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

In the Matter of the Accusation Against**:** **PARK WEST PHARMACY, INC.;** **MARGARITA KAZARIAN, OWNER** **7230 Medical Center Drive, #106** **West Hills, CA 91307-4003** **Pharmacy Permit No. PHY 46623** **and** **JERRY A. WHITTEMORE** **3300 Shelby Dr.** **Los Angeles, CA 90034** **Pharmacist License No. RPH 21221** Respondents.	Case No. 5378 **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 28, 2004, the Board of Pharmacy issued Pharmacy Permit Number PHY 46623 to Park West 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.

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3. On or about July 25, 1959, the Board issued Pharmacist License No. RPH 21221 to Jerry A. Whittemore. The pharmacist license will expire on January 31, 2016, unless renewed. Respondent Whittemore has been the pharmacist-in-charge ("PIC") of Park West Pharmacy, Inc. since June 18, 2014, 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 . . . ."

12. Section 4081 of the Code states:

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital,

institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

"(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

13. California Code of Regulations, title 16, section 1735.2, subdivision (j), provides:

"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. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education."

14. California Code of Regulations, title 16, section 1735.5 provides:,

"(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

(1) Procedures for notifying staff assigned to compounding duties of any changes in or to the policy and procedure manual.

2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

(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."

CALIFORNIA HEALTH AND SAFETY CODE

15. 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."

16. 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."

17. 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."

18. 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."

19. 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."

20. 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."

21. 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."

22. 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."

DANGEROUS DRUGS

23. 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.

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

25. Digoxin is a prescription medication used to treat atrial fibrillation and related heart rhythm problems It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

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

COST RECOVERY

27. 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.

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BACKGROUND

28. Respondent Park West Pharmacy, Inc. ("Park West" or "Respondent") is a corporate entity that holds a pharmacy permit issued by the Board. Park West is solely owned by Margarita Kazarian ("Kazarian"). Kazarian also serves as Park West's sole corporate officer and director. Kazarian is a former pharmacist whose license was revoked by the Board in an order effective November 18, 2014.[1] Kazarian served as the PIC of Park West from October 2007 to June 2014.

29. 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.

INSPECTIONS OF PARK WEST

30. On November 15, 2013, the Board conducted an inspection of Park West, during which Board inspectors found that Park West was engaged in drug compounding activities without completing a compounding self-assessment or maintaining policies and procedures for compounding as required by state law. Thereafter, on December 11 and 12, 2014, the Board conducted additional inspections of Park West, during which Board inspectors found that Park West continued to be engaged in drug compounding activities in violation of state law in that its compounding policies and procedures were incomplete and it had not completed a compounding self-assessment following a change in the designation of its PIC. During the December 2014

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

inspections, the Board also discovered a variety of additional violations of law involving misbranded and adulterated drugs. Specifically, Board inspectors documented multiple instances in which manufacturer containers found on Park West's shelves contained tablets that bore no actual relation to the container or the identifying information contained thereon, including: (1) a 60-capsule manufacturer bottle of Cymbalta 20 mg that contained 161 capsules, many of which exhibited color and imprint variations; (2) a 100-tablet manufacturer bottle of Digoxin 125 mcg that contained 120 capsules; (3) a 90-tablet manufacturer bottle of Crestor 5 mg that contained 105 tablets; and (4) a 100-tablet manufacturer bottle of Lexapro 10 mg that contained 105 tablets.

FIRST CAUSE FOR DISCIPLINE

(Prohibited Corporate Ownership and Governance)

31. Respondent Park West is subject to disciplinary action under section 4301, subdivision (o), in conjunction with section 4307, subdivision (a), in that Park West 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 28 and 29, inclusive, as though set forth fully herein.

SECOND CAUSE FOR DISCIPLINE

(Misconduct by Owner and/or Corporate Officer)

32. Respondent Park West is subject to disciplinary action under section 4302 in that a corporate officer, director and/or person holding 10 percent or more of Park West'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 28 and 29, inclusive, as though set forth fully herein.

THIRD CAUSE FOR DISCIPLINE

(Adulterated Drugs)

33. Respondent Park West and respondent Whittemore (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 paragraph 30, inclusive, as though set forth fully herein.

FOURTH CAUSE FOR DISCIPLINE

(Misbranded Drugs)

34. Respondents are subject to disciplinary action under section 4301, subdivision (j), in conjunction with section 4113, subdivision (c), and 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 paragraph 30, inclusive, as though set forth fully herein.

FIFTH CAUSE FOR DISCIPLINE

(Acquisition & Inventory Records Violation)

35. Respondents are subject to disciplinary action under section 4301, subdivision (o), in conjunction with section 4113, subdivision (c), in that Respondents failed to maintain acquisition and inventory records in compliance with section 4081. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 30, inclusive, as though set forth fully herein.

SIXTH CAUSE FOR DISCIPLINE

(Drug Compounding Self-Assessment Violation)

36. Respondents are subject to disciplinary action under section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.2, subdivision (j), in that Respondent engaged in drug compounding activities without completing a compounding self-assessment as required by state law. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 30, inclusive, as though set forth fully herein.

SEVENTH CAUSE FOR DISCIPLINE

(Drug Compounding Policy & Procedures Violation)

37. Respondents are subject to disciplinary action under section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.5, in that Respondent

engaged in drug compounding activities without having drug compounding policies and procedures in place as required by state law. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 30, inclusive, as though set forth fully herein.

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 46623, issued to Park West Pharmacy, Inc.;

2. Revoking or suspending Pharmacist License No. RPH 21221, issued to Jerry A. Whittemore;

3. Ordering Park West Pharmacy, Inc. and Jerry A. Whittemore 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 Park West 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

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

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