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8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
10 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 5189

OAH No. 2014050753

13 **ADAMS SQUARE PHARMACY;**
14 **MARGARITA KAZARIAN**
Permit No. PHY 40833

A C C U S A T I O N

15 **and**

16 **MARGARITA KAZARIAN**
Pharmacist License No. RPH 45273
17

18 Respondents.
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20 Complainant alleges:

21 **PARTIES**

22 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
23 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

24 2. On or about April 11, 1995, the Board issued Pharmacy Permit No. PHY 40833 to
25 Adams Square Pharmacy, Margarita Kazarian, owner ("Adams Square"). The pharmacy permit
26 was suspended pursuant to an Interim Suspension Order on June 16, 2014. It will expire on April
27 1, 2015, unless renewed.
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1 (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or
2 corruption, whether the act is committed in the course of relations as a licensee or otherwise, and
3 whether the act is a felony or misdemeanor or not.

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

6 ...

7 (j) The violation of any of the statutes of this state, or any other state, or of the United
8 States regulating controlled substances and dangerous drugs.

9 ...

10 (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the
11 violation of or conspiring to violate any provision or term of this chapter or of the applicable
12 federal and state laws and regulations governing pharmacy, including regulations established by
13 the board or by any other state or federal regulatory agency.

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

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

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

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

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

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

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1 14. Section 111295 of the Health and Safety Code provides:

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

4 15. Section 111305 of the Health and Safety Code provides:

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

7 16. Section 111330 of the of the Health and Safety Code provides:

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

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

12 18. Section 111390 of the Health and Safety Code provides:

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

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

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

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

18 ...

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

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

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

26 21. Section 111440 of the Health and Safety Code provides:

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

1 **FEDERAL STATUTES AND REGULATIONS**

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

3 “The following acts and the causing thereof are prohibited:

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

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

8 ...

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

11
12 23. United States Code, title 21, section 351, subdivision (a)(2)(B), provides that a drug
13 shall be deemed to be adulterated “if it is a drug and the methods used in, or the facilities or
14 controls used for, its manufacture, processing, packing, or holding do not conform to or are not
15 operated or administered in conformity with current good manufacturing practice to assure that
16 such drug meets the requirements of this chapter as to safety and has the identity and strength,
17 and meets the quality and purity characteristics, which it purports or is represented to possess.”

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

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

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

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

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

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

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

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

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

13 (d) Expiration dates shall appear on labeling in accordance with the requirements of §
14 201.17 of this chapter.

15 **COST RECOVERY**

16 29. Section 125.3 of the Code states, in pertinent part, that the Board may request the
17 administrative law judge to direct a licentiate found to have committed a violation or violations of
18 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
19 enforcement of the case.

20 **BOARD INVESTIGATION**

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

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

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

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

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

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

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

8 35. Board inspector's also found multiple examples of various manufacturer containers
9 having been overfilled with pharmaceuticals, indicating that Respondents had simply filled the
10 authentic manufacturer containers with tablets obtained from an unknown source which bore no
11 actual relation to the container or the identifying information contained thereon. For example, in
12 addition to the overfilled container of *counterfeit* Cialis described above, Board inspectors found
13 a 100-tablet container of Levoxyl contained 127 tablets of different shapes and sizes. Board
14 inspectors confiscated the bottle. Testing performed by pharmaceutical manufacturer Pfizer, Inc.
15 established that the tablets were authentic but that they had been manufactured at *two different*
16 *locations* and the lot number denoted on the container did not correspond to *any* of the tablets.
17 During its inspection, the Board also found the following discrepancies which further evidenced
18 that Respondents were simply filling authentic manufacturer containers with medications
19 obtained from unknown sources that had no actual relation to the containers or the identifying
20 information denoted thereon: a 90-tablet manufacturer bottle of Crestor contained 186 tablets; a
21 60-tablet manufacturer bottle of Namenda contained 141 tablets; a 20-tablet bottle of Zyvox
22 contained tablets that varied from each other in size and shape; and a 30-tablet bottle of Vytorin
23 was found to contain 120 tablets.² Notably, during their inspection, Board inspectors found three
24 (3) boxes on the bottom pharmacy shelf containing thousands of loose, unlabeled pills weighing
25 14.6 pounds.

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

1 331, subdivisions (a) and (b), in that Respondents violated state and federal drug laws by
2 engaging in conduct that caused the manufacture, sale, delivery, holding, offer for sale and/or
3 introduction into commerce, a misbranded drug. Complainant refers to, and by this reference
4 incorporates, the allegations set forth above in paragraphs 30 through 37, inclusive, as though set
5 forth fully herein.

6 **SEVENTH CAUSE FOR DISCIPLINE**

7 **(Violation of Federal Expiration Dating Law)**

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

14 **EIGHTH CAUSE FOR DISCIPLINE**

15 **(Transfer/Sell Dangerous Drug to Unlicensed Wholesaler)**

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

22 **NINTH CAUSE FOR DISCIPLINE**

23 **(Purchase/Trade/Sell/Transfer Adulterated Drug)**

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

1 forth fully herein.

2 **TENTH CAUSE FOR DISCIPLINE**

3 **(Purchase/Trade/Sell/Transfer Misbranded Drug)**

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

10 **ELEVENTH CAUSE FOR DISCIPLINE**

11 **(Fail to Maintain Acquisition Records and Inventory)**

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

17 **ELEVENTH CAUSE FOR DISCIPLINE**

18 **(Subvert Board Investigation)**

19 49. Respondents are subject to disciplinary action under section 4301, subdivision (q), in
20 that Respondents engaged in conduct that subverted or attempted to subvert an investigation of
21 the Board. Complainant refers to, and by this reference incorporates, the allegations set forth
22 above in paragraphs 34 and 37, as though set forth fully herein.

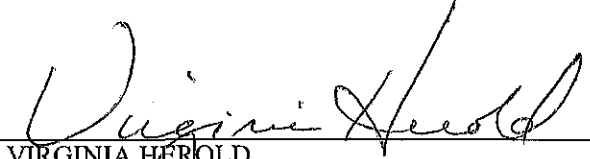
23 **PRAYER**

24 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
25 and that following the hearing, the Board of Pharmacy issue a decision:

26 1. Revoking or suspending Permit Number PHY 40833, issued to Adams Square
27 Pharmacy; Margarita Kazarian, owner;

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- 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 Vytarin 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.

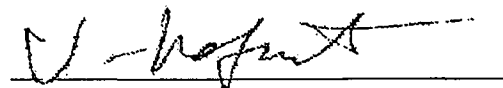
Wherefore, the following Order is hereby made:

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