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

10 In the Matter of the Accusation Against:  
11  
12 **SCRIPTE CORPORATION**  
2907 Empire Avenue  
Burbank, CA 91504  
13 **NAVID DOOSTAN, Pharmacist-in-Charge**

Case No. 5665

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

14 **Original Permit No. PHY 51624**

15 **NAVID DOOSTAN**  
15039 Burbank Boulevard, Apt. 103  
16 Van Nuys, CA 91411

17 **Original Pharmacist License No. RPH 68475**

18 Respondents.

19  
20 Complainant alleges:

21 **PARTIES**

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

24 2. On or about October 31, 2013, the Board of Pharmacy issued Original Permit Number  
25 PHY 51624 to Scripte Corporation, with Taguhi Sogomonyan as the Chief Executive Officer and  
26 Navid Doostan as the Pharmacist-in-Charge from October 31, 2013, to March 12, 2015

27 ("Respondent Pharmacy.") The Original Permit was in full force and effect at all times relevant to  
28 the charges brought herein, and the Board cancelled the license on March 9, 2016.





1 13. California Code of Regulations, title 16, section 1735, states, in pertinent part:  
2 “(a) ‘Compounding’ means any of the following activities occurring in a licensed pharmacy,  
3 by or under the supervision of a licensed pharmacist, pursuant to a prescription:

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

5 “(2) Altering the strength of a drug

6 “(3) Combining components or active ingredients

7 “(4) Preparing a drug product from chemicals or bulk drug substances.”

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

9 “(a) ‘Equipment’ means items that must be calibrated, maintained or periodically certified.

10 “(b) ‘Integrity’ means retention of potency until the expiration date noted on the label.

11 “(c) ‘Potency’ means active ingredient strength within +/- 10% of the labeled amount.

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

14 “(e) ‘Strength’ means amount of active ingredient per unit of a compounded drug product.”

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

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

19 . . . .

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

23 **COST RECOVERY**

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

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1 **FACTUAL BACKGROUND**

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

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

16 **FIRST CAUSE FOR DISCIPLINE**

17 **(Variation from Prescription)**

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

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

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

28 <sup>2</sup> As pharmacist-in-charge, Respondent Doostan is also responsible for improperly  
compounded lots that another pharmacist employed at Respondent Pharmacy verified.

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

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

#### 11 **SECOND CAUSE FOR DISCIPLINE**

##### 12 **(Compounding Quality Assurance)**

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

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

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

1 0.05% Capsaicin, 8% Tramadol and 10% Gabapentin. The Capsaicin as tested in the compound  
2 contained 115% of the expected amount, a deviation of greater than 10% as allowed by law. The  
3 compound was dispensed to patients in sixty-three (63) different prescriptions between, on or  
4 about, December 17, 2013, and December 27, 2013.

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

11 d. Respondents failed to take action regarding a dispensed compound, verified by  
12 Respondent Doostan, that was required by prescription to contain 10% Ketamine, 2% Baclofen,  
13 2% Cyclobenzaprine, 3% Diclofenac, 6% Gabapentin, 5% Orphenadrine, 2% Tetracaine, 2%  
14 Menthol, and 2% Camphor. The Tetracaine as tested in the compound contained 112% of the  
15 expected amount, a deviation of greater than 10% as allowed by law. The compound was  
16 dispensed to patients in three (3) different prescriptions between, on or about, February 5, 2014,  
17 and February 17, 2014.

18 **PRAYER**

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

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

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

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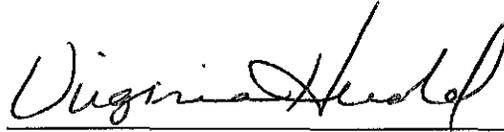
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1           3.     Ordering Scripte Corporation and Navid Doostan to pay the Board of Pharmacy the  
2 reasonable costs of the investigation and enforcement of this case, pursuant to Business and  
3 Professions Code section 125.3; and,

4           4.     Taking such other and further action as deemed necessary and proper.  
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6  
7 DATED: \_\_\_\_\_

4/15/16



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

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