct cleaning services. Respondent Tsai stated her
27 intent to re-educate and retrain pharmacy personnel in cleaning procedures, specifically the
28 cleaning of the ISO Class 5 certified LAFW. Because the viable surface sample results in the

1 ISO Class 5 certified area yielded a mold, (*Penicillium* sp.), the Board Inspector provided
2 education to Respondent Tsai regarding the remediation process involving highly pathogenic
3 microorganisms as it pertains to United States Pharmacopeia (USP) chapter 797. As per USP
4 chapter 797, “highly pathogenic microorganisms (e.g. Gram-negative rods, coagulase positive
5 staphylococcus, molds, and yeasts) can be potentially fatal to patients receiving CSPs and must be
6 immediately remedied, regardless of CFU (colony forming units) count, with the assistance of a
7 competent microbiologist, infection control professional, or industrial hygienist.” Prior to this
8 discussion, the Hospital had not been in contact with any entity to provide remediation assistance
9 with the positive growth of the highly pathogenic microorganism. After the discussion,
10 Respondent Tsai contacted the Hospital’s infection control department to assist in the remediation
11 process. The Board Inspector also discussed the self-reporting of the viable surface sampling
12 results, (received on April 29, 2022), to the California Department of Public Health (CDPH).

13 40. Although Respondent Tsai provided a policy and procedure titled ‘Compounded Sterile
14 Preparation Services’ prior to the inspection, Respondent Tsai could not provide a written policy
15 and procedure to address what actions should be taken when action levels for CFUs are exceeded.

16 41. During the May 2, 2022 inspection, the Board Inspector noted that the licensed sterile
17 compounding area was a segregated compounding area (SCA) located in an enclosed room on the
18 first floor of the Hospital, in a separate area away from the main pharmacy. The SCA contains an
19 ISO Class 5 LAFW to perform non-hazardous, low risk compounding with a maximum beyond
20 use date of 12 hours for all compounded sterile preparations. The enclosed room containing the
21 SCA was observed to be directly adjacent to construction sites. The following observations were
22 noted:

- 23 • Directly to the right of the door leading into the SCA, exposed dry wall was covered
24 with plastic sheeting and tape;
- 25 • Directly above the exposed drywall area, a displaced ceiling tile was semi-covered
26 with plastic sheeting and construction tape;
- 27 • Directly to the left of the door leading into the SCA, area was sealed off with a
28 plastic barrier and tape.

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THIRD CAUSE FOR DISCIPLINE

(Failure to Adhere to Beyond Use Date)

47. Respondents are subject to disciplinary action under Code section 4301 (o) in that Respondents violated CCR section 1751.8(d)(1) and (e) and CCR section 1735.1 (af) in that at the time of inspection on May 2, 2022, and for a period of approximately 12 hours from May 12, 2022 at 9:25 p.m. until May 13, 2022 at 9:32 a.m., the compounding area was in a location that was adjacent to construction sites, which failed to meet the definitional requirements of a segregated sterile compounding area. Without meeting such requirements for its designated space, the facility compounded CSPs and assigned beyond use dates for its CSPs which were not in accordance with the established beyond use dating regulations for sterile compounded drug preparations.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct as to Respondent Tsai)

48. Respondent Tsai is subject to disciplinary action under Code section 4301 (o) in that Respondent Tsai violated Code section 4306.5(a) when Respondent Tsai failed to exercise the appropriate use of her training and experience as a pharmacist when she failed to take appropriate action regarding the growth of a highly pathogenic microorganism within the ISO-Class 5 LAFW until May 2, 2022, even though she was made aware of it on April 29, 2022.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct as to Respondent AHMC)

49. Respondent AHMC is subject to disciplinary action under Code section 4301 in that Respondent AHMC filed an incomplete Change of Permit Application and did not respond to the Board's deficiency letters as set forth in paragraphs 42 through 44.

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1 **SIXTH CAUSE FOR DISCIPLINE**

2 **(Failure to Report to the Board as to Respondent AHMC)**

3 50. Respondent AHMC is subject to disciplinary action under Code section 4301 (o) in
4 that Respondent AHMC violated CCR section 1709(a) as follows:

5 a. By failing to report the appointment of Margaret Peterson as Chief Executive
6 Officer to the Board within 30 days of appointment as set forth in paragraph 42; and,

7 b. By failing to report Margaret Peterson’s disassociation as the Chief Executive
8 Officer to the Board within 30 days of disassociation as set forth in paragraph 43.

9 **OTHER MATTERS**

10 51. Pursuant to Code section 4307, if discipline is imposed on Hospital Pharmacy Permit
11 No. PHY 49999 and/or Sterile Compounding License No. LSC 101265 issued to AHMC
12 Anaheim Regional Medical Center, it shall be prohibited from serving as a manager,
13 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
14 the Hospital Pharmacy Permit and/or Sterile Compounding License are placed on probation or
15 until the Hospital Pharmacy Permit and/or Sterile Compounding License are reinstated if they are
16 revoked.

17 52. Pursuant to Code section 4307, if discipline is imposed on Hospital Pharmacy Permit
18 No. PHY 49999 and/or Sterile Compounding License No. LSC 101265 issued to AHMC
19 Anaheim Regional Medical Center, its PIC Pei-Chi Tsai shall be prohibited from serving as a
20 manager, administrator, owner, member, officer, director, associate, or partner of a licensee for
21 five years if the Hospital Pharmacy Permit and/or Sterile Compounding License are placed on
22 probation or until the Hospital Pharmacy Permit and/or Sterile Compounding License are
23 reinstated if they are revoked.

24 53. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No.
25 RPH 53801, issued to Pei-Chi Tsai, she shall be prohibited from serving as a manager,
26 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
27 the Pharmacist License is placed on probation or until the Pharmacist License is reinstated, if it is
28 revoked.

PRAYER

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

1. Revoking or suspending Hospital Pharmacy Permit Number HSP 49999, issued to AHMC Anaheim Regional Medical Center;
2. Revoking or suspending Sterile Compounding Permit Number LSC 101265, issued to AHMC Anaheim Regional Medical Center;
3. Revoking or suspending Pharmacist License Number RPH 53801, issued to Pei-Chi Tsai;
4. Prohibiting AHMC Anaheim Regional Medical Center from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Hospital Pharmacy Permit Number PHY 49999 and/or Sterile Compounding License Number 101265 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;
5. Prohibiting Pei-Chi Tsai from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Hospital Pharmacy Permit Number PHY 49999 and/or Sterile Compounding License Number 101265 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;
6. Prohibiting Pei-Chi Tsai from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 53801 is placed on probation or until the Pharmacist License is reinstated, if it is revoked;
7. Ordering AHMC Anaheim Regional Medical Center and Pei-Chi Tsai 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,

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

DATED: 8/8/2023

Sodergren,
Anne@DCA
ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

Digitally signed by Sodergren,
Anne@DCA
Date: 2023.08.08 11:23:57
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