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

In the Matter of the Accusation Against**:** **MEDIRATTA RX INC.** **DBA PEOPLE'S PHARMACY** **31951 Dove Canyon Drive, Suite F** **Rancho Santa Margarita, CA 92679** **Pharmacy Permit No. PHY 47303** **Sterile Compounding License No. LSC 99478** **and** **RASHIMI MEDIRATTA** **31951 Dove Canyon Drive, Suite F** **Rancho Santa Margarita, CA 92679** **Pharmacist License No. RPH 57047** Respondents.	Case No. 5942 **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 (Board), Department of Consumer Affairs.

2. On or about June 6, 2005, the Board issued Pharmacist License No. RPH 57047 to Rashimi Mediratta (Respondent Mediratta). The Pharmacist License was in full force and effect

at all times relevant to the charges brought herein and will expire on September 30, 2018, unless renewed.

3. On or about October 7, 2005, the Board issued Pharmacy Permit Number PHY 47303 to Mediratta RX Inc., doing business as People's Pharmacy (Respondent People's Pharmacy) with Rashimi Mediratta as the President and Pharmacist-in-Charge. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2017, unless renewed.

4. On or about January 18, 2008, the Board issued Sterile Compounding License Number LSC 99478 to Mediratta RX Inc., doing business as People's Pharmacy (Respondent People's Pharmacy). The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2017, unless renewed.

JURISDICTION

5. This Accusation is brought before the Board, 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.

6. Section 4011 of the Code 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.].

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

8. 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.

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STATUTORY PROVISIONS

9. Section 4022 of the Code states:

> "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:
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> (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.

10. Section 4033, subsection (a)(1) of the Code defines the term "manufacturer" as "every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer."

11. Section 4113, subsection (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."

12. 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:
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> . . . .
>
> (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.
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> . . . .
>
> (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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> . . . .

13. Health and Safety Code section 11030 defines an "Ultimate user" as "a person who lawfully possesses a controlled substance for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household."

14. Health and Safety Code section 111330 provides that any drug or device is misbranded if its labeling is false or misleading in any particular.

15. Health and Safety Code section 111425 provides that a drug or device is misbranded if it was manufactured in this state in an establishment not duly licensed by the Department of Public Health.

16. Health and Safety Code section 111430 provides that a drug or device is misbranded if it was manufactured in an establishment not duly registered with the Secretary of Health, Education, and Welfare of the United States.

17. Health and Safety Code section 111440 provides that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

18. Health and Safety Code section 111450 provides that it is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

19. Health and Safety Code section 111615 provides that no person shall manufacture any drug or device in this state unless he or she has a valid license from the Department of Public Health.

REGULATORY PROVISIONS

20. California Code of Regulations, title 16, section 1735, subsection (a): states in pertinent part:

> "Compounding" means any of the following activates 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
>
> …

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

states in pertinent part:

…

(c) Pursuant to Business and Professions Code section 4052(a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:

(1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and

(2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

…

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

…

22. California Code of Regulations, title 16, section 1735.5, Compounding Policies and Procedures, states in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

(c) The policy and procedure manual shall include the following:

…

(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

23. California Code of Regulations, title 16, section 1735.8, Compounding Quality Assurance, states that:

(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.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(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 compounding record and master formula.

(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.

DRUGS

24. Tacrolimus is a dangerous drug pursuant to Code section 4022.

25. Cyclosporine is a dangerous drug pursuant to Code section 4022.

26. Idoxuridine is a dangerous drug pursuant to Code section 4022.

27. Demecarium is a dangerous drug pursuant to Code section 4022.

COST RECOVERY

28. 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.

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FACTUAL ALLEGATIONS

29. From January 18, 2008, to the present, Respondent Rashimi Mediratta has been and is the Pharmacist-in-Charge (PIC) of Respondent People's Pharmacy. Respondent People's Pharmacy is not, and has never been, an establishment duly registered as a manufacturer with the Secretary of Health, Education and Welfare of the United States or licensed with the California Department of Public Health as a manufacturer.

30. On or about March 6, 2015, the Board conducted an annual inspection of Respondent People's Pharmacy. The inspector found the following medications in large quantities: tacrolimus, EDTA, dexamethasone, and clyclosporine.[1] Respondent Mediratta stated to the inspector that she compounds these large quantities of eye drops in anticipation of sending them to doctor's offices. These eye drops were, however, compounded without a patient specific prescriptions and outside of the compounding limits permitted under pharmacy law. The investigator also reviewed the Respondent's policies and procedures for compounding. Pharmacists are required, under California Code of Regulations, title 16 (CCR), section 1735.5, to keep "a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products." After reviewing Respondents' policies and procedures, the investigator noted that Respondents did not have a written quality assurance plan for compounding. The investigator also requested copies of Respondents' compounding logs, dispensing records, master formulas, other and documents related to Respondents' compounding practices.

31. After reviewing the documents provided by Respondents, several other violations by Respondents were noted in these records. Respondents' compounding records stated that Respondent Mediratta used sterile water for irrigation, as opposed to sterile water for injection, in compounding tacrolimus ophthalmic solution on five separate occasions. The United States Pharmacopeial Convention (USP) — a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines manufactured, distributed, and consumed

[1] The named ophthalmic solutions are commonly used in veterinary medicine for the treatment of Keratoconjunctivitis Sicca (dry eye) and other diseases of the eye in dogs.

worldwide — has standardized the use of sterile water in drug compounding so that sterile water for irrigation is below the acceptable standard for use in the compounding of ophtalmic solutions and sterile water for injection is accepted. Respondents' compounding records from six separate dates show that Respondent Mediratta used sterile water for irrigation for compounding tacrolimus opthalmic solution. These dates are: December 9, 2014; December 22, 2014; January 19, 2015; February 4, 2015; February 24, 2015; and March 4, 2015.

32. Respondent People's Pharmacy compounding records show that on March 4, 2015, Respondent Mediratta compounded 200 bottles of tacrolimus ophthalmic solution with a beyond use date — a date after which a compounded drug product should not be used — that was after the expiration date of one of its components. Under CCR section 1735.2, subsection (h), Respondent Mediratta cannot label a drug product with a beyond use date that exceeds an "expiration date of any component in the compounded drug product." The expiration date of the benalkonium chloride used in compounding the tacrolimus ophthalmic solution was August 25, 2015. The beyond use date used by Respondent Mediratta for the 200 compounded tacrolimus ophthalmic solution bottles was August 31, 2015, six days after the expiration date of the benalkonium chloride.

33. From December 1, 2014, through February 28, 2015, Respondents' compounding records show that Respondent Meditratta compounded and sold approximately 5,700 opthalmic drops or ointments which were not sold to an ultimate user. Such compounding is considered manufacturing under Code section 4033, subsection (a)(1). Respondents, who are not licensed to manufacture in California, sold these 5,700 opthalmic drops or ointments to veterinary clinics without an existing prescription and outside of the "reasonable quantity" exceptions found in CCR 1735.2, subsection (c). Furthermore, the 5,700 opthalmic drops or ointments manufactured by Respondents are misbranded as a result of being manufactured in an unlicensed facility, as defined in Health and Safety Code section 111425. As an unlicensed manufacturer, Respondents were also prohibited from manufacturing or selling these misbranded opthalmic drops and ointments under Health and Safety Code section 111440.

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FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Quality Assurance)

34. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating regulations requiring pharmacies to maintain a written policy and procedure manual for compounding that establishes methodologies for the formulation and compounding of drugs and other standard operating procedures related to compounding, as defined under CCR section 1735, subsection (a). Respondents failed to maintain documentation of the methodology used to test the integrity, potency, quality, and labeled strength of compounded drug products, as set forth in paragraphs 29 through 33, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Sale of Adulterated Drugs)

35. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating statutes regulating the adulteration of drugs as stated in the Sherman Food, Drug, and Cosmetic Act, and as defined under Health and Safety Code sections 111255 and 111260. Respondents offered for sale adulterated drugs in violation of Health and Safety Code section 111295, as set forth in paragraphs 29 through 33, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Compounding Limitation Requirements)

36. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating regulations regulating the expiration date of compounded drug products in that they compounded or manufactured drugs with a beyond use date exceeding the expiration date of a component of a the compounded drug product in violation of CCR section 1735.2, subsection (h), as set forth in paragraphs 29 through 33, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Manufacturing Compounded Drugs)

37. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating statutes regulating controlled substances and dangerous drugs and state laws governing pharmacy, in that they compounded or manufactured drugs as defined by Code section

4033(a)(1), non-patient specific drugs without being licensed by the California Department of Public Health, in violation of Health and Safety Code section 111615, as set forth in paragraphs 29 through 33, which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Sold Misbranded Drugs)

38. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating statutes regulating controlled substances and dangerous drugs and state laws governing pharmacy, in that Respondents sold misbranded drugs, as defined by Health & Safety Code sections 111330 and 111430, in violation of Health and Safety Code section 111440, as set forth in paragraphs 29 through 33, which are incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Delivery or Proffering of Misbranded Drugs)

39. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating statutes regulating controlled substances and dangerous drugs and state laws governing pharmacy, in that Respondents delivered or proffered for delivery misbranded drugs, as defined by Health & Safety Code sections 111330 and 111430 in violation of Health and Safety Code section 111450, as set forth in paragraphs 29 through 33, which are incorporated herein by reference.

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 Permit Number PHY 47303, issued to Mediratta RX Inc., doing business as People's Pharmacy;

2. Revoking or suspending Sterile Compounding License Number LSC 99478, issued to Mediratta RX Inc., doing business as People's Pharmacy;

3. Revoking or suspending Pharmacist License Number RPH 57047, issued to Rashimi Mediratta;

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4. Ordering Mediratta RX Inc., doing business as People's Pharmacy, and Rashimi Mediratta 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;

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

DATED: 1/31/17

Virginia Herold

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

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