

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

**In the Matter of the Accusation Against:**

**SOUTHERN MONTEREY COUNTY MEMORIAL HOSPITAL,  
d.b.a. GEORGE L. MEE MEMORIAL HOSPITAL,  
Original Permit No. HSP 43395;**

**and**

**GEORGE L. MEE MEMORIAL HOSPITAL,  
Sterile Compounding Permit No. LSC 100083;**

**and**

**FREDERICK RONAN RALEIGH,  
Pharmacist License No. RPH 27362**

**Respondents.**

**Agency Case No. 6226**

## 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 May 26, 2021.

It is so ORDERED on April 26, 2021.

BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA

A handwritten signature in black ink, appearing to read "Greg M. Lippe", is written over a horizontal line.

By

Greg Lippe  
Board President

1 XAVIER BECERRA  
Attorney General of California  
2 CHAR SACHSON  
Supervising Deputy Attorney General  
3 LESLIE E. BRAST  
Deputy Attorney General  
4 State Bar No. 203296  
455 Golden Gate Avenue, Suite 11000  
5 San Francisco, CA 94102-7004  
Telephone: (415) 510-3373  
6 Facsimile: (415) 703-5480  
*Attorneys for Complainant*

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

12 In the Matter of the Accusation Against:

13 **FREDERICK RONAN RALEIGH**  
14 **1990 Burnt Rock Way**  
**Templeton, CA 93465**

15 **Pharmacist License No. RPH 27362**

16 Respondent.

Case No. 6226

**STIPULATED SETTLEMENT AND  
DISCIPLINARY ORDER FOR PUBLIC  
REPROVAL**

**[Bus. & Prof. Code § 495]**

17  
18 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-  
19 entitled proceedings that the following matters are true:

20 **PARTIES**

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

25 2. Respondent Frederick Ronan Raleigh (Respondent) is represented in this proceeding  
26 by attorney Jake Reinhardt whose address is 2550 9th Street, Suite 101, Berkeley, California  
27 94710.

28 ///

1 **JURISDICTION**

2 3. On or about August 5, 1971, the Board issued Original Pharmacist License No. RPH  
3 27362 to Respondent. The License was in full force and effect at all times relevant to the charges  
4 brought in Accusation No. 6226, and will expire on December 31, 2020.

5 4. Accusation No. 6226 was filed before the Board and is currently pending against  
6 Respondent. The Accusation and all other statutorily required documents were properly served  
7 on Respondent on April 5, 2018. Respondent timely filed his Notice of Defense contesting the  
8 Accusation. A copy of Accusation No. 6226 is attached as Exhibit A and incorporated herein by  
9 reference.

10 **ADVISEMENT AND WAIVERS**

11 5. Respondent has carefully read, fully discussed with counsel, and understands the  
12 charges and allegations in Accusation No. 6226. Respondent has also carefully read, fully  
13 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary  
14 Order for Public Reproval.

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

22 7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and  
23 every right set forth above.

24 **CULPABILITY**

25 8. Respondent admits the truth of each and every charge and allegation in Accusation  
26 No. 6226.

27 9. Respondent agrees that his Pharmacist License is subject to discipline and agrees to  
28 be bound by the Disciplinary Order below.

**CONTINGENCY**

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

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

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

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

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1 **DISCIPLINARY ORDER**

2 IT IS HEREBY ORDERED that Pharmacist License No. RPH 27362 issued to Respondent  
3 Frederick Ronan Raleigh (Respondent) shall be publicly reprovved by the Board of Pharmacy  
4 under Business and Professions Code section 495 in resolution of Accusation No. 6226, attached  
5 as Exhibit A.

6 **Cost Recovery.** Respondent shall pay \$3,000 to the Board for its costs associated with the  
7 investigation and enforcement of this matter. Respondent shall be permitted to pay these costs in  
8 a payment plan approved by the Board. If Respondent fails to pay the Board costs as ordered,  
9 Respondent shall not be allowed to renew his Pharmacist License until he pays costs in full.

10 **ACCEPTANCE**

11 I have carefully read the above Stipulated Settlement and Disciplinary Order for Public  
12 Reproval and have fully discussed it with my attorney, Jake Reinhardt. I understand the  
13 stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated  
14 Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently,  
15 and agree to be bound by the Decision and Order of the Board of Pharmacy.

16  
17 DATED: \_\_\_\_\_

18 FREDERICK RONAN RALEIGH  
19 *Respondent*

20 I have read and fully discussed with my client, Respondent Frederick Ronan Raleigh, the  
21 terms and conditions and other matters contained in the above Stipulated Settlement and  
22 Disciplinary Order for Public Reproval. I approve its form and content.

23  
24 DATED: \_\_\_\_\_

25 JAKE REINHARDT  
26 *Attorney for Respondent*

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1 **DISCIPLINARY ORDER**

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12 Reproval and have fully discussed it with my attorney, Jake Reinhardt. I understand the  
13 stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated  
14 Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently,  
15 and agree to be bound by the Decision and Order of the Board of Pharmacy.

16  
17 DATED: 2/24/20

Frederick Ronan Raleigh  
FREDERICK RONAN RALEIGH  
Respondent

19  
20 I have read and fully discussed with my client, Respondent Frederick Ronan Raleigh, the  
21 terms and conditions and other matters contained in the above Stipulated Settlement and  
22 Disciplinary Order for Public Reproval. I approve its form and content.

23  
24 DATED: 2/25/20

Jake Reinhardt  
JAKE REINHARDT  
Attorney for Respondent

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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: February 9, 2021

Respectfully submitted,

XAVIER BECERRA  
Attorney General of California  
CHAR SACHSON  
Supervising Deputy Attorney General



LESLIE E. BRAST  
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: \_\_\_\_\_

Respectfully submitted,

XAVIER BECERRA  
Attorney General of California  
CHAR SACHSON  
Supervising Deputy Attorney General

LESLIE E. BRAST  
Deputy Attorney General  
*Attorneys for Complainant*

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**Exhibit A**

**Accusation No. 6226**

1 XAVIER BECERRA  
Attorney General of California  
2 CHAR A. SACHSON  
Supervising Deputy Attorney General  
3 LESLIE E. BRAST  
Deputy Attorney General  
4 State Bar No. 203296  
455 Golden Gate Avenue, Suite 11000  
5 San Francisco, CA 94102-7004  
Telephone: (415) 703-5548  
6 Facsimile: (415) 703-5480  
*Attorneys for Complainant*

7  
8 **BEFORE THE**  
**BOARD OF PHARMACY**  
9 **DEPARTMENT OF CONSUMER AFFAIRS**  
**STATE OF CALIFORNIA**

10 In the Matter of the Accusation Against:

Case No. 6226

11 **SOUTHERN MONTEREY COUNTY**  
12 **MEMORIAL HOSPITAL, d.b.a. GEORGE L.**  
13 **MEE MEMORIAL HOSPITAL**  
14 **300 Canal Street**  
**King City, CA 93930**

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

15 **Original Permit No. HSP 43395**

16 **and**

17 **GEORGE L. MEE MEMORIAL HOSPITAL**  
18 **300 Canal Street**  
**King City, CA 93930**

19 **Sterile Compounding Permit No. LSC 100083**

20 **and**

21 **FREDERICK RONAN RALEIGH**  
22 **808 Vista Cerro Dr.**  
**Paso Robles, CA 93446**

23 **Pharmacist License No. RPH 27362**

24 Respondents.

25 Complainant alleges:

26 **PARTIES**

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

1           2.     On or about February 26, 1998, the Board issued Original Permit Number HSP 43395  
2 to Southern Monterey County Memorial Hospital, d.b.a. George L. Mee Memorial Hospital  
3 (Respondent Hospital). The License was in full force and effect at all times relevant to the  
4 charges brought herein and will expire on February 1, 2019, unless renewed.

5           3.     On or about May 20, 2014, the Board issued Sterile Compounding Permit No. LSC  
6 100083 to Respondent Hospital. The License was in full force and effect at all times relevant to  
7 the charges brought herein. The License expired on February 1, 2017, and was canceled on  
8 canceled on January 24, 2018.

9           4.     On or about August 5, 1971, the Board issued Original Pharmacist License No. RPH  
10 27362 to Frederick Rohan Raleigh (Respondent Raleigh). The License was in full force and  
11 effect at all times relevant to the charges brought herein and will expire on December 31, 2018,  
12 unless renewed. Since on or about November 23, 2016, Respondent Raleigh has served and/or  
13 has been reflected in Board records as the pharmacist-in-charge (PIC) for Respondent Hospital.

#### 14                                   **JURISDICTION**

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

18           6.     Section **4011** of the Code provides that the Board shall administer and enforce both  
19 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances  
20 Act [Health & Safety Code, § 11000 et seq.].

21           7.     Section **4300(a)** of the Code provides that every license issued by the Board may be  
22 suspended or revoked.

23           8.     Section **4300.1** of the Code provides that the expiration, cancellation, forfeiture, or  
24 suspension of a Board-issued license, the placement of a license on a retired status, or the  
25 voluntary surrender of a license by a licensee, shall not deprive the Board of jurisdiction to  
26 commence or proceed with any investigation of, or action or disciplinary proceeding against, the  
27 licensee or to render a decision suspending or revoking the license.

28     ///



1 the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote  
2 compliance through self-examination and education.

3 12. California Code of Regulations, title 16, section **1735.5**, states:

4 ...

5 (b) The policy and procedure manual shall be reviewed on an annual basis by the  
6 pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

7 (c) The policy and procedure manual shall include the following:

8 (1) Procedures for notifying staff assigned to compounding duties of any changes in  
9 processes or to the policy and procedure manual.

10 ...

11 13. California Code of Regulations, title 16, section **1735.7(c)**, states:

12 Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about  
13 processes and procedures used in compounding prior to compounding any drug preparation.

14 14. California Code of Regulations, title 16, section **1735.8(c)**, states:

15 The quality assurance plan shall include written standards for qualitative and quantitative  
16 integrity, potency, quality, and labeled strength analysis of compounded drug products. All  
17 qualitative and quantitative analysis reports for compounded drug products shall be retained by  
18 the pharmacy and collated with the compounding record and master formula.

19 15. California Code of Regulations, title 16, section **1751.4**, states, in pertinent part:

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

23 ...

24 (d) Exterior workbench surfaces and other hard surfaces in the designated area, such as  
25 walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any  
26 unanticipated event that could increase the risk of contamination.

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1 16. California Code of Regulations, title 16, section 1751.7, states, in pertinent part:

2 (a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain,  
3 as part of its written policies and procedures, a written quality assurance plan including, in  
4 addition to the elements required by section 1735.8, a documented, ongoing quality assurance  
5 program that monitors personnel performance, equipment, and facilities. The end product shall be  
6 examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it  
7 meets required specifications. The Quality Assurance Program shall include at least the  
8 following:

9 ...

10 (4) Written justification of the chosen expiration dates for compounded sterile injectable  
11 products.

12 ...

13 **COST RECOVERY**

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

18 **FIRST CAUSE FOR DISCIPLINE**

19 (Failure to Complete Compounding Self-Assessment)

20 18. Respondents are each and severally subject to discipline under section 4301(o) and/or  
21 section 4113(c) of the Code, by reference to California Code of Regulations, title 16, section  
22 1735.2(j), for directly or indirectly violating, attempting to violate, or assisting in or abetting a  
23 violation of laws or regulations governing the practice of pharmacy, in that the Pharmacy Board's  
24 inspector found during an inspection at Respondent Hospital on or about December 20, 2016, that  
25 the compounding self-assessment form had not been completed.

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1 1735.5(b), for directly or indirectly violating, attempting to violate, or assisting in or abetting a  
2 violation of laws or regulations governing the practice of pharmacy, in that Respondents failed to  
3 perform, and document on an annual basis, the performance by the pharmacist-in-charge of a  
4 review of policies and procedures. The circumstances are as follows:

5 24. On or about December 20, 2016, during an inspection at Respondent Hospital, the  
6 Pharmacy Board's inspector found that the pharmacist-in-charge had not reviewed the  
7 compounding policies and procedures during the preceding year.

8 **FIFTH CAUSE FOR DISCIPLINE**

9 (Lack of Procedure to Advise of Changes to Compounding Policies and Procedures)

10 25. Respondents are each and severally subject to discipline under section 4301(o) and/or  
11 section 4113(c) of the Code, by reference to California Code of Regulations, title 16, section  
12 1735.5(c)(1), for directly or indirectly violating, attempting to violate, or assisting in or abetting a  
13 violation of laws or regulations governing the practice of pharmacy, in that Respondents failed to  
14 have any procedure for notifying staff assigned to compounding duties of any changes in policies  
15 or procedures. The circumstances are as follows:

16 26. On or about December 20, 2016, during an inspection at Respondent Hospital, the  
17 Pharmacy Board's inspector found that the facility had no policy or procedure stating how staff  
18 were to be notified of new or changed compounding policies and procedures.

19 **SIXTH CAUSE FOR DISCIPLINE**

20 (Unlawful Operation)

21 27. Respondents are each and severally subject to discipline under section 4301(o) and/or  
22 section 4113(c) of the Code, by reference to California Code of Regulations, title 16, section  
23 1751.4(a), for directly or indirectly violating, attempting to violate, or assisting in or abetting a  
24 violation of laws or regulations governing the practice of pharmacy, in that Respondents allowed  
25 and/or engaged in sterile drug preparation and compounding when Respondents knew, or should  
26 have known, that the compounding environment failed to meet criteria specified in the  
27 pharmacy's written policies and procedures for the safe compounding of sterile drug preparations.  
28 The circumstances are as follows:

28. On or about December 20, 2016, during an inspection at Respondent Hospital, the Pharmacy Board's inspector found that the compounding room was a converted patient room with a full bathroom, openable windows, no line of demarcation, and a crowded, disorganized segregated clean room.

### SEVENTH CAUSE FOR DISCIPLINE

(Inadequate Cleaning of Facility)

29. Respondents are each and severally subject to discipline under section 4301(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16, section 1751.4(d), for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that Respondents failed to clean the facility in the manner required by law. The circumstances are as follows:

30. On or about December 20, 2016, during an inspection at Respondent Hospital, the Pharmacy Board's inspector found that the compounding room's ceilings, walls, floors, shelves, tables and stools had not been cleaned weekly since the last week in April 2016.

### EIGHTH CAUSE FOR DISCIPLINE

(Inappropriate Beyond-Use Dates)

31. Respondents are each and severally subject to discipline under section 4301(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16, section 1751.7(a)(4), for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that Respondents utilized inappropriate beyond use dates for compounded sterile drug preparations. The circumstances are as follows:

32. On or about December 20, 2016, during an inspection at Respondent Hospital, the Pharmacy Board's inspector found that the facility should have a beyond-use date of no more than an hour, or immediate use. Beyond use dates assigned to sterile injectable drugs were: 12 hour, 24 hours, and longer per compounding records and master formulas.

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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 Original Permit Number HSP 43395, issued to Southern Monterey County Memorial Hospital, d.b.a. George L. Mee Memorial Hospital;

2. Revoking or suspending Sterile Compounding Permit No. LSC 100083, issued to George L. Mee Memorial Hospital;

3. Revoking or suspending Original Pharmacist License No. RPH 27362, issued to Frederick Rohan Raleigh;

4. Ordering Respondents 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,

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

DATED: 4/5/18



VIRGINIA HEROLD  
Executive Officer  
Board of Pharmacy  
Department of Consumer Affairs  
State of California  
*Complainant*