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

In the Matter of the Accusation Against: **SWAPIL VISHWASROA PATIL** **1680 Rio Vista Way** **Yuba City, CA 95993** **Original Pharmacist License No. RPH 56473** Respondent.	Case No. 5592 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about October 19, 2004, the Board of Pharmacy ("Board") issued Original Pharmacist License Number RPH 56473 to Swapil Vishwasroa Patil ("Respondent"). The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2016, unless renewed. At all times alleged herein, Respondent was the Pharmacist-In-Charge within the meaning of Business and Professions Code section 4113.

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JURISDICTION

3. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

4. Section 4300 of the Code states, in pertinent part:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

5. 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."

STATUTORY PROVISIONS

6. Section 4301 of the Code 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 procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following: . . .
>
> (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
>
> . . .
>
> (*o*) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

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7. Code section 4022 states, in pertinent part:

"Dangerous drug" . . . means any drug . . . unsafe for self-se 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.

. . .

(c) Any other drug . . . that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

8. Code section 4113 states, in pertinent part:

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

. . .

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

REGULATORY PROVISIONS

9. California Code of Regulations, title 16, section 1716 states:

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.

10. California Code of Regulations, title 16, section 1735.3 states, in pertinent part:

(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to

an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

(7) A pharmacy assigned reference or lot number for the compounded drug product.

(8) The expiration date of the final compounded drug product.

(9) The quantity or amount of drug product compounded.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

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

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going 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.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

DRUG

12. **Liothyronine (T3)** is a man-made form of a hormone that is normally produced by the thyroid gland to regulate the body's energy and metabolism, and is a dangerous drug within the meaning of Code section 4022. It is prescribed for thyroid replacement.

COST RECOVERY

13. 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.

BACKGROUND

14. At all times alleged herein, Respondent was the Pharmacist-In-Charge employed by Walgreens #933 Pharmacy located at 855 Colusa Highway, Yuba City, California, ("Walgreens"). As the Pharmacist-In-Charge, Respondent was responsible for Walgreens' compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

15. On or about January 26, 2013, Dr. D. B. prescribed the drug "T(3) 22.5 MCG SR CAP," quantity of 60, and 30 days supply to Consumer K. S. for treating her thyroid condition. The prescription was submitted to Walgreens for compounding the medication. The compounded T(3) contained a previously mixed aliquot[1] prepared by an unknown person on an unknown date. The aliquot contained up to three unknown ingredients. Respondent admittedly did not maintain a worksheet verifying the person who had mixed the aliquot, its ingredients, the date prepared, and other information required by California Code of Regulations, title 16, section 1735.5, subdivision (a).

16. On or about January 26, 2013, Respondent verified and dispensed Prescription No. RX4080895, the compounded T(3) drug, to Consumer K. S. The Consumer ingested the drug, per the prescription, for treatment of her thyroid condition. Within days of taking it, the Consumer reported to Dr. D. B. that she was not feeling well, and went on her scheduled vacation to Texas. While on vacation, Consumer K. S. was hospitalized for five days and was diagnosed that she was in "thyroid storm." [2] She had complaints of shortness of breath, palpitations, and tachycardia, and went into heart failure. The Texas hospital took the Consumer off the compounded T(3) drug. Upon her return to California, the Consumer exhibited continued symptoms of cardiomyopathy as a result of the high levels of the compounded T(3).

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[1] An aliquot is part of a medicine or chemicals.

[2] "Thyroid storm," also known as "thyrotoxic crisis," is an acute, life-threatening, hypermetabolic state induced by excessive release of thyroid hormones in individuals with thyrotoxicosis. Symptoms include fever, tachycardia, hypertension, and neurological and GI abnormalities. Hypertension may be followed by congestive heart failure that is associated with hypotension and shock.

17. On an unknown date after January 26, 2013 and after Consumer K. S. had returned from Texas, Dr. D. B. obtained the Consumer's bottle of the compounded T(3) drug, took it to Respondent at Walgreens, and requested an analysis be conducted on the drug. At least five capsules were retained and analyzed. The analysis disclosed that the compounded T(3) capsules in Prescription RX4080895 were compounded in a formulation in which each capsule contained 406.65mcg instead of the prescribed dose of 22.5mcg. Respondent dispensed Prescription RX4080895 to Consumer K. S. without properly verifying that the compounded T(3) capsules complied with Dr. D. B.'s prescription for the drug "T(3) 22.5 MCG SR CAP." Respondent's failure resulted in harm to Consumer K. S. as described in paragraph 16, above.

18. On or about October 22, 2013, Respondent admitted to the Board's investigator that he had not maintained written documentation sufficient to demonstrate that the Walgreens' personnel involved in compounding the T(3) for Prescription No. RX4080895 had the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding. He also admitted that the personnel had not been trained in compounding.

FIRST CAUSE FOR DISCIPLINE

(Deviation from Prescription Without Consent)

19. Respondent is subject to disciplinary action under Code section 4301, subdivisions (j) and (*o*), in conjunction with Code of Regulations, title 16, section 1716, in that on or about January 26, 2013, Respondent deviated from the requirements of a prescription without the prior consent of the prescribing physician, as set forth in paragraphs 14 through 17, above, incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Failure to Comply With Compounding Requirements)

20. Respondent is subject to disciplinary action under Code section 4301, subdivisions (j) and (*o*), in conjunction with Code of Regulations, title 16, section 1735.5, subdivision (a), in that on or about January 26, 2013, Respondent failed to maintain the required documentation for the aliquot, which was compounded and contained up to three ingredients, that he used in the

compound of the T(3) drug for Consumer K. S., as set forth in paragraph 15, above, incorporated herein by reference. Specifically,

a. Respondent failed to maintain a worksheet for the compounded aliquot containing the master formula;

b. Respondent failed to maintain a worksheet stating the date the compounded aliquot was compounded;

c. Respondent failed to maintain a worksheet stating the identity of the personnel who compounded the aliquot;

d. Respondent failed to maintain a worksheet stating the identity of the pharmacist reviewing the final compounded aliquot product;

e. Respondent failed to maintain a worksheet stating the quality of each drug product in the compounded aliquot;

f. Respondent failed to maintain a worksheet stating the pharmacy reference number for the compounded aliquot;

g. Respondent failed to maintain a worksheet stating the expiration date of the final compounded aliquot; and

h. Respondent failed to maintain a worksheet stating the quantity or amount of the compounded aliquot.

THIRD CAUSE FOR DISCIPLINE

(Failure to Train Pharmacy Personnel in Compounding)

21. Respondent is subject to disciplinary action under Code section 4301, subdivisions (j) and (*o*), in conjunction with Code of Regulations, title 16, section 1735.7, subdivision (a), in that he admittedly failed to comply with this regulation, as set forth in paragraph 18, above, incorporated herein by reference, as follows:

a. Respondent failed to maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding;

b. Respondent failed to develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and failed to maintain documentation of any and all training related to compounding undertaken by pharmacy personnel; and

c. Respondent failed to ensue that pharmacy personnel assigned to compounding duties could demonstrate knowledge about the processes and procedures used in compounding prior to compounding any drug product.

DISCIPLINARY CONSIDERATIONS

22. Complainant requests that the following be taken into consideration when determining the level of discipline in this matter:

a. On or about July 10, 2013, the Board issued Citation No. CI 2012 57471 against Respondent alleging that Respondent, while employed as a Pharmacist at Walgreens Pharmacy located in Yuba City, California, had compounding equipment and instruments that were in unsanitary conditions, specifically (a) the drugs were stored on equipment in the midst of extremely unclean conditions; (b) the drugs were not maintained in an orderly fashion; and, (c) the unsanitary conditions were easily visible to Consumers. Respondent was charged with violating California Code of Regulations, title 16, section 1714, subdivisions (b) and (c), and the fine of $500.00 was imposed. Respondent timely paid the fine.

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 Pharmacist License Number RPH 56473, issued to Swapil Vishwasroa Patil;

2. Ordering Swapil Vishwasroa Patil 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;

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

DATED: 1/25/16

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

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