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

In the Matter of the Accusation Against: **SCRIPTE CORPORATION** 2907 Empire Avenue Burbank, CA 91504 NAVID DOOSTAN, Pharmacist-in-Charge **Original Permit No. PHY 51624** **NAVID DOOSTAN** 15039 Burbank Boulevard, Apt. 103 Van Nuys, CA 91411 **Original Pharmacist License No. RPH 68475** Respondents.	Case No. 5665 **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 31, 2013, the Board of Pharmacy issued Original Permit Number PHY 51624 to Scripte Corporation, with Taguhi Sogomonyan as the Chief Executive Officer and Navid Doostan as the Pharmacist-in-Charge from October 31, 2013, to March 12, 2015 ("Respondent Pharmacy.") The Original Permit was in full force and effect at all times relevant to the charges brought herein, and the Board cancelled the license on March 9, 2016.

3. On or about November 28, 2012, the Board of Pharmacy issued Original Pharmacist License Number RPH 68475 to Navid Doostan ("Respondent Doostan.") The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2016, unless renewed.

JURISDICTION

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

5. Section 4300 provides, in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

6. 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. 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. Section 4036.5 states: "'Pharmacist-in-charge' means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

9. 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."

10. 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 procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

....

"(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.

11. Section 4342, subdivision (a), states: "The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

REGULATORY PROVISIONS

12. 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. Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispending of a prescription."

13. California Code of Regulations, title 16, section 1735, states, in pertinent part:

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

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

"(2) Altering the strength of a drug

"(3) Combining components or active ingredients

"(4) Preparing a drug product from chemicals or bulk drug substances."

14. California Code of Regulations, title 16, section 1735.1, states:

"(a) 'Equipment' means items that must be calibrated, maintained or periodically certified.

"(b) 'Integrity' means retention of potency until the expiration date noted on the label.

"(c) 'Potency' means active ingredient strength within +/- 10% of the labeled amount.

"(d) 'Quality' means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.

"(e) 'Strength' means amount of active ingredient per unit of a compounded drug product."

15. California Code of Regulations, title 16, section 1735.8, states, in pertinent part:

"(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

. . . .

"(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength."

COST RECOVERY

16. Section 125.3 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.

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FACTUAL BACKGROUND

17. On or about April 8, 2014, the Board conducted a routine inspection of Respondent Pharmacy and Respondent Doostan (collectively, "Respondents.") Board inspectors reviewed potency test results for drugs that had been compounded by Respondents in a report prepared by Eagle Analytical Services ("Eagle.") The Eagle test results showed that several of the drugs compounded by Respondents had an active ingredient strength that deviated by more than the 10% statutorily acceptable range.[1]

18. Following receipt of Eagle's test results, Respondent Doostan stated that Respondents conducted a product recall of all the affected medication. However, during the April 8, 2014, inspection, Board inspectors found additional compounded products that were outside of the acceptable range as identified in the Eagle report but were not part of the Respondent Pharmacy's drug recall. Board inspectors found that four (4) lots of drugs, which were distributed to patients and used in one-hundred (100) prescriptions, were identified as improperly compounded but not part of Respondents' recall. Board inspectors also identified Respondent Doostan as the pharmacist who personally verified three of the four improperly compounded lots of drugs.[2]

FIRST CAUSE FOR DISCIPLINE

(Variation from Prescription)

19. Respondents are subject to disciplinary action under section 4342 and section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1716 for selling drugs that do not conform to the standard and tests as to quality and strength as described in the United States Pharmacopoeia or the National Formulary and by deviating from the requirements of a prescription without the prior consent of the prescriber. The circumstances are as follows:

a. Respondents dispensed a compound, verified by Respondent Doostan, that was required by prescription to contain 2% Menthol, 2% Camphor, 0.05% Capsaicin, 8% Tramadol

[1] California Code of Regulations, title 16, section 1735.1, subdivision (b), defines potency to mean an active ingredient strength within plus or minus 10% of the labeled amount.

[2] As pharmacist-in-charge, Respondent Doostan is also responsible for improperly compounded lots that another pharmacist employed at Respondent Pharmacy verified.

and 10% Gabapentin. The Capsaicin as tested in the compound contained 115% of the expected amount, a deviation of greater than 10% as allowed by law. The compound was dispensed to patients in ninety-three (93) different prescriptions between, on or about, December 17, 2013, and February 3, 2014.

b. Respondents dispensed a compound, verified by Respondent Doostan, that was required by prescription to contain 10% Ketamine, 2% Baclofen, 2% Cyclobenzaprine, 3% Diclofenac, 6% Gabapentin, 5% Orphenadrine, 2% Tetracaine, 2% Menthol, and 2% Camphor. The Tetracaine as tested in the compound contained 112% of the expected amount, a deviation of greater than 10% as allowed by law. The compound was dispensed to patients in three (3) different prescriptions between, on or about, February 5, 2014, and February 17, 2014.

SECOND CAUSE FOR DISCIPLINE

(Compounding Quality Assurance)

20. Respondents are subject to disciplinary action under section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.8, subdivisions (a) and (d), for failing to comply with Respondent Pharmacy's written procedure for what to do in the event a compounded drug is discovered to be below minimum standards for integrity. The circumstances include that Respondent Pharmacy's drug recall policy required that in the event a product is discovered to be below minimum standards, that Respondents take immediate action. However, Respondents took no action until instructed to do so by Board inspectors during the April 8, 2014, inspection. As a result, Respondents failed to recall four different batches of compounded preparations totaling one hundred prescriptions, as follows:

a. Respondents failed to take action regarding a dispensed compound that was required by prescription to contain 2% Menthol, 2% Camphor, 0.05% Capsaicin, and 8% Tramadol. The Capsaicin as tested in the compound contained 120% of the expected amount, a deviation of greater than 10% as allowed by law. The compound was dispensed to patients in two (2) prescriptions between January 3, 2014, and February 4, 2014.

b. Respondents failed to take action regarding a dispensed compound, verified by Respondent Doostan, that was required by prescription to contain 2% Menthol, 2% Camphor,

0.05% Capsaicin, 8% Tramadol and 10% Gabapentin. The Capsaicin as tested in the compound contained 115% of the expected amount, a deviation of greater than 10% as allowed by law. The compound was dispensed to patients in sixty-three (63) different prescriptions between, on or about, December 17, 2013, and December 27, 2013.

c. Respondents failed to take action regarding a dispensed compound, verified by Respondent Doostan, that was required by prescription to contain 20% Flurbiprofen, 4% Amitriptyline, 7% Verapamil, and 3% Tetracaine. The Tetracaine as tested in the compound contained 111% of the expected amount, a deviation of greater than 10% as allowed by law. The compound was dispensed to patients in thirty-two (32) different prescriptions between, on or about, January 23, 2014, and February 3, 2014.

d. Respondents failed to take action regarding a dispensed compound, verified by Respondent Doostan, that was required by prescription to contain 10% Ketamine, 2% Baclofen, 2% Cyclobenzaprine, 3% Diclofenac, 6% Gabapentin, 5% Orphenadrine, 2% Tetracaine, 2% Menthol, and 2% Camphor. The Tetracaine as tested in the compound contained 112% of the expected amount, a deviation of greater than 10% as allowed by law. The compound was dispensed to patients in three (3) different prescriptions between, on or about, February 5, 2014, and February 17, 2014.

PRAYER

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

1. Revoking or suspending Original Permit Number PHY 51624 issued to Scripte Corporation, with Taguhi Sogomonyan as the Chief Executive Officer and Navid Doostan as the Pharmacist-in-Charge;

2. Revoking or suspending Original Pharmacist License Number RPH 68475 issued to Navid Doostan;

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3. Ordering Scripte Corporation and Navid Doostan 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,

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

DATED: 4/15/16

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

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