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

In the Matter of the Accusation Against: **ADAMS SQUARE PHARMACY** 1122 A East Chevy Chase Drive Glendale, CA 91205 Pharmacy Permit No. PHY 40833 **MARGARITA KAZARIAN** 3521 Country Club Drive Glendale, CA 91208 Pharmacist License No. RPH 45273 Respondent.	Case No. 5189 OAH No. 2014070120

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on November 18, 2014.

It is so ORDERED on November 18, 2014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STAN C. WEISSER
Board President

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

In the Matter of the Accusation Against: ADAMS SQUARE PHARMACY; MARGARITA KAZARIAN Permit No. PHY 40833 and MARGARITA KAZARIAN Pharmacist License No. RPH 45273 Respondents.	Case No. 5189 OAH No. 2014070120

PROPOSED DECISION

This matter came on regularly for hearing on July 31, 2014, August 1, 2014, October 2, 2014, and October 3, 2014, in Los Angeles, California, before H. Stuart Waxman, Administrative Law Judge, Office of Administrative Hearings, State of California.

Virginia Herold (Complainant) was represented by William D. Gardner, Deputy Attorney General.

Margarita Kazarian (Respondent or Kazarian) was present. Both she and Respondent, Adams Square Pharmacy, were represented by Paul L. Cass, Attorney at Law.

Oral and documentary evidence was received. The record was closed on October 3, 2014, and the matter was submitted for decision.

FACTUAL FINDINGS

1. Complainant is the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

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2. On or about April 11, 1995, the Board issued original pharmacy permit no. PHY 40833 and permit rights to Respondent, Adams Square Pharmacy, located at 1122 East Chevy Chase Drive, Glendale, California 91205. The pharmacy permit will expire on April 1, 2015, unless renewed. It was in full force and effect at all relevant times. Respondent Kazarian has been the Individual Licensed Owner of Adams Square Pharmacy since April 11, 1995, and its Pharmacist-in-Charge since May 10, 2000.

3. On or about April 3, 1991, the Board issued pharmacist license no. RPH 45273 and licensing rights to Respondent, Margarita Kazarian. The pharmacist license will expire on October 31, 2015, unless renewed.

4. On June 16, 2014, an Interim Suspension Order was issued suspending Adams Square Pharmacy's permit and Kazarian's pharmacist's license. Adams Square Pharmacy is currently closed pursuant to that Interim Suspension Order.

5. Complainant seeks to revoke the pharmacy permit and pharmacist license issued to respondents on grounds of numerous violations of the pharmacy law including unprofessional conduct, acts involving dishonesty, fraud, deceit, and/or corruption, false representation of facts, counterfeit drugs, adulterated drugs, misbranded drugs, violation of federal expiration dating law, transfer/sale of dangerous drugs to an unlicensed wholesaler, purchase, trade, sale and/or transfer of adulterated drugs, purchase, trade, sale and/or transfer of misbranded drugs, failure to maintain acquisition records and inventory, and subversion of a Board investigation. For the reasons set forth below, the pharmacy permit of Adams Square Pharmacy and Kazarian's pharmacist license shall be revoked.

6. Respondent operates Adams Square Pharmacy as a sole proprietorship under a dba. She also owns Kenneth Roads Pharmacy in Glendale and Park West Pharmacy in West Hills. Those two pharmacies are operated as corporations. Respondent owns 100 percent of the stock of each of those corporations. Adams Square Pharmacy has a lengthy history dating back to the 1920's when it first opened its doors.

7. No allegations are made in this action against either Kenneth Roads Pharmacy or Park West Pharmacy.

8. At all relevant times, Respondent purchased her medication inventory from Amerisource Bergen Corporation (Amerisource), a large drug wholesaler. Between 2007 and the present, specifically in May 2012, Respondent purchased one 30-count bottle of Cialis 20 mg from Amerisource. The purchase price was $643.56. On or about October 16, 2012, Respondent returned a 30-count bottle of Cialis to Amerisource for which she received a credit of $514.85.

9. At all relevant times, Amerisource purchased Cialis 20 mg directly from the manufacturer, Eli Lilly and Company (Lilly). Neither Lilly nor any regulatory agency recalled any Cialis 20 mg during the relevant time period.

10. With one exception, at all relevant times, Respondent used RX Reverse Distributors, Inc. for returns of medications to their respective manufacturers, whether or not for credit, and regardless of whether the medications had expired or were soon to become expired. The one exception occurred in June 2013, when Respondent, by and through her pharmacy technician, Julia Perez (Perez), hired Pharmatech Services (Pharmatech)[1] as a reverse distributor. Perez sent numerous medications to Pharmatech in one shipment (two boxes), accompanied by a four-page handwritten list of the medications in that shipment. Included in the shipment was one 30-count bottle of Cialis 20 mg intended for return to Lilly for destruction. The Cialis tablets were in authentic Lilly packaging which bore lot number A752870A and an expiration date in April 2013.

11. On June 19, 2013, Pharmatech returned the Cialis to Lilly along with other medications Lilly manufactured. Respondent received a credit of $7,730 for the returned Lilly medications. She paid Pharmatech $4,434.38 for its reverse distributor services.

12. At the time of the transaction, Pharmatech's owner, Jon Jennings, was unaware that his company was required to have a permit in order to do business in California. He is now attempting to procure that permit. Respondent did not attempt to determine whether Pharmatech possessed a proper California permit before sending the numerous medications to Florida for processing by Pharmatech.

13. On approximately October 30, 2013, a Lilly returned goods employee noticed that the tablets in lot number A752870A bore a darker color and were of a different shape and thickness from Cialis manufactured by Lilly. This finding raised a suspicion that the pills returned to Lilly by Adams Square Pharmacy, through Pharmatech, were counterfeit. One pill from the suspect bottle underwent physical and chemical testing by Lilly's Global Product Protection Technical Team, and the other pills in the same container were visually inspected. Based on those tests and observations, the team determined that, although the container which housed the tablets was an authentic Lilly container, the tablets contained within the bottle were counterfeit. The Board was notified of the test results.

14. On November 12, 2013, Board investigators Sarah Bayley and Sejal Desai[2] conducted an inspection at Adams Square Pharmacy. Respondent and Perez were both present during the inspection. Upon the inspectors' request, Respondent produced several months of purchase records. Those records did not indicate any purchase of Cialis 20 mg for the times they covered. Respondent told the inspectors that RX Reverse Distributors was the pharmacy's exclusive reverse distributor. She did not mention to the inspectors that, only five months earlier, she had used Pharmatech to return two boxes of various medications to their respective manufacturers. Based on that misrepresentation, the inspectors requested and received returned medication records from RX Reverse Distributors. There was no reference to Cialis 20 mg on any of the RX Reverse Distributors records.

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[1] Pharmatech is a reverse distributor with its offices in Odessa, Florida.

[2] Both Bayley and Desai are pharmacists licensed by the Board.

15. During their inspection, the investigators found three plastic trash bags, one box, and a plastic trash bin that were full of empty plastic bottles. Respondent had permitted Perez to store the bottles in the pharmacy until she took them home where she combined them with other items in her home and exchanged them for extra cash at a recycling center.

16. In a room behind the pharmacy area, the inspectors found a grey tote box containing numerous medications in various containers. Respondent told the investigators the medications were stored in the tote box pending their transfer to RX Reverse Distributors for return to the manufacturers. Many, but not all, of the medications had passed their expiration dates. At least one container of Levoxyl and one container of Vytorin were overfilled and contained medications other than those referenced on the labels. Prior to the time of the inspection, all Levoxyl had been recalled and taken off the market. However, that fact did not explain why other medications were discovered in the Levoxyl and Vytorin containers if those containers were earmarked for return to their manufacturers.

17. The inspectors found three "sharps" containers in the pharmacy area. They were filled to overflowing with loose tablets and capsules which Respondent claimed had been turned in by customers. Respondent further claimed she was holding the containers for pick-up by RX Reverse Distributors for destruction. She denied anticipating any kind of credit for the loose medications. At the administrative hearing, Respondent testified that she kept the loose medications in the sharps containers because those containers could not be opened. That testimony was not credible. Photographs of the sharps containers reveal a circular opening in the tops approximately three and one half inches in diameter. The opening of one of the containers was open 180 degrees, making the medications inside easily accessible to anyone who would want them. One of the sharps containers was so full that loose pills were lying on top of it. Similarly not credible was the testimony of Respondent and Perez who could not agree whether the sharps containers had been there three, four, or twelve years.

18. Inspector Bayley found nine 30-capsule containers of Norvir 100 mg in a plastic bag on a pharmacy shelf. All of the containers bore passed expiration dates. Kazarian said she had forgotten about the Norvir, and that the drug was being held for RX Reverse Distributors to pick up for destruction.

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19. The inspectors also found on a pharmacy shelf a manufacturer container of Actos 45 mg bearing a wholesale label for Park West Pharmacy and a manufacturer container of Amlodipine/Benazepril 5/20 mg bearing a wholesale label for Kenneth Road Pharmacy. Respondent told the investigators that she occasionally borrowed from her other pharmacies when she ran out of medications at Adams Square Pharmacy. She admitted her pharmacies did not maintain any records of medication transfers. Inspector Bayley found two prescription containers for two patients that had been dispensed by Kenneth Road Pharmacy. Respondent explained that Adams Square Pharmacy and Kenneth Road Pharmacy used the same delivery driver, and the patients occasionally asked that their drugs be brought to Adams Square Pharmacy so they could pick up from there.

20. Inspector Bayley also located on a pharmacy shelf a bottle of Zyvox containing tablets of differing shades of red and varying thicknesses of the imprints on the tablets. Respondent told Bayley that such variations were normal. Bayley disagreed.

21. Inspector Bayley listed the various overfilled containers and medications of disparate color and shapes, which included Cialis 20 mg, Crestor 10 mg, Namenda 5 mg, Zyvox 600 mg, Levoxyl 88 meg, and Vytorin 10/40 mg, and she confiscated at least one bottle of each. She asked Respondent to inventory those medications and to create a drug recall report for those dispensed between November 12, 2011 and November 12, 2013. Either Respondent or Perez completed a seven-page list of medications found in overfilled containers and medications beyond their expiration dates the inspectors had discovered in Adams Square Pharmacy. Although the large number of empty containers and the three sharps containers filled to overflowing with loose medications did not violate the Pharmacy Law, they raised what Inspector Bayley described at the administrative hearing as "red flags."

22. Inspector Bayley placed the seized medications in evidence bags which she sealed and kept in her office for safekeeping until November 21, 2013. On that date, she met with United States Food and Drug Administration Special Agent Keith Hadley, who was assigned to the Department of Justice, Bureau of Medi-Cal Fraud and Elder Abuse. Hadley took custody of the single containers of Crestor, Levoxyl, Cialis, Vytorin, Namenda, and Zyvoz, and Bayley gave Hadley a reverse official receipt for those medications. After inspecting some of the Cialis pills on a white sheet of paper, Hadley returned the pills to their container and placed the medications in an evidence bag which was then heat-sealed. The original label on the Cialis container indicated the container held 30 tablets. It actually contained 92.

23. On November 25, 2013, Hadley sent the Cialis container, with the tablets inside, to Lilly's Global Product Protection Technical Team. The team notified Hadley on or about December 5, 2013, that, based on visual and laboratory testing, it had determined the tablets to be counterfeit.

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24. Subsequent testing of the Levoxyl by its manufacturer, Pfizer, revealed that the tablets and container seized at Adams Square Pharmacy were authentic. However, the Levoxyl tablets found within the container were of different lots and were created at different manufacturing sites.

25. Of the various allegations in the First Amended Accusation, Respondent admits only that she should not have permitted overfills by the co-mingling of like medications with disparate lot numbers in her pharmacy.

26. At the administrative hearing, Respondent testified that, when she sent overfills to RX Reverse Distributors, that company would remove the excess number of pills from the container and then ship the container with the correct number of pills to the manufacturer for destruction. That testimony was not credible. Not only did Respondent fail to produce evidence of such fraudulent conduct by RX Reverse Distributors, Respondent admitted she erred in sending overfilled containers back to the manufacturers. However, Respondent's testimony did establish that overfilling containers and returning overfilled containers was conduct in which she had engaged over some period of time, thus eliminating the likelihood that the overfills the inspectors discovered in the pharmacy on November 12, 2013 represented an isolated incident.

27. Between 2005 and 2014, Respondent purchased 420 Cialis 20 mg tablets from Amerisource. During that time, she dispensed 148 tablets to customers. In October 2012, Respondent returned a container housing 30 Cialis 20 mg tablets. She did the same in June 2013. In November 2013, the Board investigator seized 92 two of the tablets. Respondent is unable to account for the remaining 120 tablets. As referenced in Factual Finding 8, above, Respondent purchased Cialis 20 mg exclusively from Amerisource. She purchased only one bottle of Cialis 20 mg from Amerisource between 2007 and the present. She returned that bottle in October 2012. Respondent failed to explain where she obtained the bottle of Cialis 20 mg she returned to Amerisource in June 2013 or why she sent it to Amerisource instead of the wholesaler from which she purchased it.

28. At the administrative hearing, Respondent admitted that she never takes inventory of any of the non-scheduled drugs in her pharmacy.

29. Paragraph 50, subparagraphs (a) and (b) allege that, on August 18, 2004, and September 18, 2008, respectively, the Board issued citations against Adams Square Pharmacy and Kazarian. No evidence was offered on that issue.[3]

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[3] Page one of Bayley's investigation report (Exhibit 10) contains references to such citations, but neither the citations nor other evidence concerning them was offered in evidence. Exhibit 17 contains copies of citations dated in 2013 but none from 2004 or 2008.

30. On or about March 21, 2013, the Board issued Citation No. CI 2011 50111 to Adams Square Pharmacy, and Citation No. CI 2012 55327 to Kazarian. (Exhibit 17.) Both citations alleged violations of Business and Professions Code section 6169, subdivision (a)(1) (purchasing dangerous drugs from unlicensed wholesalers), Business and Professions Code section 4169, subdivision (a)(3) (purchase and sale of misbranded dangerous drugs), and Business and Professions Code section 4059, subdivision (a) (furnishing dangerous drugs without a prescription). The evidence did not disclose the status of those citations.

31. The Board incurred investigation costs of $26,316, and prosecution costs, including attorney fees, of $21,552.50, in connection with the investigation and prosecution of this action. Those costs are found to be reasonable.

LEGAL CONCLUSIONS

As to Respondent, Adams Square Pharmacy

1. Cause exists to discipline Respondent's pharmacy permit pursuant to Business and Professions Code section 4301, subdivisions (f), (g), (j), and (o), for unprofessional conduct, as set forth in Findings 6 through 28.

2. Cause exists to discipline Respondent's pharmacy permit pursuant to Business and Professions Code section 4301, subdivision (f), for acts involving dishonesty, fraud, deceit, and/or corruption, as set forth in Findings 6 through 28.

3. Cause exists to discipline Respondent's pharmacy permit pursuant to Business and Professions Code section 4301, subdivision (g), for false representation of facts, as set forth in Findings 6 through 28.

4. Cause exists to discipline Respondent's pharmacy permit pursuant to Business and Professions Code section 4301, subdivision (j), in conjunction with Health and Safety Code section 110330, and title 21 United States Code section 331(i)(3), for violating state and federal drug laws by selling, dispensing, and/or holding for sale or dispensing, a counterfeit drug, as set forth in Findings 6 through 14, 21, 22, 23, 27, and 28.

5. Cause exists to discipline Respondent's pharmacy permit pursuant to Business and Professions Code section 4301, subdivision (j), in conjunction with Health and Safety Code section 110330, and title 21 United States Code section 331(i)(3), for violating state and federal drug laws by engaging in conduct that caused the sale, delivery, holding, offering for sale and/or introduction into commerce an adulterated drug, as set forth in Findings 6 through 28.

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6. Cause exists to discipline Respondent's pharmacy permit pursuant to Business and Professions Code section 4301, subdivision (j), in conjunction with Health and Safety Code section 110330, and title 21 United States Code section 331(i)(3), for violating state and federal drug laws by engaging in conduct that caused the sale, delivery, holding, offering for sale and/or introduction into commerce a misbranded drug, as set forth in Findings 6 through 28.

7. Cause exists to discipline Respondent's pharmacy permit pursuant to 21 Code of Federal Regulations part 4169(a)(1), for engaging in conduct that violated federal drug expiration dating requirements, as set forth in Findings 6 through 28.

8. Cause exists to discipline Respondent's pharmacy permit pursuant to Business and Professions Code section 4301, subdivision (o), in conjunction with Business and Professions Code section 4169, subdivision (a)(1), for transferring or selling dangerous drugs to a person or entity not licensed by the Board as a wholesaler or pharmacy, as set forth in Findings 6 through 13.

9. Cause exists to discipline Respondent's pharmacy permit pursuant to Business and Professions Code section 4301, subdivision (o), in conjunction with Business and Professions Code section 4169, subdivision (a)(2), for purchasing, trading, selling and/or transferring dangerous drugs that were known or reasonably should have been known to be adulterated, as set forth in Findings 6 through 28.

10. Cause exists to discipline Respondent's pharmacy permit pursuant to Business and Professions Code section 4301, subdivision (o), in conjunction with Business and Professions Code section 4169, subdivision (a)(3), for purchasing, trading, selling and/or transferring dangerous drugs that were known or reasonably should have been known to be misbranded, as set forth in Findings 6 through 28.

11. Cause exists to discipline Respondent's pharmacy permit pursuant to Business and Professions Code section 4301, subdivision (o), in conjunction with Business and Professions Code section 4181, for failing to maintain accurate records of all sales, acquisitions, and/or dispositions of dangerous drugs, as set forth in Findings 6 through 28.

12. Cause exists to discipline Respondent's pharmacy permit pursuant to Business and Professions Code section 4301, subdivision (q), for subverting or attempting to subvert a Board investigation, as set forth in Findings 6 through 14.

13. Cause exists to order Respondent to pay the costs claimed under Business and Professions Code section 125.3, as set forth in Finding 31.

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As to Respondent, Margarita Kazarian

14. Cause exists to discipline Respondent's pharmacist license pursuant to Business and Professions Code section 4301, subdivisions (f), (g), (j), and (o), for unprofessional conduct, as set forth in Findings 6 through 28.

15. Cause exists to discipline Respondent's pharmacist license pursuant to Business and Professions Code section 4301, subdivision (f), for acts involving dishonesty, fraud, deceit, and/or corruption, as set forth in Findings 6 through 28.

16. Cause exists to discipline Respondent's pharmacist license pursuant to Business and Professions Code section 4301, subdivision (g), for false representation of facts, as set forth in Findings 6 through 28.

17. Cause exists to discipline Respondent's pharmacist license pursuant to Business and Professions Code section 4301, subdivision (j), in conjunction with Health and Safety Code section 110330, and title 21 United States Code section 331 (i)(3), for violating state and federal drug laws by selling, dispensing, and/or holding for sale or dispensing, a counterfeit drug, as set forth in Findings 6 through 14, 21, 22, 23, 27, and 28.

18. Cause exists to discipline Respondent's pharmacist license pursuant to Business and Professions Code section 4301, subdivision (j), in conjunction with Health and Safety Code section 110330, and title 21 United States Code section 331(i)(3), for violating state and federal drug laws by engaging in conduct that caused the sale, delivery, holding, offering for sale and/or introduction into commerce an adulterated drug, as set forth in Findings 6 through 28.

19. Cause exists to discipline Respondent's pharmacist license pursuant to Business and Professions Code section 4301, subdivision (j), in conjunction with Health and Safety Code section 110330, and title 21 United States Code section 331(i)(3), for violating state and federal drug laws by engaging in conduct that caused the sale, delivery, holding, offering for sale and/or introduction into commerce a misbranded drug, as set forth in Findings 6 through 28.

20. Cause exists to discipline Respondent's pharmacist license pursuant to 21 Code of Federal Regulations part 4169 (a)(1), for engaging in conduct that violated federal drug expiration dating requirements, as set forth in Findings 6 through 28.

21. Cause exists to discipline Respondent's pharmacist license pursuant to Business and Professions Code section 4301, subdivision (o), in conjunction with Business and Professions Code section 4169, subdivision (a)(1), for transferring or selling dangerous drugs to a person or entity not licensed by the Board as a wholesaler or pharmacy, as set forth in Findings 6 through 13.

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22. Cause exists to discipline Respondent's pharmacist license pursuant to Business and Professions Code section 4301, subdivision (o), in conjunction with Business and Professions Code section 4169, subdivision (a)(2), for purchasing, trading, selling and/or transferring dangerous drugs that were known or reasonably should have been known to be adulterated, as set forth in Findings 6 through 28.

23. Cause exists to discipline Respondent's pharmacist license pursuant to Business and Professions Code section 4301, subdivision (o), in conjunction with Business and Professions Code section 4169, subdivision (a)(3), for purchasing, trading, selling and/or transferring dangerous drugs that were known or reasonably should have been known to be misbranded, as set forth in Findings 6 through 28.

24. Cause exists to discipline Respondent's pharmacist license pursuant to Business and Professions Code section 4301, subdivision (o), in conjunction with Business and Professions Code section 4181, for failing to maintain accurate records of all sales, acquisitions, and/or dispositions of dangerous drugs, as set forth in Findings 6 through 28.

25. Cause exists to discipline Respondent's pharmacist license pursuant to Business and Professions Code section 4301, subdivision (q), for subverting or attempting to subvert a Board investigation, as set forth in Findings 6 through 14.

26. Cause exists to order Respondent to pay the costs claimed under Business and Professions Code section 125.3, as set forth in Finding 31.

Analysis and Discussion

27. The standard of proof applicable to this case is clear and convincing evidence to a reasonable certainty. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) This means the burden rests on Complainant to establish the charging allegations by proof that is clear, explicit and unequivocal--so clear as to leave no substantial doubt, and sufficiently strong to command the unhesitating assent of every reasonable mind. (*In re Marriage of Weaver* (1990) 224 Cal.App.3d 478.) "Evidence of a charge is clear and convincing so long as there is a 'high probability' that the charge is true. [Citations.] The evidence need not establish the fact beyond a reasonable doubt." (*Broadman v. Comm'n on Judicial Performance* (1998) 18 Cal.4th 1079, 1090.)

28. Business and Professions Code section 4113, subdivision (c) 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.

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29. Business and Professions Code section 4302 states:

The 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.

30. Business and Professions Code section 4301 states in relevant part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . Unprofessional conduct shall include, but is not limited to, any of the following:

[¶] . . . [¶]

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(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 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.

[¶] . . . [¶]

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

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31. Business and Professions Code section 4169, subdivision (a), states in relevant part:

(a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

32. Business and Professions Code section 4081 states in pertinent part:

(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 a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

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33. Business and Professions Code defines "dangerous drug" as follows:

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

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

[¶] . . . [¶]

(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.

34. Health and Safety Code section 110330 states:

It is unlawful for any person to do any act that causes any . . . drug . . . to be a counterfeit, or to sell, dispense, or hold for sale or dispensing, the counterfeit . . . drug . . . .

35. Health and Safety Code section 111260 states:

Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

36. Health and Safety Code section 111285 states:

Any drug or device is adulterated if its strength differs from, or its purity or quality is below, that which it is represented to possess.

37. Health and Safety Code section 111295 states:

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

38. Health and Safety Code section 111305 states:

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.

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39. Health and Safety Code section 111330 states:

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

40. Health and Safety Code section 111340 states in relevant part:

Any drug or device is misbranded unless it bears a label containing all of the following information:

[¶] . . . [¶]

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Reasonable variations from the requirements of subdivision (b) shall be permitted. Requirements for placement and prominence of the information and exemptions as to small packages shall be established in accordance with regulations adopted pursuant to Section 110380.

41. Health and Safety Code section 111390 states:

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

42. Health and Safety Code section 111395 states in pertinent part:

Any drug is misbranded in any of the following cases:

(a) It is an imitation of another drug.

[¶[. . . [¶]

(c) The contents of the original package have been, wholly or partly, removed and replaced with other material in the package.

43. Health and Safety Code section 111420 states:

A drug or device is misbranded if a trademark, trade name, or other identifying mark, imprint, or device of another person, or any likeness of the trademark, trade name, or other identifying mark, imprint, or device of another person, has been placed on the drug or device, or upon its container.

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44. Health and Safety Code section 111440 states:

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

45. Title 21 United States Code section 331 states in pertinent part:

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded.

(b) The adulteration or misbranding of any . . . drug . . . in interstate commerce.

[¶] . . . [¶]

(i)(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

46. Title 21 United States Code section 351(a)(2)(B) defines a drug to be adulterated "if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess."

47. Title 21 United States Code section 352(a) defines a drug as misbranded "if its labeling is false or misleading in any particular."

48. According to title 21 United States Code section 352(b)(2), a drug is misbranded unless its label contains "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. . . ."

49. According to title 21 United States Code section 352(i), a drug is misbranded "[i]f it is a drug and its container is so made, formed, or filled as to be misleading or . . . if it is an imitation of another drug."

50. 21 Code of Federal Regulations part 201.18 states: "The lot number on the label of a drug should be capable of yielding the complete manufacturing history of the package. An incorrect lot number may be regarded as causing the article to be misbranded."

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51. 21 Code of Federal Regulations part 211.137 states:

(a) To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in § 211.166.

(b) Expiration dates shall be related to any storage conditions stated on the labeling, as determined by stability studies described in § 211.166.

(c) If the drug product is to be reconstituted at the time of dispensing, its labeling shall bear expiration information for both the reconstituted and unreconstituted drug products.

(d) Expiration dates shall appear on labeling in accordance with the requirements of § 201.17 of this chapter.

52. Respondent committed numerous violations of the pharmacy law but admitted only one—overfilling medication bottles. She offered little by way of explanation of her violations, and she offered no evidence of rehabilitation. She did not offer any evidence of changes made to her pharmacy practice to prevent recurrences of the violations, and she did not offer to make any such changes.

53. Respondent argued that there **may** have been an interruption in the chain of custody for the two samples of Cialis that were sent to Lilly for testing, and that the testing itself **may** have been insufficient because of the number of tablets sampled.

54. The chain of custody and adequacy of the testing were established at the hearing. As stated in Legal Conclusion 27, Complainant need establish only a high probability that the charge is true, not evidence beyond a reasonable doubt. (*Broadman v. Comm'n on Judicial Performance, supra.*) Complainant satisfied that criterion. An additional safeguard is found in the matching of the lot numbers on the products sent and received. A reference to "Huntington Pharmacy" on a Certified Inventory of Evidence was not material because the document bore the correct lot number as well as the name "Adams Square Pharmacy." Further, for the chain of custody to serve as grounds for dismissal of the First Amended Accusation or some of the causes for discipline within it, one would have to find that the chain of custody was interrupted for both of the samples sent to Lilly. One sample came from Pharmatech in Florida, the other from the Board investigators via the FDA in California. Respondent failed to establish even one such defense, much less two.

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55. Respondent also questioned the quality of the evidence regarding differences in tablet colors to establish the likelihood of counterfeit tablets. She argued that Inspector Bayley may have misperceived minute color differences between the pills, and she questioned Bayley as to whether the cell phone camera Bayley had used to photograph the pills had been checked for color accuracy. She also questioned the accuracy of the photographic evidence offered during the administrative hearing. Those arguments were not persuasive. The photographic evidence clearly showed color differences. The photographs were printed on plain white photocopy paper. If some hues varied slightly from a witness's recollection, the difference could easily be due to differences between the human eye and pixels in a cell phone camera, the difference between pixels in a cell phone camera and the capabilities and characteristics of a color printer, or the myriad effects of light and shadow. In any event, the testimony and photographic evidence were more than adequate to satisfy the clear and convincing evidence standard.

56. Pursuant to California Code of Regulations, title 16, section 1760, the Board established its Disciplinary Guidelines (Rev. 10/2007), which are to be consulted when determining the level of discipline to be imposed on a licensee. In those guidelines, the Board ranked various violations ranging from the most minor (Category 1) through the most severe (Category IV). The levels of recommended discipline escalate with the severity of the violations. Each of respondents' violations falls into either Category II or Category III. In this case, the result is the same in either category.

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57. To determine the level of discipline to be imposed, the Guidelines recommend specific criteria be considered. Those criteria read as follows:

1. actual or potential harm to the public
2. actual or potential harm to any consumer
3. prior disciplinary record, including level of compliance with disciplinary order(s)
4. prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s)
5. number and/or variety of current violations
6. nature and severity of the act(s), offense(s) or crime(s) under consideration
7. aggravating evidence
8. mitigating evidence
9. rehabilitation evidence
10. compliance with terms of any criminal sentence, parole, or probation
11. overall criminal record
12. if applicable, evidence of proceedings for case being set aside and dismissed pursuant to Section 1203.4 of the Penal Code
13. time passed since the act(s) or offense(s)
14. whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct
15. financial benefit to the respondent from the misconduct.

No single one or combination of the above factors is required to justify the minimum and/or maximum penalty in a given case, as opposed to an intermediate one.

58. Respondents did poorly with respect to most of the above criteria.

a. Although Complainant did not prove any actual harm to a consumer or to the public, the potential for harm to both groups from counterfeit, adulterated, and misbranded drugs was extremely high. (Criteria 1 and 2.)

b. There is no record of prior discipline. However, the Board has issued at least one citation to each respondent. (Criteria 3 and 4.)

c. The number and severity of the current violations is high. Complainant established all 12 of the causes for discipline alleged in the First Amended Accusation. Except for a cause for discipline based on poor record keeping, all of the causes for discipline involve counterfeit, adulterated and/or misbranded drugs kept in the pharmacy. (Criteria 5 and 6.)

d. Respondent Kazarian's inability to explain the numerous and serious violations occurring in her pharmacy despite her position as owner and pharmacist-in-charge, and her lack of rehabilitation, serve as factors in aggravation. (Criteria 7, 8, and 9.)

e. Criteria 10, 11, and 12 are not applicable to this case.

f. The acts occurring in 2013 are temporally recent. (Criterion 13.)

g. At the very least, Respondent Kazarian's conduct was negligent and demonstrated incompetence. At worst, it was intentional and fraudulent. Complainant failed to prove the latter. Regardless, Respondent was unable to explain or even admit to the violations in her pharmacy. She could not account for numerous missing Cialis tablets, she failed to take inventories of non-scheduled drugs, and she failed to maintain records of medications being transferred between her three pharmacies. As the pharmacist-in-charge, she is charged with knowledge and knowing participation in all aspects of her pharmacy business. As the owner of the pharmacy, she is vicariously liable for the wrongful actions of her employees. (*Rob-Mac, Inc. v. Department of Motor Vehicles* (1983) 148 Cal.App.3d 793, 797; *Camacho v. Youde* (1979) 95 Cal.App.3d 161, 165.) (Criterion 14.)

h. Respondents stood to gain a financial benefit from the misconduct both through sales of counterfeit, adulterated, and misbranded drugs, and through credits earned for products returned to the manufacturers through reverse distributors. (Criterion 15.)

59. The Board's Guidelines call for maximum discipline of license revocation for both Category II and Category III violations. In this case, given the number and nature of the violations, the number and nature of proven causes for discipline, the poor showing on the Board's disciplinary criteria, including a lack of rehabilitation, and the absence of a plan to improve respondents' compliance with the pharmacy law, continued licensure would bode poorly for the health, safety, welfare, and interest of the public. The public interest can be served only by permit/license revocation.

60. The First Amended Accusation does not contain a prayer for discipline against Respondent Kazarian's other pharmacies, Kenneth Square Pharmacy and Park West Pharmacy, and it does not contain a prayer regarding her continued involvement with those pharmacies. Accordingly, no findings, conclusions, or orders are made in connection with them.

ORDER

1. Pharmacy Permit number PHY 40833, issued to Respondent, Adams Square Pharmacy, is revoked.

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2. Respondent owner, Margarita Kazarian, shall, by the effective date of this decision, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the Board of all controlled substances and dangerous drugs and devices. Respondent owner shall provide written proof of such disposition, submit a completed Discontinuance of Business form and return the wall and renewal license to the Board within five days of disposition.

3. Respondent owner, Margarita Kazarian shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the Board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding 60 days.

4. Pharmacist License number RPH 45273, issued to Respondent, Margarita Kazarian, is revoked.

5. Respondent, Margarita Kazarian, shall relinquish her wall license and pocket renewal license to the Board within 10 days of the effective date of this decision. Respondent may not reapply or petition the Board for reinstatement of her revoked license for three years from the effective date of this decision.

6. Respondents shall pay to the Board its costs of investigation and prosecution in the amount of $47,868.50 within15 days of the effective date of this decision. Liability for the payment of investigation and prosecution costs shall be joint and several.

Dated: October 16, 2014

H. STUART WAXMAN
Administrative Law Judge
Office of Administrative Hearings

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

In the Matter of the Accusation Against:	Case No. 5189
	OAH No. 2014050753
ADAMS SQUARE PHARMACY; MARGARITA KAZARIAN **Permit No. PHY 40833**	**ACCUSATION**
and	
MARGARITA KAZARIAN **Pharmacist License No. RPH 45273**	
Respondents.	

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 (Board).

2. On or about April 11, 1995, the Board issued Pharmacy Permit No. PHY 40833 to Adams Square Pharmacy, Margarita Kazarian, owner ("Adams Square"). The pharmacy permit was suspended pursuant to an Interim Suspension Order on June 16, 2014. It will expire on April 1, 2015, unless renewed.

3. On or about April 3, 1992, the Board issued Pharmacist License No. RPH 45273 to Margarita Kazarian. The pharmacist license will expire on October 31, 2015, unless renewed. Pursuant to an Interim Suspension Order issued on June 16, 2014, Respondent is currently prohibited from serving as the pharmacist-in-charge ("PIC") of any pharmacy and from performing any duties of a PIC. At all times relevant to the allegations contained herein, Respondent Kazarian was PIC of Adams Square.

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."

CALIFORNIA PHARMACY LAW

6. 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."

7. 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."

8. 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:

"(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

"(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, 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.

. . .

"(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

9. Section 4169 of the Code states, in pertinent part:

"(a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

10. 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.

CALIFORNIA HEALTH AND SAFETY CODE

11. Section 110330 of the Health and Safety Code provides:

"It is unlawful for any person to do any act that causes any food, drug, device, or cosmetic to be a counterfeit, or to sell, dispense, or hold for sale or dispensing, the counterfeit food, drug, device, or cosmetic."

12. Section 111260 of the Health and Safety Code provides:

"Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess."

13. Section 111285 of the Health and Safety Code provides:

"Any drug or device is adulterated if its strength differs from, or its purity or quality is below, that which it is represented to possess."

14. 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."

15. 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."

16. 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."

17. 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."

18. 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."

19. Section 111395 of the Health and Safety Code provides:

"Any drug is misbranded in any of the following cases:

"(a) It is an imitation of another drug.

. . .

"(c) The contents of the original package have been, wholly or partly, removed and replaced with other material in the package.

20. Section 111420 of the Health and Safety Code provides:

"A drug or device is misbranded if a trademark, trade name, or other identifying mark, imprint, or device of another person, or any likeness of the trademark, trade name, or other identifying mark, imprint, or device of another person, has been placed on the drug or device, or upon its container."

21. 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."

FEDERAL STATUTES AND REGULATIONS

22. United States Code, title 21, section 331, provides in pertinent part:

"The following acts and the causing thereof are prohibited:

"(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

"(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce

...

"(i) (3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

23. United States Code, title 21, section 351, subdivision (a)(2)(B), provides that a drug shall be deemed to be adulterated "if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess."

24. United States Code, title 21, section 352, subdivision (a), provides in pertinent part that a drug shall be deemed to be misbranded "[i]f If its labeling is false or misleading in any particular."

25. United States Code, title 21, section 352, subdivision (b)(2), provides in pertinent part that a drug shall be deemed to be misbranded unless it bears a label containing "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count . . . ."

26. United States Code, title 21, section 352, subdivision (i), provides in pertinent part that a drug shall be deemed to be misbranded "[i]f it is a drug and its container is so made, formed, or filled as to be misleading or . . . if it is an imitation of another drug."

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27. Code of Federal Regulations, title 21, section 201.18 provides:

"The lot number on the label of a drug should be capable of yielding the complete manufacturing history of the package. An incorrect lot number may be regarded as causing the article to be misbranded."

28. Code of Federal Regulations, title 21, section 211.137 provides:

(a) To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in § 211.166.

(b) Expiration dates shall be related to any storage conditions stated on the labeling, as determined by stability studies described in § 211.166.

(c) If the drug product is to be reconstituted at the time of dispensing, its labeling shall bear expiration information for both the reconstituted and unreconstituted drug products.

(d) Expiration dates shall appear on labeling in accordance with the requirements of § 201.17 of this chapter.

COST RECOVERY

29. 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.

BOARD INVESTIGATION

30. In November 2013, pharmaceutical manufacturer Eli Lilly and Company ("Lilly") notified the Board that Adams Square had fraudulently submitted a bottle of thirty counterfeit Cialis 20 mg tablets to Lilly as "returned" product for which a refund was owed.[1] Specifically, Lilly informed the Board that a bottle of purported Cialis 20 mg tablets bearing Lot Number A752870A and having an expiration date of April 2013.

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[1] Cialis is a dangerous drug pursuant to Business and Professions Code section 4022.

had been determined to be counterfeit. Lilly further informed the Board the bottle which held the counterfeit Cialis had been determined to be genuine.

31. To effect their "return" of the counterfeit Cialis to Lilly, Respondents used Pharmatech Services, Inc. ("Pharmatech"), a third-party pharmaceutical return company/reverse distributor. The counterfeit Cialis tablets were part of Respondents' return to Lilly, via Pharmatech, of fourteen (14) dangerous drugs that had a combined value of nearly $8,000.00 as "returned expired product." Included in the package was a handwritten inventory, prepared by Adams Square, which listed each pharmaceutical it had sent to Pharmatech for manufacturer return. Pharmatech is a Florida corporation that is not licensed by the Board to operate in California as a nonresident wholesaler.

32. After Lilly notified the Board that Adams Square had attempted to pass off counterfeit Cialis as returned product, the Board initiated an investigation that included an onsite inspection of Adams Square on November 12, 2013. Respondent Margarita Kazarian, the owner and PIC of Respondent Adams Square (collectively, "Respondents"), was present for the inspection.

33. During the inspection, Board inspectors found a single bottle of Cialis 20 mg on the pharmacy shelves. The bottle indicated that it contained thirty (30) Cialis 20 mg tablets from Lot Number A918499A with an expiration date of August 2014. Inside the bottle, however, the inspectors found ninety-two (92) tablets of purported Cialis which appeared to vary in appearance from authentic Cialis tablets. Board inspectors confiscated the bottle of tablets. Thereafter, Lilly performed physical and chemical analyses of the tablets and determined that they were also counterfeit. Once again, however, the container in which the counterfeit Cialis had been found (i.e., a bottle denoting thirty (30) Cialis 20 mg tablets from Lot Number A918499A) was determined to be a genuine Lilly container. During their inspection of Adams Square on November 12, 2013, Board inspectors found three (3) 13-gallon draw string trash bags full of empty manufacturer pharmaceutical containers, as well as a plastic trash bin labeled "Bottles" that was filled with empty manufacturer pharmaceutical bottles.

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34. During their inspection of November 12, 2013, Board inspectors also found a gray tote box located in the back of the pharmacy that was filled with a variety of different medications. When asked about the medications, Respondent Kazarian stated that they were expired drugs that had been gathered in the tote for destruction. When the inspectors examined the tote, however, they found that Respondent Kazarian's explanation was not truthful. Although many of the manufacturer containers were in fact expired, many others still had proper dating and were not scheduled to expire for months.

35. Board inspector's also found multiple examples of various manufacturer containers having been overfilled with pharmaceuticals, indicating that Respondents had simply filled the authentic manufacturer containers with tablets obtained from an unknown source which bore no actual relation to the container or the identifying information contained thereon. For example, in addition to the overfilled container of *counterfeit* Cialis described above, Board inspectors found a 100-tablet container of Levoxyl contained 127 tablets of different shapes and sizes. Board inspectors confiscated the bottle. Testing performed by pharmaceutical manufacturer Pfizer, Inc. established that the tablets were authentic but that they had been manufactured at *two different locations* and the lot number denoted on the container did not correspond to *any* of the tablets. During its inspection, the Board also found the following discrepancies which further evidenced that Respondents were simply filling authentic manufacturer containers with medications obtained from unknown sources that had no actual relation to the containers or the identifying information denoted thereon: a 90-tablet manufacturer bottle of Crestor contained 186 tablets; a 60-tablet manufacturer bottle of Namenda contained 141 tablets; a 20-tablet bottle of Zyvox contained tablets that varied from each other in size and shape; and a 30-tablet bottle of Vytorin was found to contain 120 tablets.[2] Notably, during their inspection, Board inspectors found three (3) boxes on the bottom pharmacy shelf containing thousands of loose, unlabeled pills weighing 14.6 pounds.

[2] Levoxyl, Namenda, Crestor, Zyvox and Vytorin are dangerous drugs pursuant to Business and Professions Code section 4022.

36. In addition, during the inspection, Respondent Kazarian revealed that Respondents had further violated the law by transferring pharmaceuticals from and between two other pharmacies owned by Respondent Kazarian without maintaining appropriate drug acquisition/inventory records of those transfers. For example, during the inspection, Board inspectors found a container of Actos 45 mg that had been transferred to Adams Square from Park West Pharmacy and a container of amlodipine/benazepril 5/20 mg that had been transferred from Kenneth Road Pharmacy.[3]

37. Finally, during the inspection, the Board inspectors asked to review all of Adams Square's records related to their use of reverse distributors/return companies for the return of pharmaceuticals to their manufacturers. Respondents failed to provide any records related to their return, via Pharmatech, of the counterfeit Cialis described above, and when asked to identify all of the reverse distributors Adams Square had used in the past two years, Respondent Kazarian failed to mention Pharmatech, falsely stating that Adams Square had only used a company called Rx Reverse Distributors.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

38. Respondents are subject to disciplinary action under section 4301 in that Respondents engaged in unprofessional conduct. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 30 through 37, inclusive, as though set forth fully herein.

SECOND CAUSE FOR DISCIPLINE

(Act Involving Dishonesty/Fraud/Deceit/Corruption)

39. Respondents are subject to disciplinary action under section 4301, subdivision (f), in that Respondents engaged in an act involving moral turpitude, dishonesty, fraud, deceit, or corruption. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 30 through 37, inclusive, as though set forth fully herein.

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[3] Actos and amlodipine/benazepril are dangerous drugs pursuant to Business and Professions Code section 4022.

THIRD CAUSE FOR DISCIPLINE

(False Representation of Facts)

40. Respondents are subject to disciplinary action under section 4301, subdivision (g), in that Respondents knowingly made and/or signed a document that falsely represented the existence of a state of facts. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 31, inclusive, as though set forth fully herein.

FOURTH CAUSE FOR DISCIPLINE

(Counterfeit Drugs)

41. Respondents are subject to disciplinary action under section 4301, subdivision (j), in conjunction with Heath and Safety Code section 110330 and United States Code, title 21, section 331, subdivision (i)(3), in that Respondents violated state and federal drug laws by engaging in conduct that caused a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 30 through 33, inclusive, as though set forth fully herein.

FIFTH CAUSE FOR DISCIPLINE

(Adulterated Drugs)

42. Respondents are subject to disciplinary action under section 4301, subdivision (j), in conjunction with Heath and Safety Code section 110330 and United States Code, title 21, section 331, subdivisions (a) and (b), in that Respondents violated state and federal drug laws by engaging in conduct that caused the manufacture, sale, delivery, holding, offer for sale and/or introduction into commerce an adulterated drug. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 30 through 37, inclusive, as though set forth fully herein.

SIXTH CAUSE FOR DISCIPLINE

(Misbranded Drugs)

43. Respondents are subject to disciplinary action under section 4301, subdivision (j), in conjunction with Heath and Safety Code section 111440 and United States Code, title 21, section

331, subdivisions (a) and (b), in that Respondents violated state and federal drug laws by engaging in conduct that caused the manufacture, sale, delivery, holding, offer for sale and/or introduction into commerce, a misbranded drug. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 30 through 37, inclusive, as though set forth fully herein.

SEVENTH CAUSE FOR DISCIPLINE

(Violation of Federal Expiration Dating Law)

44. Respondents are subject to disciplinary action under section 4301, subdivision (j), in conjunction with Code of Federal Regulations, title 21, section 211.137, in that Respondents violated federal drug law regulating standards of drug identify, strength, quality and purity by engaging in conduct that resulted in inaccurate expiration dating on dangerous drugs. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 30 through 37, inclusive, as though set forth fully herein.

EIGHTH CAUSE FOR DISCIPLINE

(Transfer/Sell Dangerous Drug to Unlicensed Wholesaler)

45. Respondents are subject to disciplinary action under section 4301, subdivision (o), in conjunction with section 4169, subdivision (a)(1), in that Respondents violated state pharmacy law by transferring and/or selling dangerous drugs to a person or entity that was not licensed by the Board as a wholesaler or pharmacy. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 31, inclusive, as though set forth fully herein.

NINTH CAUSE FOR DISCIPLINE

(Purchase/Trade/Sell/Transfer Adulterated Drug)

46. Respondents are subject to disciplinary action under section 4301, subdivision (o), in conjunction with section 4169, subdivision (a)(2), in that Respondents violated state pharmacy law by purchasing, trading, selling, and/or transferring a dangerous drug that Respondents knew or reasonably should have known was adulterated. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 30 through 37, inclusive, as though set

forth fully herein.

TENTH CAUSE FOR DISCIPLINE

(Purchase/Trade/Sell/Transfer Misbranded Drug)

47. Respondents are subject to disciplinary action under section 4301, subdivision (o), in conjunction with section 4169, subdivision (a)(3), in that Respondents violated state pharmacy law by purchasing, trading, selling, and/or transferring a dangerous drug that Respondents knew or reasonably should have known was misbranded. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 30 through 37, inclusive, as though set forth fully herein.

ELEVENTH CAUSE FOR DISCIPLINE

(Fail to Maintain Acquisition Records and Inventory)

48. Respondents are subject to disciplinary action under section 4301, subdivision (o), in conjunction with section 4081, subdivisions (a) and (b), in that Respondents violated state pharmacy law by failing to maintain accurate records of all sales, acquisition, and/or disposition of dangerous drugs. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 36, inclusive, as though set forth fully herein.

ELEVENTH CAUSE FOR DISCIPLINE

(Subvert Board Investigation)

49. Respondents are subject to disciplinary action under section 4301, subdivision (q), in that Respondents engaged in conduct that subverted or attempted to subvert an investigation of the Board. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 34 and 37, 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 Permit Number PHY 40833, issued to Adams Square Pharmacy; Margarita Kazarian, owner;

2. Revoking or suspending Pharmacist License No. RPH 45273 issued to Margarita Kazarian;

3. Ordering respondent Adams Square Pharmacy and Margarita Kazarian 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; and,

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

DATED: 6/26/14

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

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

In the Matter of the Petition for Interim Suspension Order Against: ADAMS SQUARE PHARMACY 1122 East Chevy Chase Drive, Suite A Glendale, California 91205-2511, Original Pharmacy Permit No. PHY-40833, and MARGARITA KAZARIAN, Pharmacist License No. RPH-45273, Respondents.	Case No. 5189 OAH No. 2014050753

ORDER ON PETITION FOR INTERIM SUSPENSION

Vincent Nafarrete, Administrative Law Judge of the Office of Administrative Hearings, heard this matter at Los Angeles on June 9, 2014. Petitioner was represented by William D. Gardner, Deputy Attorney General. Respondents Adams Square Pharmacy and Margarita Kazarian were represented by Paul L. Cass, Attorney at Law.

At the outset of the hearing on the Petition for Interim Suspension, respondent presented the Declaration of Margarita Kazarian in Support of Opposition to Petition for Interim Suspension, which was marked as Exhibit A. Petitioner presented the Petition for Interim Suspension Order, Memorandum of Points and Authorities in Support of the Petition for Interim Suspension Order, and declarations, which were marked collectively as Exhibit 1. Both parties presented oral argument. On June 10, 2014, following an order by the Administrative Law Judge, petitioner filed a Proposed Order, which is hereby marked as Exhibit 2.

Documentary evidence having been received and oral argument heard, the Administrative Law Judge submitted this matter for decision on June 10, 2014, and finds as follows:

FACTUAL FINDINGS

1. On or about April 11, 1995, the Board of Pharmacy, Department of Consumer Affairs, State of California (Board), issued original pharmacy permit no. PHY-40833 and permit rights to respondent Adams Square Pharmacy located at 1122 East Chevy Chase Drive, Glendale, California 91205. Said pharmacy permit expired on April 1, 2014, unless it was renewed, and was in full force and effect at all times relevant herein.

2. On or about April 3, 1991, the Board issued pharmacist license no. RPH-45273 and licensing rights to respondent Margarita Kazarian. Said pharmacist license expires on October 31, 2015, unless renewed, and is in full force and effect. Respondent Kazarian is the owner and pharmacist-in-charge of Adams Square Pharmacy.

3. (A) On April 25, 2014, the Petition for Interim Suspension Order, Case No.5189, was made by William D. Gardner, Deputy Attorney General, and on behalf of Virginia K. Herold, Executive Officer, Board of Pharmacy, Department of Consumer Affairs, State of California (petitioner).

(B) On May 16, 2014, petitioner served the Petition for Interim Suspension Order upon respondent Adams Square Pharmacy and respondent Kazarian at their addresses of record and upon their counsel Paul L. Cass, Attorney at Law, at his office in Citrus Heights. Service was made by Federal Express delivery. Said petition was properly served on respondents with the Memorandum of Points and Authorities and the supporting declarations with attached exhibits.

(C) On May 16, 2014, petitioner properly served respondents and their counsel with a Notice of Hearing on the Petition for Interim Suspension Order by Federal Express delivery.

4. On June 9, 2014, the noticed hearing was held on the Petition for Interim Suspension Order pursuant to Business and Professions Code section 494. Prior to the hearing, petitioner had filed the Petition for Interim Suspension Order, Memorandum of Points and Authorities in Support of Petition for Interim Suspension Order, Declaration of Keith Hadley, Declaration of Michael P. Dalton, Declaration of Jon Jennings, Declaration of Eleanora Layman, Declaration of Sejal Desai, and Declaration of Sarah Bayley. At the hearing on June 9, 2014, respondents filed the Declaration of Margarita Kazarian in Support of Opposition to Petition for Interim Suspension Order.

5. Respondent Adams Square Pharmacy is a retail pharmacy that was first opened in Glendale in the 1920's. Said pharmacy has been owned and operated by respondent Kazarian since 1995. Kazarian also owns two other pharmacies, Kenneth Road Pharmacy in Glendale and Park West Pharmacy in West Hills. She is the pharmacist-in-charge at both Adams Square Pharmacy and Park West Pharmacy.

6. As set forth in her declaration dated May 5, 2014, Eleanora Layman works as a legal specialist for Amerisource Bergen Corporation (ABC), which maintains medication sales and return data. According to Layman, ABC records demonstrated that, from 2006 to the present, ABC purchased Cialis 20 milligrams (mg) directly from the manufacturer Eli Lilly and Corporation (Lilly) and that there were no recalls of Cialis 20 mg by Lilly or any regulatory agency. ABC records also show that, from 2007 to the present, Adams Square Pharmacy purchased only one 30-tablet container of Cialis 20 mg from ABC, which purchase cost $643.56 and occurred on or about May 11, 2012. ABC records further show that Adams Square Pharmacy returned a bottle of Cialis to ABC on or about October 16, 2012, and received a credit of $514.85.

7. (A) As set forth in his Declaration dated April 29, 2014, Jon Jennings is the owner of Pharmatech Services (Pharmatech), a pharmaceutical reverse distributor located in Odessa, Florida. Adams Square Pharmacy is an enrolled customer of Pharmatech and uses its reverse distributor services to return medications to manufacturers. According to Jennings, on June 19, 2013, Pharmatech received two boxes from Adams Square Pharmacy, which contained several hundred tablets or pills of approximately 82 medications, including 30 tablets of purported Cialis 20 mg. The Cialis was in a Lilly packaging or container that had Lot Number A752870A and an expiration date of April 2013. The shipment included a written inventory from Adams Square Pharmacy that itemized the medications. The written inventory stated, in part, "Cialis 20 mg."

(B) Pharmatech packed the Cialis and other medications manufactured by Lilly in a carton and shipped the medications to Lilly on June 19, 2013. The medications in the carton to Lilly had an estimated value of $7,730, which amount was credited by Pharmatech to Adams Square Pharmacy. On June 19, 2013, Pharmatech billed Adams Square Pharmacy the amount of $4,434.38 for its reverse distributor services. Adams Square Pharmacy paid the invoice.

8. As set forth in his Declaration dated March 27, 2014, Michael P. Dalton is an advisor for Lilly's Global Product Protection Technical Team whose duties include supervising the physical and chemical analysis of samples suspected to be counterfeit and performing examinations of suspected samples. Dalton has experience in testing and analyzing products and samples which are suspected to be counterfeit Lilly products. According to Dalton, on October 30, 2013, a Lilly returned goods employee noticed that the Cialis 20 mg returned by Adams Square Pharmacy via Pharmatech, Lot Number A752870A, was darker in color and had a different shape and thickness than Cialis tablets manufactured by Lilly. On or about November 14, 2013, the product returned by Adams Square Pharmacy was analyzed physically and chemically by Lilly's Global Product Protection Technical Team and found to be a counterfeit Lilly drug product. The Cialis had been returned in a genuine Lilly packaging or container.

9. As set forth in her Declaration in Support of Petition for Interim Suspension Order, Sarah Bayley is a licensed pharmacist and has been a Board inspector since October 2000. As set forth in his Declaration, Sejal Desai is a licensed pharmacist with a background

in retail pharmacy and quality assurance and has been a Board inspector since August 2011. The factual findings set forth below in Findings 10 – 12 and 15 – 16 below are based upon the declarations of Bayley and Desai.

10. (A) On or about November 7, 2013, Bayley was assigned to inspect Adams Square Pharmacy after the Board learned that counterfeit Cialis had been returned from Adams Square Pharmacy to the manufacturer Lilly by Pharmatech, a reverse distributor. Desai assisted Bayley on the inspection.

(B) On November 12, 2013, Bayley and Desai went to Adams Square Pharmacy and conducted an inspection of the pharmacy premises. Respondent Kazarian, the pharmacist-in-charge and owner, and pharmacy technician Julie Perez were present during the inspection. Kazarian indicated that the pharmacy purchased medications from ABC, Anda, ParMed, and River City Pharma. Bayley reviewed several months of the pharmacy's purchase records and did not find a record of a purchase of Cialis 20 mg. Kazarian stated the pharmacy used RX Reverse Distributors to return expired medications and did not use any other reverse distributors. The inspectors reviewed the returned medication records from RX Reverse Distributors and did not find any mention of Cialis in those records.

(C) In a room in the back of the pharmacy, the inspectors found three trash bags and a box full of empty manufacturer medication bottles. In the dispensing area of the pharmacy, there was a blue plastic trash bin which was full of empty manufacturer containers. Someone had written "Bottles" on a note affixed to the trash bin. Kazarian stated the empty bottles were all being held for recycling. The inspectors instructed Kazarian to dispose of the empty bottles in the trash.

(D) In a room that appeared to be an office, Desai found a tote box commonly used by wholesalers to send drugs to a pharmacy, which was full of medications and/or manufacturer containers of medications. Kazarian stated these drugs had expired and were being held for RX Revers Distributors to pick-up for destruction. Many of the drug containers had expiration dates that had passed. However, there were also manufacturer containers in the tote box that had medications that had not expired and would not expire for several months. Desai opened a container of Levoxyl and a container of Vytorin and found that the two containers were over-filled with medications of varying shapes, sizes, and colors.

(E) In the pharmacy, the Board inspectors found three "sharps" containers which are commonly used to dispose of syringes and needles. The three sharps containers were filled with loose medication tablets and capsules. Kazarian indicated that the drugs in the sharps containers had been returned by patients and were being held for RX Reverse Distributors to pick up for destruction. The three sharps containers weighed approximately 14.6 pounds.

(F) On a shelf above the sharps containers, Bayley found nine amber vials that were filled with loose pills. Seven of the vials had prescription labels that were torn and contained inconsistent information about the sources of the medications. Three of the vials contained Montelukast (Singulair) with child safety caps. Bayley found another amber vial on a pharmacy shelf that was full of 30 tablets and did not have a label.

(G) On the pharmacy shelves, Bayley found nine 30-capsule containers of Norvir 100 mg in a black plastic bag. All of the containers of Norvir had expiration dates that had already passed. Kazarian said she had forgotten about the Norvir and that the drug was being held for RX Reverse Distributors to pick up for destruction.

(H) On the pharmacy shelves, the inspectors found a manufacturer container of Actos 45 mg that had a wholesale label for Park West Pharmacy and a manufacturer container of Amlodipine/Benazepril 5/20 mg that had a wholesaler label for Kenneth Road Pharmacy. Kazarian explained that, when she ran out of medications at Adams Square Pharmacy, she borrowed medications from the two other pharmacies that she owned. Kazarian stated her pharmacies did not maintain any records of transfers of medications. Bayley found two prescription containers for two patients that had been dispensed by Kenneth Road Pharmacy. Kazarian stated that Adams Square Pharmacy and Kenneth Road Pharmacy used the same delivery driver and the patients asked that their drugs be brought to Adams Square Pharmacy so that they could pick up from there.

(I) On a pharmacy shelf, Bayley inspected a bottle of Zyvox that contained tablets with differing shades of the color red and differing thicknesses of the imprints on the tablets. When Bayley pointed out the variations of the tablets, Kazarian replied that she did not pay attention to those details, poured out tablets from a bottle, showed the differences in the color of the tablets, and said that the color variations in the tablets of Zyvox were normal.

11. On November 12, 2013, Bayley made a list of the medications that were found at Adams Square Pharmacy in containers were over-filled and medications that had variations in color, shapes, and sizes, which included 92 tablets of Cialis 20 mg, 186 tablets of Crestor 10 mg, 141 tablets of Namenda 5 mg, 20 tablets of Zyvox 600 mg, 127 tablets of Levoxyl 88 mcg, and 120 tablets of Vytorin 10/40 mg. Bayley had Kazarian complete an inventory of these medications: Crestor 10 mg, Levoxyl 88 mcg, Cialis 20 mg, Vytorin 10 mg/40 mg, and Namenda 5 mg. The Board inspector also asked Kazarian to provide a drug recall report for these medications dispensed from November 12, 2011, through November 12, 2013. Bayley seized or took into evidence one container each of these medications. Kazarian and/or the pharmacy technician also completed a list of the medications that were found in over-filled containers and medications with past expiration dates; the list was seven pages in length.

12. On November 21, 2013, Bayley met with Keith Hadley, Special Agent with the U.S. Food and Drug Administration, and Paul Ramirez, Special Agent with the Department of Justice, Bureau of Medi-Cal Fraud and Elder Abuse. Bayley issued to Hadley a reverse official receipt for the single containers of Crestor 10 mg, Levoxyl 88 mcg, Cialis

20 mg, Vytorin 10 mg/ 40 mg, Namenda 5 mg, and Zyvox 600 mg that Bayley had seized from Adams Square Pharmacy.

13. (A) As set forth in his Declaration dated May 9, 2014, Keith Hadley is a special agent with the U.S. Food and Drug Administration (FDA), Office of Criminal Investigation. His duties include investigating the manufacture, sale, and distribution of counterfeit pharmaceuticals in order to enforce the federal Prescription Drug Marketing Act which was enacted to prevent the introduction and sale of substandard, ineffective, and/or counterfeit drugs. His investigations require him to work with state regulatory agencies, including the Board, and pharmaceutical manufacturers.

(B) On November 21, 2013, Hadley obtained custody of six different pharmaceutical medications in their manufacturer packaging from Board Inspector Bayley. One of the pharmaceutical medications was a manufacturer container of 92 tablets of Cialis 20 mg with Lot Number A918499A and an expiration date of August 2014. On November 25, 2013, Hadley sent the container of Cialis 20 mg in double heat-sealed plastic bags to Lilly's Global Product Protection Technical Team. On or about December 5, 2013, Hadley was informed by Lilly Global Security representative that the Cialis 20 mg was subjected to visual inspection and laboratory testing and determined to be a counterfeit product.

(C) Respondent Kazarian has questioned whether Hadley forwarded the Cialis 20 mg that was actually taken from Adams Square Pharmacy to the manufacturer for analysis. Kazarian noted that the FDA form used to send the Cialis to the manufacturer contained a reference to another pharmacy, Huntington Pharmacy. Respondent's argument was not persuasive, for the FDA form correctly described the medication Cialis 20 mg by its lot number and indicated that it originated from Adams Square Pharmacy.

14. As set forth in the Declaration of Michael P. Dalton, on or about December 5, 2013, Lilly's Global Product Protection Technical Team received a sample of Cialis 20 mg tablets from FDA special agent Keith Hadley. The sample of Cialis had been seized from Adams Square Pharmacy by Board inspectors. The Cialis sample was identified by Lot Number A918499A, had an expiration date of August 2014, and was received in genuine Lilly packaging. On or about December 18, 2013, Lilly's Global Product Protection Technical Team determined that this sample of purported Cialis 20 mg was counterfeit Lilly product.

15. On January 13, 2014, Bayley was informed of the results of Lilly's laboratory testing of the Cialis 20 mg taken during the inspection of Adams Square Pharmacy. Shortly thereafter, Bayley received the Lilly Authentication Reports for the counterfeit Cialis returned by Pharmatech and for the counterfeit Cialis taken by her during the inspection of Adams Square Pharmacy.

16. On January 24, 2014, Bayley learned the results of an authenticity evaluation by Pfizer of the container of Levoxyl 88 mcg taken by her from Adams Square Pharmacy during her November 12, 2013 inspection. The Levoxyl was determined to be authentic drug

product in authentic drug packaging but was comprised of tablets of Levoxyl of different manufacturing sites and lots. The lot number and expiration date on the container of Levoxyl was not correct for all of the tablets in the container.

17. (A) As set forth in her Declaration dated June 9, 2014, respondent Kazarian has denied all of the allegations contained in the Petition for Interim Suspension Order that pertain to Cialis 20mg and any other medications. She has ostensibly denied selling counterfeit Cialis 20mg tablets to the public from Adams Square Pharmacy or endangering the public. She claimed that the counterfeit Cialis analyzed by Lilly must have come from her distributor Amerisource Bergen or another source. Kazarian did admit that she committed error in allowing excess number of tablets to be placed in a medication bottle.

(B) From January 1, 2011, through June 9, 2014, Kazarian emphasized that Adams Square Pharmacy sold only six tablets of Cialis 20 mg to customers. Kazarian stated that, to her knowledge, all six tablets, which were all sold in 2012, were authentic product. She indicated she did not receive any complaint about the efficacy of Cialis from any of her customers.

(C) Respondent Kazarian further stated that, from 2005 through June 9, 2014, Adams Square Pharmacy purchased 420 tablets of Cialis 20 mg from Amerisource Bergen. 148 of the tablets were dispensed to customers, 30 of the tablets were returned to the manufacturer for a $450 credit, and 92 of the tablets were taken by the Board inspectors on November 12, 2013. However, Kazarian could not account for the remaining 150 tablets of Cialis 20 mg and does not know whether the tablets were sold, disposed, or stolen.

18. (A) With respect to the tote box that was full of medications, many of which had expired, Kazarian stated that Adams Square Pharmacy uses the tote box to store expired and unexpired medications that are to be returned to manufacturers for reimbursement.

(B) Kazarian stated that she did not have expired medications on the shelves of Adams Square Pharmacy. She claimed that the Vytorin was being stored in a back room for pick-up and destruction by RX Reverse Distributors and that the three sharps containers contained loose medication tablets were on the floor of the pharmacy and being stored for destruction by RX Reverse Distributors. Kazarian stated that said reverse distributor comes to the pharmacy every two or three years to pick up medications for destruction.

(C) Kazarian admitted that Adams Square Pharmacy had excess tablets of Crestor, Vytorin, Namenda, and Levoxyl in single bottles of the medications. She stated that pharmacy technicians at Adams Square Pharmacy have, on occasion, placed an excess number of tablets of Cialis, Crestor, and Namenda into plastic bottles of the same medication and those medications were being stored on the pharmacy shelves for sale to the public. Kazarian stated that the placement of excess tablets in the single bottles was an error and should not have occurred. She claimed that the Levoxyl was being stored in a back room for return to the manufacturer because the medication had been recalled by the manufacturer.

With respect to the Zyvox, Kazarian claimed that this medication was authentic product and came in varied shapes from the manufacturer.

19. Since becoming the owner of Adams Square Pharmacy in 1995, respondent Kazarian has not been present at Adams Square Pharmacy every day since she is the pharmacist-in-charge at Park West Pharmacy as well. Respondent Kazarian employs several persons at her three pharmacies, including pharmacists and pharmacy technicians. She averred that the interim suspensions of her pharmacist license and the pharmacy permit of Adams Square Pharmacy would cause her irreparable harm inasmuch as she would have to lay off employees at Adams Square Pharmacy, hire pharmacists-in-charge, and lose income. Adams Square Pharmacy had gross sales of approximately $1.9 million in 2013 and gross sales of $442,389 in the first quarter of 2014.

20. (A) Based on the declarations set forth in Findings 6 – 16 above, the preponderance of the evidence demonstrated that, on or about June 19, 2013, respondents Kazarian and Adams Square Pharmacy knowingly prepared and made a written inventory for a shipment of medications to reverse distributor Pharmatech in which respondents falsely represented that the Cialis 20 mg contained in the shipment was authentic manufacturer product, in violation of Business and Professions Code section 4301, subdivision (g).

(B) Based on the declarations set forth in Findings 6 – 16 above, the preponderance of the evidence demonstrated that, on or about June 19, 2013, respondents Kazarian and Adams Square Pharmacy possessed counterfeit Cialis 20 mg and attempted to return the counterfeit Cialis mg to the manufacturer for a credit or refund, which constituted acts involving dishonesty, fraud, or deceit, in violation of Business and Professions Code section 4301, subdivision (f).

21. (A) Based on the declarations set forth in Findings 6 – 16 above, the preponderance of the evidence demonstrated that, on November 12, 2013, respondent Kazarian engaged in conduct in an attempt to subvert the Board's investigation by falsely telling investigators that she used only RX Reverse Distributors to return medications to manufacturers when, in fact, Kazarian and Adams Square Pharmacy used Pharmatech as a reverse distributor and by falsely telling investigators that the medications found in the tote box in Adams Square Pharmacy were scheduled for destruction when, in fact, the tote box contained medications that had not expired, which constituted violations of Business and Professions Code section 4301, subdivision (q).

(B) Based on the declarations set forth in Findings 6 – 16 above, the preponderance of the evidence demonstrated that, on or about November 12, 2013, respondents Kazarian and Adams Square Pharmacy did not have or maintain records of the transfers of medications from Kazarian's two other pharmacies to Adams Square Pharmacy and thus failed to maintain all records of the sale, acquisition, and disposition of medications for the required time period, in violation of Business and Professions Code section 4301, subdivisions (j) and (o), in conjunction with Business and Professions Code sections 4081, subdivision (a), and 4333, and California Code of Regulations, title 16, section 1718.

(C) Based on the Declaration of Margarita Kazarian as set forth in Finding 17 – 19 above, the preponderance of the evidence demonstrated that, on November 12, 2013, respondent Kazarian and Adams Square Pharmacy were unable to account for 150 tablets of Cialis 20 mg that had been purchased and thus failed to maintain all records of the sale, acquisition, and disposition of the medication Cialis 20 mg for the required time period, in violation of Business and Professions Code section 4301, subdivisions (j) and (o), in conjunction with Business and Professions sections 4081, subdivision (a), and 4333, and California Code of Regulations, title 16, section 1718.

(D) Based on the declarations set forth in Findings 6 – 16 above, the preponderance of the evidence demonstrated that, on November 12, 2013, respondents Kazarian and Adams Square Pharmacy possessed for sale Cialis 20 mg, which was counterfeit, and Levoxyl 88 mg in a single container that was of incorrect lot numbers and expiration dates, which constituted conduct or acts involving dishonesty, fraud, or deceit, in violation of Business and Professions Code section 4301, subdivision (f).

(E) Based on the declarations set forth in Findings 6 – 16 above, the preponderance of the evidence demonstrated that, on November 12, 2013, respondents Kazarian and Adams Square Pharmacy kept the following medications on the shelves of the pharmacy: expired Norvir 100 mg, varying tablets of Zyvox, counterfeit Cialis 20 mg, the incorrectly labeled container of Levoxyl 88 mg, overfilled containers of Namenda 5 mg, Crestor 10 mg, and Vytorin 10mg/ 40 mg, and seven amber vials with torn prescription labels. As such, respondents Kazarian and Adams Square Pharmacy engaged in unprofessional conduct by selling or attempting to sell drugs that were adulterated or drugs that did not conform to the standard and tests as to quality and strength provided by state and federal law, in violation of Business and Professions Code section 4301, subdivisions (j) and (o), in conjunction with Business and Professions Code section 4342 and Health and Safety Code section 111255.

22. (A) Based on Findings 1 – 21 above, respondents Kazarian and Adams Square Pharmacy dispensed or attempted to dispense prescription medications from containers that were not correctly labeled with the strength of the drugs to be dispensed, in violation of Business and Professions Code sections 4301, subdivisions (j) and (o).

(B) Based on Findings 1 – 21 above, respondents Kazarian and Adams Square Pharmacy engaged in unprofessional conduct within the meaning of Business and Professions Code section 4301.

Based on the foregoing findings of fact, the Administrative Law Judge makes the following determination of issues:

Conclusions of Law

1. Grounds exist to issue an interim order of suspension pursuant to Business and Professions Code section 494, subdivision (a)(1), in that the declarations and exhibits in support of the Petition for Interim Suspension Order demonstrate that respondents Kazarian and Adams Square Pharmacy have engaged in acts or omissions constituting violations of the Pharmacy Law, as set forth in Findings 1- 22 above.

2. Grounds exist to issue an interim order of suspension pursuant to Business and Professions Code section 494, subdivision (a)(2), in that the declarations in support of the Petition for Interim Suspension Order show that permitting respondent Adams Square Pharmacy and respondent Kazarian as the pharmacist-in-charge to continue to engage in the business of a pharmacy without restriction will endanger the public health, safety, or welfare, based on Findings 1 – 22 above.

3. Discussion--Based on the declarations in support of the Petition for Interim Suspension Order, petitioner established by a preponderance of the evidence that respondents Kazarian and Adams Square Pharmacy currently operate a permitted pharmacy that is in violation of the Pharmacy Law. Adams Square Pharmacy does not appear to be well-organized or maintained and does not have the records or the internal system or procedure to keep track of the medications in stock, being returned to manufacturers, or being held for destruction. The image that emerges from the Board's November 12, 2013 inspection is of a pharmacy that retains many loose and expired tablets and has medication containers over-filled with medications sitting on its shelves.

Here, the evidence specifically showed respondents attempted to return counterfeit Cialis 20 mg to the manufacturer Lilly and had counterfeit Cialis 20 mg in stock in the pharmacy when the Board inspectors conducted their inspection. Respondents also had medications on shelves, which meant that the medications were for sale to the public, that had already expired, had torn labels, were overfilled in containers, had varying sizes and imprints, consisted of different lot numbers and expiration dates, and had been transferred from Kazarian's other two pharmacies. The evidence thus showed that there is a danger that Adams Square Pharmacy may dispense medications to customers that are counterfeit, adulterated, or non-effective.

In addition, Kazarian's own declaration did not instill any confidence that she is presently able to operate and supervise Adams Square Pharmacy in compliance with the Pharmacy Law. The pharmacist-in-charge admitted she does not know what happened to 150 tablets of Cialis 20 mg, that the pharmacy technicians occasionally over-fill containers,

and that she is not physically present at Adams Square Pharmacy every day since she is also the pharmacist-in-charge at another one of her pharmacies.

Under these circumstances, the evidence demonstrated that respondent Adams Square Pharmacy and respondent Kazarian as the pharmacist-in-charge represent a danger to the public health and safety if allowed to continue operating as a pharmacy establishment. The likelihood of injury to the public in not issuing a suspension order is not outweighed by the likelihood of injury to respondents if the suspension is ordered. Respondents' loss of income if the suspension order is issued is not a probative reason to deny the suspension order and is far less important than the danger posed to the public if Adams Square Pharmacy were to make an error and unknowingly dispense non-efficacious, expired, or counterfeit medications to its customers. Public safety and welfare require the suspension of the pharmacy permit issued to Adams Square Pharmacy and a restriction prohibiting respondent Kazarian from acting or working as a pharmacist-in-charge at any permitted pharmacy.

Wherefore, the following Order is hereby made:

ORDER

The Petition for Interim Suspension Order, Case No. 5189, OAH No. 2014050753, filed and heard under Business and Professions Code section 494 is granted, in part, as follows:

1. The pharmacy permit no. PHY-40833 and permit rights issued to Adams Square Pharmacy shall be suspended pending a hearing and decision on the Accusation.

2. Pharmacist license no. RPH-45273 and licensing rights issued to respondent Margarita Kazarian shall be restricted such that respondent Kazarian is prohibited from and not allowed to act, work, or perform the duties of a pharmacist-in-charge of any pharmacy or pharmacy establishment, within the meaning of Business and Professions Code section 4113 pending a hearing and decision on the Accusation.

3. Petitioner shall file an accusation within 15 days as required by Business and Professions Code section 494, subdivision (f).

Dated: June 16, 2014

Vincent Nafarrete
Administrative Law Judge
Office of Administrative Hearings