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

In the Matter of the Citation Against: **THE MEDICINE SHOPPE** **3024 Pacific Avenue** **Livermore, CA 94550** **Pharmacy License No. PHY 48618** **PRITI CHATWANI** **3024 Pacific Avenue** **Livermore, CA 94550** **Pharmacist License No. RPH 53463** Respondent.	Case No. 4574 **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 June 11, 2007, the Board of Pharmacy issued Pharmacy License Number PHY 48618 to Puchkar International LLC; Pushkar International Inc., to do business as "The Medicine Shoppe" (Respondent Medicine Shoppe).[1] The Pharmacy License was in full force and

[1] The business entity was changed from an LLC to a corporation on September 26, 2009.

effect at all times relevant to the charges brought herein and will expire on June 1, 2015, unless renewed.

3. On or about May 7, 2002, the Board of Pharmacy issued Pharmacist License Number RPH 53463 to Priti Chatwani (Respondent Chatwani). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on April 30, 2015, unless renewed.

4. Records of the California State Board of Pharmacy show that Priti Chatwani, RPH 53463 is and has been President and Pharmacist-in-Charge of Respondent Medicine Shoppe since June 11, 2007.

JURISDICTION

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

6. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

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 125.3 of the Code provides, 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

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STATUTORY AND REGULATORY PROVISIONS

9. Section 4301 of the Code provides: "The board shall take again 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:

. . .

(c) Gross Negligence

. . .

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

. . .

(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 of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state of federal regulatory agency."

10. Section 4076, subdivision (a) of the Code states:

"A pharmacist shall not dispense any prescriptions except in a container that meets the requirements of the state and federal law and is correctly labeled with all of the following..."

. . .

"(7) The strength of the drug or the drug dispensed"

. . .

"(9) The expiration date of the effectiveness of the drug dispensed."

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11. Section 4077, subdivision (a) of the Code states:

"Except as provided in subdivisions (b) and (c), no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by section 4076."

12. Section 4113, subdivision (c) of the Code 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."

13. California Code of Regulations, title 16, section 1711, provides:

"(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assess medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors."

. . .

"(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain the following:

1. the date, location, and participants in the quality assurance review;

2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c).

3. the findings and determinations generated by the quality assurance review; and,

4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program."

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14. California Code of Regulations, title 16, section 1715 provides:

The pharmacist-in-charge of each pharmacy shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law before July 1 of every off-numbered year.

15. California Code of Regulations, title 16, section 1716, provides:

Pharmacists shall not deviate from the requirements of a prescriptions except upon the prior consent of the prescriber.

16. California Code of Regulations, title 16, section 1735.2, provides:

"(j) prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board."

. . .

"(f) The pharmacist preforming or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

17. California Code of Regulations, title 16, section 1735.3, subdivisions (a)(3)(4)(6) and (8) provide: that for each compounded drug product, the pharmacy records shall include the identity of the pharmacy personnel who compounded the product, the identity of the pharmacist reviewing the final drug product, the manufacturer, expiration date and lot number of each component, and the expiration date of the final compounded drug product.

18. California Code of Regulations, title 16, section 1735.4, subdivision (a) provides: As related to Business and Professions Code section 4076 subdivision (a)(9), the label of a compounded drug product shall contain the expiration date of the effectiveness of the drug dispensed.

19. California Code of Regulations, title 16, section 1735.7, subdivision (a) provides: 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.

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20. California Code of Regulations, title 16, section 1735.8, provides:

"(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.

. . .

"(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounded record and master formula."

21. California Code of Regulations, title 16, section 1761, provides:

No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

FACTUAL BACKGROUND

22. On or about September 6, 2011, Patient "A" presented with a prescription for liothyronine, thyroid medication, "T-3", at 3024 Pacific Avenue in Livermore, California, the Respondent pharmacy establishment known as The Medicine Shoppe.[2] [3]

23. Respondent Chatwani compounded and filled the prescription, which was designated as RX 6101993, on or about September 6, 2011. The prescription either read "150 mcg" (150 micrograms), or "150 mg" (150 milligrams). The compounded product was dispensed in a

[2] Liothyronine or Liothyronine sodium is a synthetic version of one of the two hormones made by the thyroid gland. It is used for treating persons who are hypothyroid (do not produce enough thyroid hormones).

[3] Mcg refers to "micrograms." Mg refers to "milligrams." Micrograms are 1000 times smaller than milligrams.

container that read "150 mcg," but Respondent Chatwani later reported that it was her intention to compound the product in a 150 mg strength.

24. Thereafter, Patient "A" began taking the medication as prepared by Respondents and suffered injury as a result by having to be admitted to a hospital for 7 days.

25. Subsequent chemical lab analysis of the T-3 prescription prepared by Respondents demonstrated the compounded capsules were neither 150 micrograms nor 150 milligrams. The T-3 capsules contained on average 9406 mcg of liothyronine – a compound strength that was dangerous to Patient "A" and resulted in her hospitalization.

26. On or about May 15, 2012, a Board Inspector conducted an inspection and investigation of Respondent Medicine Shoppe. The inspector met with Respondent Chatwani and noted that RX 6101993 was labeled as T-3 150 mcg but not compounded as such.

27. The Board Inspector requested the completed Community Pharmacy Self-Assessment form and Compounding Pharmacy Self-Assessment form. The most recent Community Pharmacy Self-Assessment available was completed on or about July 10, 2009. There was no Compounding Pharmacy Self-Assessment completed. The version of the Community Pharmacy Self-Assessment Respondent Chatwani used on or about July 10, 2009 contained sterile compounding questions only and did not apply to Respondent Medicine Shoppe's non-sterile compounding.

28. Written training documentation for Respondent Pharmacist-in-Charge Chatwani was not available during inspection.

29. The Board Inspector reviewed the pharmacy compounding log books. Respondent Chatwani presented the page and the compound record book containing prescriptions compounded for Patient "A". The Board Inspector noted the compounded records for RX 6101991, 6101992 and 6101993 were missing the following required items: (1) the identity of the pharmacy personnel who compounded the drug product; (2) the identity of the pharmacist who reviewed the final drug product; (3) the expiration date of the final compounded drug product; and (4) the lot number for each compound component.

30. The Board Inspector asked Respondent Chatwani if she had completed any compound product testing in the past year. She replied she had not. Respondent Chatwani estimated her pharmacy compounds to be approximately 50 medications each month. Respondent Chatwani further indicated she was the only pharmacist checking compounding medications.

31. The Board Inspector asked Respondent Chatwani for the pharmacy's Compounding Policy and Procedures. Respondent Chatwani could not locate the Compounding Policy and Procedures.

32. The Board Inspector asked Respondent Chatwani about the incident involving Patient "A" on September 6, 2011. Respondent Chatwani indicated the dose for liothyronine was 150 milligrams and stated that she compounded the prescription for 150 milligrams. However, the label for Patient A on RX 6101993 showed "T-3 150 mcg."

33. The Board Inspector reviewed the Quality Assurance Report for RX 6101993 for the incident related to Patient "A". The document was missing the date of the review, recorded the complaint as "Mislabel (T-3 150 mcg)" and contained only the comment "Patient states-wrong strength." No other details were provided. There were no findings, determinations, or recommended changes to policies, procedures, systems, or processes.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – No Self-Assessment By Pharmacist-In-Charge)

34. Respondents are subject to disciplinary action under section 4301(j) and/or (o), and/or 4113(c), and/or California Code of Regulations, title 16, section 1715 in that Respondents failed to complete a self-assessment as pharmacist-in charge to ensure pharmacy compliance with state and federal law.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct – No Compounding Self-Assessment)

35. Respondents are subject to disciplinary action under section 4301(j) and/or (o), and/or 4113(c), and/or California Code of Regulations, title 16, section 1735.2(j) in that Respondents failed to complete a self-assessment for compounding pharmacies prior to allowing any drug to be compounded in the pharmacy.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Variation from Prescription)

36. Respondents are subject to disciplinary action under section 4301(j) and/or (o), and/or 4113(c), and/or California Code of Regulations, title 16, section 1716, in that Respondents deviated from the requirements of a prescription without the consent of the prescriber.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Uncertain Prescription)

37. Respondents are subject to disciplinary action under section 4301(j) and/or (o), and/or 4113(c), and/or California Code of Regulations, title 16, section 1761, in that Respondents compounded or dispensed a prescription which contained a significant error, omission, irregularity, uncertainty, ambiguity or alteration. Specifically, Respondents compounded and dispensed RX 6101993 to Patient "A" without accurately confirming the dose with the prescriber when the prescription appeared to be written with an uncertain dose.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Quality Assurance Review Lack of Detail)

38. Respondents are subject to disciplinary action under section 4301(j) and/or (o), and/or 4113(c), and/or California Code of Regulations, title 16, section 1711(e), in that Respondents' Quality Assurance review record for RX 6101993 dispensed to Patient "A" on September 6, 2011, lacked a date, participants, pertinent data reviewed relating to the reported medication error, findings, determinations, and recommendations on changes to or maintaining pharmacy policies, procedures, systems or processes.

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SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Dispensing Dangerous Drug Incorrectly)

39. Respondents are subject to disciplinary action under section 4301(j) and/or (o), and/or 4113(c), and/or 4076(a)(7)/4077 in that Respondents labeled and dispensed RX 6101993 to Patient "A" as T-3 150 mcg when in fact the product was not compounded as such and therefore did not meet state and federal labeling requirements.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Drugs Lacking Quality or Strength)

40. Respondents are subject to disciplinary action under section 4301 and/or 4113(c) in that Respondents labeled RX 6101993 for Patient "A" as T-3 150 mcg when the compounded medication contained an average of T-3 9,406 mcg per capsule.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Failure to Exercise Professional Judgment)

41. Respondents are subject to disciplinary action under section 4301 and/or 4306.5, and/or 4113(c), in that according to the compound record and a statement from Respondents, Respondents failed to appropriately exercise professional judgment in preparing a compounded medication that matched neither the prescription authorized by the prescriber nor the label placed on the container.

NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Gross Negligence)

42. Respondents are subject to disciplinary action under sections 4301(c), and/or 4113(c), in that according to the compound record and a statement from Respondents,

Respondents failed to appropriately exercise professional judgment in preparing a compounded medication that matched neither the prescription authorized by the prescriber nor the label placed on the container.

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TENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – No Expiration Dates on Compounded Drugs Labels)

43. Respondents are subject to disciplinary action under section 4301(j) and/or (o), 4076(a)(9)/4077, and/or 4113(c), and/or California Code of Regulations, title 16, section 1735.4(a) in that Respondents labeled and dispensed RX 6101991, RX 6101992, and RX 6101993 to Patient "A" with no product expiration date on the label as required.

ELEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Compound Record Missing Required Items)

44. Respondents are subject to disciplinary action under section 4301(j) and/or (o), and/or 4113(c) and/or California Code of Regulations, title 16, section 1735.3(a)(3)(4)(6)(8) and (9), in that Respondents labeled and dispensed RX 6101991, RX 6101992, and RX 6101993 to Patient "A" when the compound record for each was missing: the identity of the pharmacy personnel who compounded the product; the identity of the pharmacist reviewing the final drug product; the lot number of each component.

TWELFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – No Documentation of Training for Compounding Staff)

45. Respondents are subject to disciplinary action under section 4301(j) and/or (o), and/or 4113(c), and/or California Code of Regulations, title 16, section 1735.7(a), in that on May 15, 2012, Respondent Chatwani stated during an inspection, and the Board inspector determined, that there was no compounding training documentation on record for Respondent Chatwani as the compounding pharmacist.

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THIRTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - No Compounding Quality Assurance)

46. Respondents are subject to disciplinary action under section 4301(j) and/or (o), and/or 4113(c), and California Code of Regulations, title 16, section 1735.8(c), in that Respondents, during an inspection by the Board on May 15, 2012, had no qualitative or quantitative Compounding Quality Assurance records available from the past year, for a reported volume of approximately 50 compounded prescriptions each month.

FOURTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Responsibility for Integrity, Potency and Quality of Drug)

47. Respondents are subject to disciplinary action under section 4301 and/or California Code of Regulations, title 16, section 1735.2(f), in that on or about September 6, 2011, Respondents dispensed a compounded product pursuant to RX 6101993 for Patient "A" that was lacking in integrity, potency, quality, and/or label strength.

FIFTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Making a False Statement)

48. Respondents are subject to disciplinary action under section 4301(g) and/or 4113(c) in that there were conflicts in various records made and provided by Respondents.

- On or about June 13, 2012, Respondents provided a statement about the compounding of RX 6101993 containing information which conflicted with the compounded record provided by the Respondents on May 15, 2012.

- The compound record for RX 6101993 stated 4.5 grams of liothyronine powder was used to compound RX 6101993. The Compound Rx Report provided by Respondents and the patient receipt stated .0450 grams of liothyronine powder was used to compound RX 6101993.
- The compound record for RX 6101992 stated 0.0008 grams of liothyronine powder and 7.17 grams of cellulose were used to compound RX 6101992. The Compound Rx Report provided by Respondents and the patient receipt for RX 6101992 stated 0.008 grams of liothyronine powder and 5.067 grams of acidophilus lactobacillus powder 1BU/gram was used to compound RX 6101992.

OTHER MATTERS

49. To determine the level of discipline, if any, to be imposed on Respondent Medicine Shoppe and/or Respondent Chatwani (collectively Respondents), Complainant further alleges:

a. On or about December 15, 2010, Citation No. CI 2010 46106, was issued to Respondent Medicine Shoppe, for (1) dispensing dangerous drugs incorrectly labeled, Bus. & Prof. Code Section 4077(a)/4076(a)(11)(A); (2) Varying from prescription, California Code of Regulation, Title 16, Section 1716; (3) Failure to have written policies and procedures, Bus. & Prof Code Section 4101(b); (4) Failing to comply with self-assessment form, California Code of Regulations, Title 16 Section 1715(a); (4) unprofessional conduct – false representation, Bus. & Prof. Code Section 4301(g). A fine of $5,000 was issued and paid.

b. On or about December 15, 2010, Citation No. CI 2012 53638 was issued to Respondent Chatwani, for (1) dispensing dangerous drugs incorrectly labeled, Bus. & Prof. Code Section 4077(a)/4076(a)(11)(A); (2) Varying from prescription, California Code of Regulation, Title 16, Section 1716; (3) Failure to have written policies and procedures, Bus. & Prof Code Section 4101(b); (4) Failing to comply with self-assessment form, California Code of Regulations, Title 16 Section 1715(a); (4) unprofessional conduct – false representation, Bus. & Prof. Code Section 4301(g). A fine of $5,000 was issued and paid.

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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 Pharmacy License Number PHY 48618, issued to Respondent Medicine Shoppe;

2. Revoking or suspending Pharmacist License Number RPH 53463, issued to Respondent Chatwani;

3. Ordering Respondents 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;

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

DATED: 9/22/14

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

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