

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

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

**RADY CHILDREN'S HOSPITAL – SAN DIEGO, dba  
CHILDREN'S HOSPITAL & HEALTH CENTER PHARMACY,  
Sterile Compounding Permit No. LSC 100603;**

**and**

**SUSANNE PLAHUTA WIEDEMAN,  
Pharmacist License No. RPH 52083,**

**Respondents**

**Agency Case No. 7123**

**OAH No. 2021110416**

## DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reapproval 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 25, 2022.

It is so ORDERED on April 25, 2022.

BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA

A handwritten signature in black ink, appearing to read "Seung W. Oh". The signature is fluid and cursive, with the first name "Seung" and last name "Oh" being clearly legible, and "W." in the middle.

Seung W. Oh, Pharm.D.  
Board President

1 ROB BONTA  
Attorney General of California  
2 MARICHELLE S. TAHIMIC  
Supervising Deputy Attorney General  
3 DIANE DE KERVOR  
Deputy Attorney General  
4 State Bar No. 174721  
600 West Broadway, Suite 1800  
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7 Facsimile: (619) 645-2061  
*Attorneys for Complainant*

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

11 In the Matter of the Accusation Against:

Case No. 7123

12 **RADY CHILDREN'S HOSPITAL - SAN**  
13 **DIEGO, DBA CHILDREN'S HOSPITAL &**  
14 **HEALTH CENTER PHARMACY**  
15 **3010 Children's Way, Room 2220**  
**San Diego, CA 92123**

OAH No. 2021110416

**STIPULATED SETTLEMENT AND**  
**DISCIPLINARY ORDER FOR PUBLIC**  
**REPROVAL AS TO RESPONDENT**  
**RADY CHILDREN'S HOSPITAL – SAN**  
**DIEGO ONLY**

16 **Sterile Compounding Permit No. LSC**  
17 **100603**

**[Bus. & Prof. Code § 495]**

18 **And**

19 **SUSANNE PLAHUTA WIEDEMAN**  
20 **3020 Children's Way**  
**San Diego, CA 92123**

21 **Pharmacist License No. RPH 52083**

22 Respondents.

23  
24 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-  
25 entitled proceedings that the following matters are true:

26 **PARTIES**

27 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy  
28 (Board). She brought this action solely in her official capacity and is represented in this matter by

1 Rob Bonta, Attorney General of the State of California, by Diane De Kervor, Deputy Attorney  
2 General.

3 2. On or about June 27, 2014, the Board issued Sterile Compounding Permit Number  
4 LSC 100603 to Rady Children's Hospital - San Diego, dba Children's Hospital & Health Center  
5 Pharmacy (Respondent). The Sterile Compounding Permit was in full force and effect at all times  
6 relevant to the charges brought herein and will expire on August 1, 2022, unless it is renewed.

7 3. Respondent is represented in this proceeding by attorney Marilyn R. Moriarty, Esq.,  
8 whose address is Lewis, Brisbois, Bisgaard & Smith, LLP, 550 West "C" Street, Suite 1700  
9 San Diego, CA 92101.

### 10 **JURISDICTION**

11 4. Accusation No. 7123 was filed before the Board and is currently pending against  
12 Respondent. The Accusation and all other statutorily required documents were properly served  
13 on Respondent on August 3, 2021. Respondent timely filed its Notice of Defense contesting the  
14 Accusation. A copy of Accusation No. 7123 is attached as exhibit A and incorporated herein by  
15 reference.

### 16 **ADVISEMENT AND WAIVERS**

17 5. Respondent has carefully read, fully discussed with counsel, and understands the  
18 charges and allegations in Accusation No. 7123. Respondent has also carefully read, fully  
19 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary  
20 Order for Public Reproval.

21 6. Respondent is fully aware of its legal rights in this matter, including the right to a  
22 hearing on the charges and allegations in the Accusation; the right to confront and cross-examine  
23 the witnesses against it; the right to present evidence and to testify on its own behalf; the right to  
24 the issuance of subpoenas to compel the attendance of witnesses and the production of  
25 documents; the right to reconsideration and court review of an adverse decision; and all other  
26 rights accorded by the California Administrative Procedure Act and other applicable laws.

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

1 **CULPABILITY**

2 8. Respondent understands and agrees that the charges and allegations in Accusation  
3 No. 7123, if proven at a hearing, constitute cause for imposing discipline upon its Sterile  
4 Compounding Permit

5 9. For the purpose of resolving the Accusation without the expense and uncertainty of  
6 further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual  
7 basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest  
8 those charges.

9 10. Respondent agrees that its Sterile Compounding Permit is subject to discipline and  
10 they agree to be bound by the Disciplinary Order below.

11 **CONTINGENCY**

12 11. This stipulation shall be subject to approval by the Board. Respondent understands  
13 and agrees that counsel for Complainant and the staff of the Board may communicate directly  
14 with the Board regarding this stipulation and settlement, without notice to or participation by  
15 Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that  
16 they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board  
17 considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order,  
18 the Stipulated Settlement and Disciplinary Order for Public Reapproval 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 for Public Reapproval, including PDF  
23 and facsimile signatures thereto, shall have the same force and effect as the originals.

24 13. This Stipulated Settlement and Disciplinary Order for Public Reapproval is intended by  
25 the parties to be an integrated writing representing the complete, final, and exclusive embodiment  
26 of their agreement. It supersedes any and all prior or contemporaneous agreements,  
27 understandings, discussions, negotiations, and commitments (written or oral). This Stipulated  
28 Settlement and Disciplinary Order for Public Reapproval may not be altered, amended, modified,

1 supplemented, or otherwise changed except by a writing executed by an authorized representative  
2 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 Sterile Compounding Permit No. LSC 100603 issued to  
8 Respondent Rady Children's Hospital-San Diego, dba Children's Hospital & Health Center  
9 Pharmacy shall be publicly reprovved by the Board of Pharmacy under Business and Professions  
10 Code section 495 in resolution of Accusation No. 7123, attached as exhibit A.

11 **Cost Recovery.** Within one year of the effective date of the Decision, Respondent shall  
12 pay \$9,510.37 to the Board for its costs associated with the investigation and enforcement of this  
13 matter pursuant to Business and Professions Code Section 125.3. If Respondent fails to pay the  
14 Board costs as ordered, Respondent shall not be allowed to renew its Sterile Compounding Permit  
15 until Respondent pays costs in full. In addition, the Board may enforce this order for payment of  
16 its costs in any appropriate court, in addition to any other rights the Board may have.

17 **Consultant Review of Pharmacy Operations.** Within 30 days, Respondent shall retain, at  
18 its own expense, an independent consultant who shall review the operations of the facility, during  
19 the period of probation, on a monthly basis for compliance of the facility with state and federal  
20 laws and regulations governing the practice of pharmacy, and compliance by Respondent. The  
21 consultant shall provide the board with an inspection agenda for approval prior to conducting the  
22 inspection. Any inspection conducted without prior approval of the inspection agenda shall not  
23 be accepted. The consultant shall also provide the board with reports documenting the inspection.  
24 The reports shall be provided directly to the board, and receive confirmation of receipt from the  
25 board, prior to providing to the respondent. Should the board determine that the consultant is not  
26 appropriately assessing the operations of Respondent, or providing the appropriate written  
27 reports, the board shall require Respondent to obtain a different consultant through the same  
28 process outlined above, by submitting a new name of an expert within sixty (60) days of

1 respondent being notified of the need for a new consultant. During the period of review, the board  
2 shall retain discretion to reduce the frequency of the consultant's review.

3 Respondent shall submit the name of the proposed consultant for approval within thirty (30)  
4 days of the effective date of this decision. The consultant shall be a pharmacist licensed by and  
5 not on probation with the board or other professional as appropriate and not on probation with the  
6 board, who has been approved by the board to serve in this position. The consultant shall have  
7 sufficient education, training, and professional experience to be able to provide guidance to  
8 Respondent related to the causes for discipline in Case No. 7123. Assumption of any  
9 unauthorized supervision responsibilities shall be considered a violation of this agreement.

10 Respondent shall maintain the consultant for reviews for one year from the date of the  
11 order. Failure to timely seek approval for, timely retain, or ensure timely reporting by the  
12 consultant shall be considered a violation of probation.

13 **Full Compliance.** As a resolution of the charges in Accusation No. 7123, this stipulated  
14 settlement is contingent upon Respondent's full compliance with all conditions of this Order. If  
15 Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for  
16 discipline, including outright revocation, of Respondent's Sterile Compounding Permit No. LSC  
17 100603.

### 18 ACCEPTANCE

19 I have carefully read the above Stipulated Settlement and Disciplinary Order for Public  
20 Reproval and have fully discussed it with my attorney, Marilyn R. Moriarty, Esq. I understand the  
21 stipulation and the effect it will have on my Sterile Compounding Permit. I enter into this  
22 Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and  
23 intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

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

25 \_\_\_\_\_  
26 NICHOLAS HOLMES MD MBA  
27 Senior Vice President and Chief Operating Officer  
28 As the Authorized Representative of  
RADY CHILDREN'S HOSPITAL-SAN DIEGO,  
DBA CHILDREN'S HOSPITAL & HEALTH  
CENTER PHARMACY  
Respondent

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8 Respondent related to the causes for discipline in Case No. 7123. Assumption of any  
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16 discipline, including outright revocation, of Respondent's Sterile Compounding Permit No. LSC  
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20 Reapproval and have fully discussed it with my attorney, Marilyn R. Moriarty, Esq. I understand the  
21 stipulation and the effect it will have on my Sterile Compounding Permit. I enter into this  
22 Stipulated Settlement and Disciplinary Order for Public Reapproval voluntarily, knowingly, and  
23 intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

24 DATED: 3/7/2022



25 NICHOLAS HOLMES MD MBA  
26 Senior Vice President and Chief Operating Officer  
27 As the Authorized Representative of  
28 RADY CHILDREN'S HOSPITAL-SAN DIEGO,  
DBA CHILDREN'S HOSPITAL & HEALTH  
CENTER PHARMACY  
Respondent



1 I have read and fully discussed with Respondent Rady Children's Hospital-San Diego, dba  
2 Children's Hospital & Health Center Pharmacy the terms and conditions and other matters  
3 contained in the above Stipulated Settlement and Disciplinary Order for Public Reapproval. I  
4 approve its form and content.

5 DATED: \_\_\_\_\_

MARILYN R. MORIARTY, ESQ.  
*Attorney for Respondent*

7  
8  
9 **ENDORSEMENT**

10 The foregoing Stipulated Settlement and Disciplinary Order for Public Reapproval is hereby  
11 respectfully submitted for consideration by the Board of Pharmacy of the Department of  
12 Consumer Affairs.

13 DATED: \_\_\_\_\_

Respectfully submitted,

15 ROB BONTA  
Attorney General of California  
16 MARICHELLE S. TAHIMIC  
Supervising Deputy Attorney General

17  
18 DIANE DE KERVOR  
Deputy Attorney General  
19 *Attorneys for Complainant*

20 SD2021800659  
83283533

1 I have read and fully discussed with Respondent Rady Children's Hospital-San Diego, dba  
2 Children's Hospital & Health Center Pharmacy the terms and conditions and other matters  
3 contained in the above Stipulated Settlement and Disciplinary Order for Public Reapproval. I  
4 approve its form and content.

5 DATED: March 3, 2022

*Marilyn R. Moriarty*  
MARILYN R. MORIARTY, ESQ.  
*Attorney for Respondent*

7  
8  
9 **ENDORSEMENT**

10 The foregoing Stipulated Settlement and Disciplinary Order for Public Reapproval is hereby  
11 respectfully submitted for consideration by the Board of Pharmacy of the Department of  
12 Consumer Affairs.

13 DATED: March 7, 2022

14 Respectfully submitted,

15 ROB BONTA  
16 Attorney General of California  
17 MARICHELLE S. TAHIMIC  
18 Supervising Deputy Attorney General

*Diane de Kervor*

19 DIANE DE KERVOR  
20 Deputy Attorney General  
21 *Attorneys for Complainant*

22 SD2021800659  
23 83283533  
24  
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27  
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**Exhibit A**

**Accusation No. 7123**

1 ROB BONTA  
Attorney General of California  
2 JAMES M. LEDAKIS  
Supervising Deputy Attorney General  
3 DIANE DE KERVOR  
Deputy Attorney General  
4 State Bar No. 174721  
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7 Facsimile: (619) 645-2061  
*Attorneys for Complainant*

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15 **HEALTH CENTER PHARMACY**  
16 **3010 Children's Way, Room 2220**  
**San Diego, CA 92123**

**ACCUSATION**

17 **Sterile Compounding Permit No. LSC**  
**100603,**

18 **and**

19 **SUSANNE PLAHUTA WIEDEMAN**  
20 **3020 Children's Way**  
**San Diego, CA 92123**

21 **Pharmacist License No. RPH 52083**

22 Respondents.  
23

24 **PARTIES**

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

27 2. On or about June 27, 2014, the Board of Pharmacy issued Sterile Compounding  
28 Permit Number LSC 100603 to Rady Children's Hospital - San Diego, dba Children's Hospital &

1 Health Center Pharmacy (Respondent Rady). The Sterile Compounding Permit was in full force  
2 and effect at all times relevant to the charges brought herein and will expire on August 1, 2022,  
3 unless it is renewed.

4 3. On or about September 8, 2000, the Board of Pharmacy issued Pharmacist License  
5 Number RPH 52083 to Susanne Plahuta Wiedeman (Respondent Wiedeman). The Pharmacist  
6 License was in full force and effect at all times relevant to the charges brought herein and will  
7 expire on April 30, 2022, unless renewed.

### 8 **JURISDICTION**

9 4. This Accusation is brought before the Board of Pharmacy (Board), Department of  
10 Consumer Affairs, under the authority of the following laws. All section references are to the  
11 Business and Professions Code (Code) unless otherwise indicated.

12 5. Section 118, subdivision (b), of the Code provides that the suspension expiration,  
13 surrender, or cancellation of a license shall not deprive the Board/Registrar/Director of  
14 jurisdiction to proceed with a disciplinary action during the period within which the license may  
15 be renewed, restored, reissued or reinstated.

16 6. Section 4300 of the Code states:

17 (a) Every license issued may be suspended or revoked.

18 (b) The board shall discipline the holder of any license issued by the board,  
19 whose default has been entered or whose case has been heard by the board and found  
guilty, by any of the following methods:

20 (1) Suspending judgment.

21 (2) Placing him or her upon probation.

22 (3) Suspending his or her right to practice for a period not exceeding one year.

23 (4) Revoking his or her license.

24 (5) Taking any other action in relation to disciplining him or her as the board in  
25 its discretion may deem proper.

26 . . . .

27 (e) The proceedings under this article shall be conducted in accordance with  
Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the  
28 Government Code, and the board shall have all the powers granted therein. The  
action shall be final, except that the propriety of the action is subject to review by the

superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

7. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

8. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

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

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

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

9. Section 4402, subsection (a), of the Code provides that any license that is not renewed within three years following its expiration may not be renewed, restored, or reinstated and shall be cancelled by operation of law at the end of the three-year period.

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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:

• • • •

• • • •

11. Section 4306.5 states, in pertinent part:

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

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

## REGULATORY PROVISIONS

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code. Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription.

13. California Code of Regulations, title 16, section 1735.4 (a) states:

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

(4) The beyond use date for the drug preparation;

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

14. California Code of Regulations, title 16, section 1735.7 states:

(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.

(b) The pharmacy shall develop and maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

### **COST RECOVERY**

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

### **FACTUAL ALLEGATIONS**

16. Patient JE, a five year old girl, was cared for by Rady's Children's Hospital Home Care and has been followed in specialty clinics for the management of her chronic kidney disease,



1 and mitochondrial disorder. She routinely receives dextrose-based fluid with electrolytes, a  
2 complex fluid, while at home.

3 17. On July 9, 2019, the patient was admitted to Children's Hospital & Health Center  
4 Pharmacy for replacement of her Broviac Catheter, and GJ tube. The patient's home medications  
5 including the dextrose-based fluid were identified through the medication reconciliation process  
6 and were ordered to be continued.

7 18. As it was from Home Care, the dextrose complex fluid order was non-formulary and  
8 was not recognized, and not integrated with the electronic health record used at the facility  
9 ("Epic"). Pharmacy practice is to rebuild these orders within Epic fluid builder which engages  
10 clinical alerts. However, this order was not rebuilt into fluid builder as it was determined to not be  
11 necessary.

12 19. On that day, the dextrose complex fluid order was prepared using a one-liter bag of  
13 dextrose 5%, because the final volume was greater than 1000ml. This fluid was compounded  
14 correctly, released to the floor and administered without issue.

15 20. On 7/10/2019, the dextrose complex fluid order was changed. It was ordered with a  
16 reduced volume (810ml). Pharmacy Technicians identified the reduced volume and suggested to  
17 Pharmacist A that the CSP be compounded using the Baxa Compounder, rather than manually  
18 removing fluid from a liter bag and manually adding electrolytes. The Baxa Compounder uses  
19 standard manufacturer solutions for compounding. The only dextrose solution on the Baxa  
20 Compounder is dextrose 70%.

21 21. Assuming the dextrose complex fluid order was "built" in Epic fluid builder software,  
22 Pharmacist A modified the order from dextrose 5% base solution to dextrose 70%, assuming the  
23 fluid builder software would auto-calculate the quantity of sterile water to achieve a final dextrose  
24 concentration of 5%.

25 22. An alert was fired to Pharmacist A that "the ordered dextrose dose of 567 grams did  
26 not match the ordered administration dose of 810 mL". The significance of this obscure alert was  
27 not recognized, and the order/production label was released by Pharmacist A into the sterile  
28 compounding area.

1           23. The production order was received by Technician A and was manually entered into  
2 the compounder. Dextrose 70% was pumped by the compounder for the entire 810 ml volume; no  
3 sterile water was added to dilute the dextrose 70%.

4           24. The compounded solution was labeled with a medication label and initialed by  
5 Technician A. The compounder production label was initialed by Technician A and along with  
6 the complex fluid solution passed to the front-end pharmacist for verification. Pharmacist A  
7 collected the labeled IV solution, the production label and MixCheck Report to verify the  
8 preparation.

9           25. The production label and MixCheck Report clearly indicate 810 ml of dextrose 70%  
10 was utilized in the production. Pharmacist A failed to recognize that sterile water was not added  
11 to the dextrose 70% based compound. Pharmacist A placed the production label on the reverse of  
12 the MixCheck Report and initialed the production label and the label on the IV solution.

13           26. The IV solution label failed to identify the concentration of dextrose contained within  
14 the bag. This appears to be secondary to the original nonintegrated, non-formulary order.

15           27. The IV bag was released to the floor.

16           28. The floor nurse reviewed the medication label and used a barcode scanner to match  
17 the medication label on the bag to the patient's identification band and to the medication order in  
18 the medication administration record. This barcode confirmation assures patient-order-product  
19 label match; it does not confirm IV solution ingredients. After a match was confirmed a smart  
20 pump was programmed to administer the IV solution.

21           29. At 0225 on 7/11/2019 the RN noted tachycardia on the central monitor (HR 140's).  
22 The RN assessed the patient and noted desaturation, and that the patient was unresponsive to  
23 touch or verbal stimulation. A rapid response was called. The covering resident arrived at 0240,  
24 and the Rapid Response team and charge nurse at 0243. The patient was noted to begin seizing  
25 and was transported to the pediatric intensive care unit (PICU) at 0300.

26           30. The patient was noted to be hyperglycemic (increased glucose), hyponatremic  
27 (decreased sodium) and have profound metabolic acidosis. The intravenous fluids were stopped  
28 within the first hour of admission to the pediatric intensive care unit.

1           31. The patient was supported in the pediatric intensive care unit (PICU) until her death  
2 on July 20, 2019.

3           32. Full disclosures were provided to the family of this patient regarding this medication  
4 error. The facility investigated the incident and it was reported to the California Department of  
5 Public Health. The California Department of Public Health prepared a report and recommended  
6 corrective actions.

7 Causes for Discipline Against Respondent Rady (LSC 100603)

8 **FIRST CAUSE FOR DISCIPLINE**

9 (Unprofessional Conduct – Variation from Prescription)

10           33. Respondent Rady is subject to disciplinary action under Code section 4301,  
11 subsections (j) and (o) and Code of Regulations section 1716 in that the prescription at issue was  
12 a variation from the ordered prescription, as described in paragraphs 16 to 32 above and as  
13 follows:

14           34. Regulations section 1716 states that pharmacists shall not deviate from the  
15 requirements of a prescription except upon the prior consent of the prescriber or to select the drug  
16 product in accordance with Section 4073 of the Business and Professions Code. Nothing in this  
17 regulation is intended to prohibit a pharmacist from exercising commonly accepted  
18 pharmaceutical practice in the compounding or dispensing of a prescription.

19           35. On July 10, 2019, Respondent's Rady was not compliant with Pharmacy Law or with  
20 this regulation when order 93114558 was prescribed for dextrose 5%, was compounded and  
21 dispensed with dextrose 70%, and then administered to the 5-year-old JE who passed away on  
22 July 20, 2019.

23 **SECOND CAUSE FOR DISCIPLINE**

24 (Unprofessional Conduct – Incorrect Compounding Label)

25           36. Respondent Rady is subject to disciplinary action under Code section 4301,  
26 subsections (j) and (o) and Code of Regulations section 1735.4(a) in that the prescription at issue  
27 had an incorrect compounding label, as described in paragraphs 16 to 35 above and as follows:  
28

1 37. California Code of Regulations section 1735.4(a) states that each compounded drug  
2 preparation shall be affixed with a container label prior to dispensing that contains at least the  
3 Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed  
4 IV solutions, the intravenous solution utilized shall be included.

5 38. On July 10, 2019, Respondent Rady was not compliant with Pharmacy Law or with  
6 this regulation when order 93114558 was not labeled with the intravenous solution utilized and  
7 the label only stated "dextrose" not dextrose 70%.

8 **THIRD CAUSE FOR DISCIPLINE**

9 (Unprofessional Conduct – Lack of Compounding Training)

10 39. Respondent Rady is subject to disciplinary action under Code section 4301,  
11 subsections (j) and (o) and Code of Regulations section 1735.7 in that the prescription at issue  
12 was prepared by untrained and unskilled personnel, as described in paragraphs 16 to 38 above and  
13 as follows:

14 40. California Code of Regulations section 1735.7 provides that a pharmacy engaged in  
15 compounding shall maintain documentation demonstrating that personnel involved in  
16 compounding has the skills and training required to properly and accurately perform their  
17 assigned responsibilities and documentation demonstrating that all personnel involved in  
18 compounding are trained in all aspects of policies and procedures. This training shall include but  
19 is not limited to support personnel (e.g. institutional environmental services, housekeeping),  
20 maintenance staff, supervising pharmacist and all others whose jobs are related to the  
21 compounding process. Pharmacy personnel assigned to compounding duties shall demonstrate  
22 knowledge about processes and procedures used in compounding prior to compounding any drug  
23 preparation and the Pharmacist in Charge shall ensure that all pharmacy personnel engaging in  
24 compounding sterile drug preparations has training and demonstrated competence in the safe  
25 handling and compounding of sterile drug preparations, including hazardous agents if the  
26 pharmacy compounds products with hazardous agents.

27 39. On July 10, 2019, Respondent Rady was not compliant with Pharmacy Law or with  
28 this regulation when a Pharmacy Technician was allowed to compound order 93114558 for

1 patient JE with a Baxa compounder, without completing training that demonstrated her ability to  
2 properly and accurately do so. The Pharmacy Technician had no training or demonstrated  
3 competence for the use of this compounding equipment and the medication she prepared was not  
4 correctly compounded.

5 Causes for Discipline Against Respondent Wiedeman (RPH 52083)

6 **FOURTH CAUSE FOR DISCIPLINE**

7 (Unprofessional Conduct – Variation from Prescription)

8 41. Respondent Weideman is subject to disciplinary action under Code section 4301,  
9 subsections (j) and (o), and Code of Regulations section 1716 in that the prescription at issue was  
10 a variation from the prescription, as described in paragraphs 16 to 40 above and as follows:

11 42. California Code of Regulations section 1716 states that pharmacists shall not  
12 deviate from the requirements of a prescription except upon the prior consent of the prescriber or  
13 to select the drug product in accordance with Section 4073 of the Business and Professions Code.  
14 Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly  
15 accepted pharmaceutical practice in the compounding or dispensing of a prescription.

16 43. On July 10, 2019, Respondent Weideman was not compliant with Pharmacy Law or  
17 with this regulation when, while working as a Pharmacist at Children's Hospital, she allowed  
18 order 93114558, prescribed for dextrose 5%, to be compounded and dispensed with dextrose  
19 70%, and then administered to the 5-year-old JE, who passed away on July 20, 2019.

20 **FIFTH CAUSE FOR DISCIPLINE**

21 (Unprofessional Conduct – Incorrect Compounding Label)

22 44. Respondent Wiedeman is subject to disciplinary action under Code section 4301,  
23 subsections (j) and (o) and Code of Regulations section 1735.4(a) in that the prescription at issue  
24 had an incorrect compounding label, as described in paragraphs 16 to 43 above and as follows:

25 45. California Code of Regulations section 1735.4(a) states that each compounded drug  
26 preparation shall be affixed with a container label prior to dispensing that contains at least the  
27 Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed  
28 IV solutions, the intravenous solution utilized shall be included.

46. On July 10, 2019, Respondent Weideman was not compliant with Pharmacy Law or with this regulation when, while working as a Pharmacist at Children’s Hospital, she allowed order 93114558 to not be labeled with the intravenous solution utilized and the label only stated “dextrose” not dextrose 70%.

### **SIXTH CAUSE FOR DISCIPLINE**

(Unprofessional Conduct – Failure to Exercise and Implement Best Professional Judgment)

47. Respondent Wiedeman is subject to disciplinary action under Code section 4301, subsections (j) and (o), and 4306.5(b) in that she failed to exercise and implement her best professional judgment as described in paragraphs 16 to 47 above and as follows:

48. Section 4306.5(b) provides that unprofessional conduct for a pharmacist may include acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

49. On July 10, 2019, Respondent Weideman was not compliant with Pharmacy Law or with this section when, while working as a Pharmacist at Children's Hospital, she failed to exercise or implement her best professional judgment when she entered order 93114558 - which was prescribed for dextrose 5% but entered for dextrose 70%. Respondent Wiedeman then supervised a Pharmacy Technician, who was untrained, while compounding order 93114558. Finally, Respondent Wiedeman verified and dispensed order 93114558 which deviated from the prescriber's order. Order 93114558 was administered to the 5-year-old JE who passed away on July 20, 2019. Respondent Wiedeman failed to exercise or implement her best professional judgment, which lead to a patient's death.

## OTHER MATTERS

50. Pursuant to Code section 4307, if discipline is imposed on Sterile Compounding Permit Number LSE 100603 issued to Rady Children's Hospital - San Diego, DBA Children's Hospital & Health Center Pharmacy, Rady Children's Hospital - San Diego, DBA Children's Hospital & Health Center Pharmacy shall be prohibited from serving as a manager, administrator,

owner, member, officer, director, associate, or partner of a licensee for five years if Sterile Compounding Permit Number LSE 100603 is placed on probation or until Sterile Compounding Permit Number LSE 100603 is reinstated if it is revoked.

51. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 52083 issued to Susanne Plahuta Wiedeman, then Susanne Plahuta Wiedeman shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any position with management or control of a license for five years if Pharmacist License No. RPH 52083 is placed on probation or until Sterile Compounding Permit Number LSE 100603 is reinstated if it is 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 Sterile Compounding Permit Number LSC 100603, issued to Rady Children's Hospital-San Diego, dba Children's Hospital & Health Center Pharmacy;

2. Revoking or suspending Pharmacist License Number RPH 52083, issued to Susanne Plahuta Wiedeman;

3. Prohibiting Rady Children's Hospital-San Diego, dba Children's Hospital & Health Center Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Sterile Compounding Permit Number LSC 100603 is placed on probation or until Sterile Compounding Permit Number LSC 100603 is reinstated if Sterile Compounding Permit Number LSC 100603 issued to Rady Children's Hospital-San Diego, dba Children's Hospital & Health Center Pharmacy is revoked;

4. Prohibiting Susanne Plahuta Wiedeman from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 45895 is placed on probation or until Pharmacist License Number RPH 52083 is reinstated if Pharmacist License Number RPH 52083 issued to Susanne Plahuta Wiedeman is revoked;

5. Ordering Rady Children's Hospital-San Diego, dba Children's Hospital & Health Center Pharmacy and Susanne Plahuta Wiedeman 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,

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

DATED: 7/29/2021

Signature on File

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

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