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

In the Matter of the Accusation Against**:** **KENNETH ROAD PHARMACY, INC.;** **MARGARITA KAZARIAN, OWNER** **1400 W. Kenneth Road** **Glendale, CA 91201** **Pharmacy Permit No. PHY 50214** **and** **ROBERT S. LIPP** **9332 Crystal View Dr.** **Tujunga, CA 91042** **Pharmacist License No. RPH 32284** Respondents.	Case No. 5377 **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 May 4, 2010, the Board of Pharmacy issued Pharmacy Permit Number PHY 50214 to Kenneth Road Pharmacy, Inc.; Margarita Kazarian, sole owner, corporate officer and director. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2016, unless renewed.

3. On or about August 9, 1978, the Board issued Pharmacist License No. RPH 32284 to Robert S. Lipp. The pharmacist license will expire on April 30, 2016, unless renewed. Robert S. Lipp has been the pharmacist-in-charge ("PIC") of Kenneth Road Pharmacy, Inc. since May 4, 2010, and at all times relevant to the charges brought herein.

JURISDICTION

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

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."

6. Section 4300 of the Code states that "[e]very license issued may be suspended or revoked."

7. Section 4011 of the Code states:

"The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code)."

CALIFORNIA PHARMACY LAW

8. Section 4113, subdivision (c), states that "[t]he 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."

9. Section 4301 of the Code states:

"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, or 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.

10. Section 4302 provides that "[t]he board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee."

. . .

11. Section 4307 provides in pertinent part:

"(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee . . . ."

CALIFORNIA HEALTH AND SAFETY CODE

12. Section 111255 of the Health and Safety Code provides:

"Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."

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13. Section 111295 of the Health and Safety Code provides:

"It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

14. Section 111305 of the Health and Safety Code provides:

"It is unlawful for any person to receive in commerce any drug or device that is adulterated or to deliver or proffer for delivery any drug or device."

15. Section 111330 of the of the Health and Safety Code provides:

"Any drug or device is misbranded if its labeling is false or misleading in any particular."

16. Section 111340, subdivision (b), provides that a drug is misbranded unless it bears a label containing "[a]n accurate statement of the quantity of the contents in terms of weight, measure, or numerical count."

17. Section 111390 of the Health and Safety Code provides:

"Any drug or device is misbranded if its container is so made, formed, or filled as to be misleading."

18. Section 111395, subdivision (c) of the Health and Safety Code provides that a drug is misbranded if "[t]he contents of the original package have been, wholly or partly, removed and replaced with other material in the package."

19. Section 111440 of the Health and Safety Code provides:

"It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

COST RECOVERY

20. 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.

DANGEROUS DRUGS

21. Aciphex is a prescription medication used to treat acid reflux. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

22. Afeditab is a prescription blood pressure medication. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

23. Atorvastatin is a prescription medication used to lower cholesterol and triglyceride levels in the blood. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

24. Crestor is a prescription medication used to lower cholesterol and triglyceride levels in the blood. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

25. Cymbalta is a prescription antidepressant medication. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

26. Diovan is a prescription blood pressure medication. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

27. Fenofibrate is a prescription medication used to lower cholesterol and triglyceride levels in the blood. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

28. Moxifloxacin is a prescription antibiotic. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

29. Namenda is a prescription medication used to treat patients with dementia and memory loss related to Alzheimer's disease. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

30. Trilipix is a prescription medication used to lower cholesterol and triglyceride levels in the blood. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

BACKGROUND

31. Respondent Kenneth Road Pharmacy, Inc. ("Kenneth Road" or "Respondent") is a corporate entity that holds a pharmacy permit issued by the Board. Kenneth Road is solely owned by Margarita Kazarian ("Kazarian"). Kazarian also serves as Kenneth Road's sole

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corporate officer and director. Kazarian is a former pharmacist whose license was revoked by the Board in an order effective November 18, 2014.[1]

32. The revocation of Kazarian's pharmacist license resulted from numerous violations of state and federal law while doing business as Adams Square Pharmacy ("Adams Square"). Among other things, those violations included selling and/or holding for sale counterfeit drugs, adulterated drugs and misbranded drugs, engaging in dishonest acts and subverting the Board's investigation into that misconduct. Specifically, the Board's case showed that Adams Square obtained a variety of pharmaceutical tablets, including counterfeit product, from unknown sources and then placed those medications inside authentic manufacturer containers which bore lot numbers and expiration dates that had no actual relation to the tablets themselves. Adams Square's pharmacy permit and Kazarian's pharmacist license were both revoked by the Board as a result of these and other violations.

INSPECTION OF KENNETH ROAD

33. On November 26, 2013, the Board conducted an inspection of Kenneth Road, during which Board inspectors discovered violations of law involving misbranded and adulterated drugs. Specifically, Board inspectors documented multiple instances in which manufacturer containers found on Kenneth Road's shelves contained tablets that bore no actual relation to the container or the identifying information contained thereon, including: (1) a 90-tablet manufacturer bottle of Diovan that contained 120 tablets; (2) a 90-tablet manufacturer bottle of Crestor that contained 92 tablets; (3) an open manufacturer bottle of Aciphex containing tablets that were not uniform and exhibited imprint variations; (4) an open manufacturer bottle of Namenda containing tablets that exhibited color variations; (5) an open manufacturer bottle of Cymbalta containing tablets that exhibited both color and imprint variations; and (6) an open manufacturer bottle of Afeditab containing tablets that exhibited variations in color and imprint. In addition, the inspectors found an amber vial containing 206 tablets with a handwritten label reading "Atorvastatin 20 mg Exp

[1] *In the Matter of the Accusation Against Adams Square Pharmacy; Margarita Kazarian, et al.* (Case No. 5189; OAH No. 2014050753).

09/14." that contained a mixture of two different generic versions of atorvastatin (brand name "Lipitor"), one manufactured by the Apotex corporation and one manufactured by Mylan Pharmaceuticals.

34. On December 11, 2014, the Board conducted another inspection of Kenneth Road, which revealed additional violations of law involving misbranded and adulterated drugs. Specifically, Board inspectors again documented multiple instances in which manufacturer containers found on Kenneth Road's shelves contained tablets that bore no actual relation to the container or the identifying information contained thereon, including: (1) an open 90-tablet manufacturer bottle of Trilipix 135 mg that contained 125 tablets; (2) another open 90-tablet manufacturer bottle of Trilipix 135 mg that contained 124 tablets; (3) an open 90-tablet manufacturer bottle of fenofibrate 145 mg that contained 108 tablets; (4) and an open manufacturer container of moxifloxacin 400 mg that contained tablets that were not uniform and exhibited different degrees of age and wear.

FIRST CAUSE FOR DISCIPLINE

(Prohibited Corporate Ownership and Governance)

35. Respondent Kenneth Road is subject to disciplinary action under section 4301, subdivision (o), in conjunction with section 4307, subdivision (a), in that Kenneth Road is operating with an owner, officer and/or director who is prohibited from serving in any one of those capacities. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 18 and 19, inclusive, as though set forth fully herein.

SECOND CAUSE FOR DISCIPLINE

(Misconduct by Owner and/or Corporate Officer)

36. Respondent Kenneth Road is subject to disciplinary action under section 4302 in that a corporate officer, director and/or person holding 10 percent or more of Kenneth Road's corporate stock engaged in conduct that constitutes grounds for disciplinary action. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 16 and 17, inclusive, as though set forth fully herein.

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THIRD CAUSE FOR DISCIPLINE

(Adulterated Drugs)

37. Respondent Kenneth Road and respondent Lipp (collectively, "Respondents") are subject to disciplinary action under section 4301, subdivision (j), in conjunction with section 4113, subdivision (c), and Heath and Safety Code sections 111255, 111295 and 111305 in that Respondents received adulterated drugs in commerce and/or held or offered adulterated drugs for sale. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 20 and 21, inclusive, as though set forth fully herein.

FOURTH CAUSE FOR DISCIPLINE

(Misbranded Drugs)

38. Respondents are subject to disciplinary action under section 4301, subdivision (j), in conjunction with Heath and Safety Code sections 111330, 111340, subdivision (b), 111390, 111395, subdivision (c), and 111440 in that Respondents held and/or offered for sale misbranded drugs. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 20 and 21, inclusive, as though set forth fully herein.

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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 Permit Number PHY 50214, issued to Kenneth Road Pharmacy, Inc.;

2. Revoking or suspending Pharmacist License No. RPH 32284, issued to Robert S. Lipp;

3. Ordering Kenneth Road Pharmacy, Inc. and Robert S. Lipp 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. Ordering that Margarita Kazarian is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensed pharmacy pursuant to Business and Professions Code section 4307;

5. Ordering that any transfer of Kenneth Road Pharmacy Inc.'s pharmaceutical inventory be subject to Board oversight and that any misbranded, adulterated or otherwise illicit pharmaceuticals contained in that inventory be destroyed;

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

DATED: 4/24/15

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

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