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

## In the Matter of the Accusation Against:

## DAVID EUGENE ENGLAND, Respondent

## Registered Pharmacist License No. RPH 36116

## Agency Case No. 6882

## OAH No. 2020100589

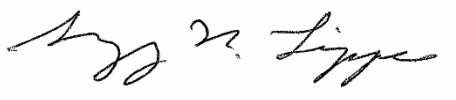
## DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval 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 12, 2021.

It is so ORDERED on April 12, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Greg Lippe
Board President

XAVIER BECERRA
Attorney General of California
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Supervising Deputy Attorney General
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*Attorneys for Complainant*

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

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|---|---|
| In the Matter of the Accusation Against**:**<br><br>**DAVID EUGENE ENGLAND**<br>**4430 N. Chieftain**<br>**Las Vegas, NV 89129**<br><br>**Registered Pharmacist License No. RPH 36116**<br><br>Respondent. | Case No. 6882<br><br>OAH No. 2020100589<br><br>**STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL**<br><br>**[Bus. & Prof. Code § 495]** |

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

## PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Joshua B. Eisenberg, Deputy Attorney General.

2. Respondent David Eugene England (Respondent) is represented in this proceeding by attorney Robert F. Hahn of the law firm Gould, Hahn, & Reinhardt, PLC, whose address is: 2550 Ninth Street, Suite 101, Berkeley, CA 94710.

## JURISDICTION

3. On or about December 19, 1980, the Board issued Registered Pharmacist License No. RPH 36116 to David Eugene England (Respondent). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 6882 and will expire on December 31, 2022, unless renewed.

4. Accusation No. 6882 was filed before the Board and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on May 27, 2020. Respondent timely filed his Notice of Defense contesting the Accusation. A copy of Accusation No. 6882 is attached as exhibit A and incorporated herein by reference.

## ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6882. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

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

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

## CULPABILITY

8. Respondent understands that the charges and allegations in Accusation No. 6882, if proven at a hearing, constitute cause for imposing discipline upon his Registered Pharmacist License.

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

10. Respondent agrees that his Registered Pharmacist License is subject to discipline and he agrees to be bound by the Disciplinary Order below.

## CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent 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 Reproval 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.

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

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

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

**DISCIPLINARY ORDER**

IT IS HEREBY ORDERED that Registered Pharmacist License No. RPH 36116 issued to Respondent David Eugene England (Respondent) shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 6882, attached as exhibit A.

**Coursework**. No later than one year from the effective date of the public reproval, Respondent, at his own expense, shall enroll, successfully complete and submit verification of course(s) in the areas of pharmacy law and operations (5 hours) and compounding (5 hours). At least 50% of the coursework must be completed via live webinar and/or in-person. Respondent shall obtain prior approval from the Board before enrolling in the course(s). Respondent shall submit to the Board the original transcripts or certificates of completion for the above-required course(s).

**Cost Recovery**. No later than one year from the effective date of the Decision, Respondent shall pay $5,000 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew his Registered Pharmacist License until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

**Full Compliance**. As a resolution of the charges in Accusation No. 6882, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Registered Pharmacist License No. RPH 36116.

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## ACCEPTANCE

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

DATED: _____

DAVID EUGENE ENGLAND
*Respondent*

I have read and fully discussed with Respondent David Eugene England the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: _____

ROBERT F. HAHN
*Attorney for Respondent*

## ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval 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
KAREN R. DENVIR
Supervising Deputy Attorney General

JOSHUA B. EISENBERG
Deputy Attorney General
*Attorneys for Complainant*

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## ACCEPTANCE

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

DATED: 3/8/2021

DAVID EUGENE ENGLAND
*Respondent*

I have read and fully discussed with Respondent David Eugene England the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 3/8/2021

ROBERT F. HAHN
*Attorney for Respondent*

## ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval 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
KAREN R. DENVIR
*Supervising Deputy Attorney General*

JOSHUA B. EISENBERG
Deputy Attorney General
*Attorneys for Complainant*

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## ACCEPTANCE

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DATED: _____

DAVID EUGENE ENGLAND
*Respondent*

I have read and fully discussed with Respondent David Eugene England the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: _____

ROBERT F. HAHN
*Attorney for Respondent*

## ENDORSEMENT

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

DATED: 3/8/21

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
KAREN R. DENVIR
Supervising Deputy Attorney General

JOSHUA B. EISENBERG
Deputy Attorney General
*Attorneys for Complainant*

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# Exhibit A

**Accusation No. 6882**

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Supervising Deputy Attorney General
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Deputy Attorney General
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*Attorneys for Complainant*

**BEFORE THE**
**BOARD OF PHARMACY**
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| In the Matter of the Accusation Against**:**<br><br>**DAVID EUGENE ENGLAND**<br>**4430 N. Chieftain**<br>**Las Vegas, NV 89129**<br><br>**Registered Pharmacist License No. RPH 36116**<br><br>Respondent. | Case No. 6882<br><br>**ACCUSATION** |

## PARTIES

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.

2. On or about December 19, 1980, the Board of Pharmacy issued Registered Pharmacist License Number RPH 36116 to David Eugene England (Respondent). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on December 31, 2020, unless renewed.

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## JURISDICTION

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

4. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

5. Code section 4300, subdivision (a) provides that every license issued by the Board may be suspended or revoked.

6. Code section 4300.1 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.

## STATUTORY PROVISIONS

7. Code section 4022 states:

> "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:
>
> (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
>
> (b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
>
> (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

8. Code section 4301 states in pertinent part:

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

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

…

(j) The violation of any of the statutes of this state, or 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 any other state or federal regulatory agency

…

9. Code section 4306.5 states, in pertinent part:

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

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

10. Code section 4113, subdivision (c) states:

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.

**REGULATORY PROVISIONS**

11. Code of Federal Regulations, title 21, section 1301.12(a) states:

A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

12. Code of Federal Regulations, title 21, section 1305.04 states:

(a) Only persons who are registered with DEA under section 303 of the Act (21 U.S.C. 823) to handle Schedule I or II controlled substances, and persons who are registered with DEA under section 1008 of the Act (21 U.S.C. 958) to export these substances may obtain and use DEA Form 222 (order forms) or issue electronic orders for these substances. Persons not registered to handle Schedule I or II controlled substances and persons registered only to import controlled substances are not entitled to obtain Form 222 or issue electronic orders for these substances.

(b) An order for Schedule I or II controlled substances may be executed only on behalf of the registrant named on the order and only if his or her registration for the substances being purchased has not expired or been revoked or suspended.

13. Code of Federal Regulations, title 21, section 1305.06 states, in pertinent part:

An order for Schedule I and II controlled substances, whether on a DEA Form 222 or an electronic order, may be filled only by a person registered with DEA as a manufacturer or distributor of controlled substances listed in Schedule I or II pursuant to section 303 of the Act (21 U.S.C. 823) or as an importer of such substances pursuant to section 1008 of the Act (21 U.S.C. 958), except for the following:

. . .

(c) A person registered to dispense Schedule II substances may distribute the substances to another dispenser with either a DEA Form 222 or an electronic order only in the circumstances described in §1307.11 of this chapter.

14. Code of Federal Regulations, title 21, section 1307.11 states, in pertinent part:

(a) A practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to—

(1) Another practitioner for the purpose of general dispensing by the practitioner to patients, provided that—

(i) The practitioner to whom the controlled substance is to be distributed is registered under the Act to dispense that controlled substance;

(ii) The distribution is recorded by the distributing practitioner in accordance with §1304.22(c) of this chapter and by the receiving practitioner in accordance with §1304.22(c) of this chapter;

(iii) If the substance is listed in Schedule I or II, an order form is used as required in part 1305 of this chapter; and

(iv) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section and §1301.25 of this chapter during each calendar year in which the practitioner is registered to dispense does not exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the same calendar year.

(2) A reverse distributor who is registered to receive such controlled substances.

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15. California Code of Regulations, title 16, section 1250.4 states, in pertinent part:

> The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:
>
> . . .
>
> 4. A sink with hot and cold running water must be within the parenteral solution compounding area or adjacent to it.

16. California Code of Regulations, title 16, section 1714 states, in pertinent part:

> . . .
>
> (c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

17. California Code of Regulations, title 16, section 1735.2 states, in pertinent part:

> (e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:
> . . .
>
> (2) Equipment to be used.
> . . .
>
> (4) Inactive ingredients to be used.

18. California Code of Regulations, title 16, section 1751.1 states, in pertinent part:

> (a) In addition to the records required by section 1735.3, any pharmacy engaged in any compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:
>
> (1) Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.
>
> (2) Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.
>
> (3) Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.

19. California Code of Regulations, title 16, section 1751.3 states, in pertinent part:

> (a) Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:
>
> (1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.
>
> . . .
>
> (9) Facility management including certification and maintenance of controlled environments and related equipment.
>
> . . .
>
> (14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.
>
> . . .
>
> (19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.
>
> . . .
>
> (20) Record keeping requirements.
>
> . . .
>
> (24) Visual inspection and other final quality checks of sterile drug preparations.
>
> . . .
>
> (b) For lot compounding, the pharmacy shall maintain written policies and procedures that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:
>
> (1) Use of master formula documents and compounding logs.
>
> (2) Appropriate documentation.
>
> (3) Appropriate sterility and potency testing.
>
> . . .

(e) All personnel involved must read the policies and procedures before compounding sterile drug preparations. All personnel involved must read all additions, revisions, and deletions to the written policies and procedures. Each review must be documented by a signature and date.

20. California Code of Regulations, title 16, section 1751.5 states, in pertinent part:

(a) When compounding sterile drug preparations the following standards must be met:

(1) Personal protective equipment consisting of a non-shedding gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times. For hazardous compounding double shoe covers are required.

. . .

(5) Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

21. California Code of Regulations, title 16, section 1751.6 states, in pertinent part:

(e) Pharmacies that compound sterile drug preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

. . .

(C) Sterile preparation compounding documentation.

. . .

(E) Aseptic preparation procedures.

. . .

(G) General conduct in the controlled area (aseptic area practices).

(H) Cleaning, sanitizing, and maintaining of the equipment and the controlled area.

. . .

22. California Code of Regulations, title 16, section 1793.7 states, in pertinent part:

. . .

(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

. . .

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.

## COST RECOVERY

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

## DRUGS

24. *Fentanyl* is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (c)(8), and a dangerous drugs pursuant to Code section 4022. It is used to treat pain.

25. *Vancomycin* is a dangerous drug pursuant to Code section 4022. It is used as an antibiotic.

## FACTUAL ALLEGATIONS

### UKIAH VALLEY MEDICAL CENTER

26. On or about November 1, 2017, Board Inspector P.P. conducted an inspection for renewal of the sterile compounding license at Ukiah Valley Medical Center in Ukiah, CA (UVMC). Upon arrival, Inspector P.P. was assisted by Respondent, the Pharmacist-in-charge at UVMC. During the inspection, Inspector P.P. observed and identified several areas of non-compliance with state and federal regulations related to garbing, operational standards, policies and procedures, master formulas, training of compounding staff, lot compounding without policy

and procedures or potency testing, process validation not completed in equipment as required, and direct supervision of technicians.

**FIRST CAUSE FOR DISCIPLINE**

**(Failure to Follow or Comply with Regulations Pertaining to Pharmacy Practice)**

27. Respondent is subject to disciplinary action under Code section 4301, subdivisions (o) and (j), in that he failed to follow or comply with regulations pertaining to the practice of pharmacy. The violations are as follows:

a. **Cal. Code Regs., tit. 16, § 1751.5, subds. (a)(1), (5):** Respondent failed to ensure the preparation of sterile compounded products while donning a non-shedding gown. Instead, the staff donned isolation gowns which are typically used for infection control in the hospital and known to tear easily.

b. **Cal. Code Regs., tit. 16, § 1714, subd. (c) and Cal. Code Regs., tit. 24, §1250.4, subd. (4):** Respondent failed to have hot water available in the sink located in the ante room.

c. **Cal. Code Regs., tit. 16, § 1751.3, subds. (a)(1), (9), (14), (19), (20), and (24):** Respondent failed to have policies and procedures for compounding. Respondent was aware that the policies and procedures were not written specifically to comport with current regulations. Specifically, Inspector P.P. reviewed policies and procedures and observed that they had been written prior to the change in regulations on January 1, 2017. The policies and procedures were deficient as follows:

i. They stated that maintenance/certification was conducted in a laminar flow hood, and did not reflect the facility's current use of a Compounding Aseptic Isolator (CAI), testing procedures within the CAI by compounders, or proper conduct associated with the use of a CAI.

ii. They failed to identify action levels detected during viable surface sampling, glove fingertip, media fill or during viable air sampling.

iii. They did not outline training and competency evaluation of all staff involved in the preparation of sterile compounded products.

/ / /

iv. They stated to train with an ASHP module when in fact, several staff received didactic training from Critical Point modules.

v. They failed to identify quality assurance requirements of process validation in both hoods and the documentation thereof.

vi. They did not specifically state record keeping requirements for all documents required of sterile compounding.

vii. They did not include lot compounding and the requirement of sterility and potency testing. Specifically, at inspection, there were other policies and procedures or standard operating procedures available to some of the staff making the procedures followed by compounding staff inconsistent and could increase the risk of errors.

d. **Cal. Code Regs., tit. 16, § 1735.2, subds. (e)(2), (4):** Respondent failed to have master formulas which contained all of the regulatory elements. Specifically, when requested at inspection, none of the staff, including Respondent, could retrieve the master formulas.

e. **Cal. Code Regs., tit. 16, § 1751.6, subds. (e)(1)(A), (C), (E), (G), and (H):** Respondent failed to comply with training requirements within this code. Specifically, training documentation was not available at inspection for all compounders of at least the following: didactic training, aseptic technique, sterile compounding documentation, general conduct in the controlled area, cleaning and sanitizing of equipment in the controlled area. Additionally, Respondent failed to produce training and proof of competency for all compounders within a month of the inspection.

f. **Cal. Code Regs., tit. 16, § 1751.3, subd. (b):** Respondent failed to establish a policy and procedure for lot compounding.

g. **Cal. Code Regs., tit. 16, § 1751.1, subds. (a)(1), (2), and (3):** Respondent failed to maintain sterile compounding records for three years including, documents related to training and competency, results of fingertip and media fill conducted in both the BSC and CAI hoods, and master formulas.

/ / /

**SECOND CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct)**

28. Respondent is subject to disciplinary action under Code section 4113, subdivision (c) as it relates to Code section 4306.5, subdivision (a), in that he failed to ensure the pharmacy's compliance with state and federal regulations, as set forth in paragraphs 26-27, above.

**FACTUAL ALLEGATIONS**

**EMANUEL SPECIALTY CLINIC MEDICAL ONCOLOGY PHARMACY**

29. On or about January 21, 2019, Respondent became the Pharmacist-in-charge at Emanuel Specialty Clinic Medical Oncology Pharmacy (Emanuel Oncology), located in Turlock, CA.

30. On or about April 16, 2019, Board Inspector J.W. (Inspector J.W.) visited Emanuel Oncology for a renewal inspection of their sterile compounding license. Upon arrival, Inspector J.W. made contact with Respondent, who was introduced as the interim Director of Pharmacy/Pharmacist-in-charge. During the inspection of Emanuel Oncology, Inspector J.W. discovered that the oncology pharmacy was preparing hazardous compounded sterile products and narcotic compounded sterile products, such as batch compounding of Patient-Controlled Epidural Analgesia (PCEA) for Emanuel Medical Center. Following this discovery, Inspector J.W. requested that Respondent produce a copy of the pharmacy's DEA registration. Respondent informed the Inspector that the that the pharmacy does not have a DEA registration.

**THIRD CAUSE FOR DISCIPLINE**

**(Failure to Follow or Comply with Regulations Pertaining to Pharmacy Practice)**

31. Respondent is subject to disciplinary action under Code section 4301, subdivisions (o) and (j), in that Respondent violated the federal laws regulating controlled substances, as follows:

a. **C.F.R., tit. 21, § 1301.2, subd. (a):** On or between January 21, 2019 and April 15, 2019, while acting as Pharmacist-in-charge of Emanuel Oncology, Respondent prepared sterile controlled substance compounded products for patients of Emanuel Medical Center without a DEA registration.

b. **C.F.R., tit. 21, § 1305.04:** On or between January 21, 2019 and April 15, 2019, while acting as Pharmacist-in-charge of Emanuel Oncology, Respondent transferred Schedule II controlled substance(s) to Emanuel Oncology, to prepare sterile controlled substance compounded products for patients of Emanuel Medical Center. During this time, Emanuel Oncology was not registered with the DEA.

c. **C.F.R., tit. 21, § 1305.06, subd. (c):** On or between January 21, 2019 and April 15, 2019, while acting as Pharmacist-in-charge of Emanuel Oncology, Respondent transferred Schedule II controlled substance(s) from Emanuel Medical Center to Emanuel Oncology to prepare sterile controlled substances compounded products for patients of Emanuel Medical Center. During this time, Emanuel Oncology was not registered with the DEA.

**FOURTH CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct)**

32. Respondent is subject to disciplinary action under Code section 4113, subdivision (c) in that Respondent failed to ensure Emanuel Oncology's compliance with federal law, as set forth more particularly in paragraphs 29-31, above.

**DISCIPLINE CONSIDERATIONS**

33. To determine the degree of discipline, if any, to be imposed on Respondent, Complainant alleges that on or about February 12, 2016, the Board issued Citation Number CI 2015 69023 against Respondent. Respondent was cited for violations of California Code of Regulations, title 16, sections 1714(d) (failure to secure pharmacy), 1735.2(d) (failure to ensure the pharmacy created master formulas prior to compounding oral and sterile IV medications), 1735.8(a) (failure to ensure sterile compounding end product testing was being completed), and 1735.8(b) (failure to ensure microbiological testing was performed at the correct temperature and length of time). Respondent was assessed a civil penalty in the amount of $2,000.00 which Respondent paid in full.

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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 Registered Pharmacist License Number RPH 36116, issued to David Eugene England;

2. Ordering David Eugene England 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,

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

DATED: May 26, 2020

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

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