

1 EDMUND G. BROWN JR.
Attorney General of California
2 GREGORY J. SALUTE
Supervising Deputy Attorney General
3 HELENE E. SWANSON
Deputy Attorney General
4 State Bar No. 130426
300 So. Spring Street, Suite 1702
5 Los Angeles, CA 90013
Telephone: (213) 620-3005
6 Facsimile: (213) 897-2804
Attorneys for Complainant

7
8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

10 In the Matter of the Accusation Against:

Case No. 3823

11 **PETROS BAGDASARIAN, OWNER, DBA**
12 **ARARAT PLAZA PHARMACY**
13 **1248 S. Glendale Avenue, Suite M**
Glendale, CA 91205
14 **Pharmacy Permit No. PHY 42130**

A C C U S A T I O N

15 **MICHAEL MYUNG Y. LEE**
16 **10206 Hillhaven Avenue, Suite 2**
Tujunga, CA 91042
17 **Pharmacist-in-Charge**
Pharmacy License No. RPH 44619

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.

24 2. On or about February 6, 1997, the Board of Pharmacy issued Original Pharmacy
25 Permit Number PHY 42130 to Petros Bagdasarian, the owner of Ararat Plaza Pharmacy who was
26 doing business as Ararat Plaza Pharmacy (Respondents and/or Respondent Bagdasarian and
27 Respondent Pharmacy). The Original Permit was in full force and effect at all times relevant to
28 the charges brought herein and will expire on February 1, 2011, unless renewed.

1 that meets the requirements of state and federal law and is correctly labeled with all
2 of the following:

3 (1) Except where the prescriber . . . or the pharmacist who functions
4 pursuant to a policy, procedure or protocol pursuant to either subparagraph (D) of
5 paragraph (4), or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a)
6 of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or
7 the generic name and the name of the manufacturer. Commonly used abbreviations
8 may be used. Preparations containing two or more active ingredients may be
9 identified by the manufacturer's trade name or the commonly used name or the
10 principal active ingredients.

11 (2) The directions for the use of the drug.

12 (3) The name of the patient or patients.

13 (4) The name of the prescriber or, if applicable. . . the pharmacist who
14 functions pursuant to a policy, procedure or protocol. . .

15 (5) The date of issue.

16 (6) The name and address of the pharmacy, and prescription number or
17 other means of identifying the prescription.

18 (7) The strength of the drug or drugs dispensed.

19 (8) The quantity of the drug or drugs dispensed.

20 (9) The expiration date of the effectiveness of the drug dispensed.

21 (10) The condition or purpose for which the drug was prescribed if the
22 condition or purpose is indicated on the prescription."

23 9. Section 4081 of the Code states:

24 "(a) All records of manufacture and of sale, acquisition, or disposition of
25 dangerous drugs or dangerous devices shall be at all times during business hours open
26 to inspection by authorized officers of the law, and shall be preserved for at least
27 three years from the date of making. A current inventory shall be kept by every
28 manufacturer, wholesaler, pharmacy. . . 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. . . shall be jointly
responsible, with the pharmacist-in-charge or designated representative-in-charge, for
maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or designated representative-in-charge shall
not be criminally responsible for acts of the owner, officer, partner, or employee that
violate this section and of which the pharmacist-in-charge or designated
representative-in-charge had no knowledge, or in which he or she did not knowingly
participate."

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12. Section 4113 of the Code states:

“(a) Every pharmacy shall designate a pharmacist-in-charge and within 30 days thereof, shall notify the Board in writing of the identity and license number of that pharmacist and the date he or she was designated.

(b) The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.

(c) 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.”

13. Section 4115, subdivision (h), states that “[t]he pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

14. Section 4160, subdivision (a) of the Code states that no person shall act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the Board.

15. Section 4161 states, in pertinent part:

(a) A person located outside this state that (1) ships, sells, mails, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler.

(b) A nonresident wholesaler shall be licensed by the board prior to shipping, selling, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, or distributing dangerous drugs or devices within this state.

16. Section 4169 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.

1 (4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices
after the beyond use date on the label.

2 (5) Fail to maintain records of the acquisition or disposition of dangerous
3 drugs or dangerous devices for at least three years.

4 (b) Notwithstanding any other provision of law, a violation of this section
or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has
5 committed the violation to a fine not to exceed the amount specified in Section 125.9
for each occurrence, pursuant to a citation issued by the board.”

6 17. Section 4300 of the Code permits the Board to take disciplinary action to suspend or
7 revoke a license issued by the Board.

8 18. Section 4301 states that:

9 “The board shall take action against any holder of a license who is guilty
10 of unprofessional conduct or whose license has been procured by fraud or
misrepresentation or issued by mistake. Unprofessional conduct shall include, but is
11 not limited to, any of the following:

12 * * *

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

14 * * *

15 (o) Violating or attempting to violate, directly or indirectly, or assisting
16 in or abetting the violation of or conspiring to violate any provision or term of
Chapter 9 (commencing with Section 4000) of the Business and Professions Code or
17 of the applicable federal and state laws and regulations governing pharmacy,
including regulations established by the Board.”

18 19. Section 4342 states, in pertinent part, that:

19 “(a) The board may institute any action or actions as may be provided by
20 law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical
preparations and drugs that do not conform to the standard and tests as to quality and
21 strength, provided in the latest edition of the United States Pharmacopoeia or the
National Formulary, or that violate any provision of the Sherman Food, Drug and
22 Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the
Health and Safety Code.”

23 **REGULATORY PROVISIONS**

24 20. California Code of Regulations, title 16, Section 1714 states, in pertinent part:

25 * * *

26 “(b) Each pharmacy licensed by the board shall maintain its facilities,
27 space, fixtures, and equipment so that drugs are safely and properly prepared,
maintained, secured and distributed. The pharmacy shall be of sufficient size and
28 unobstructed area to accommodate the safe practice of pharmacy.

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2 (d) Each pharmacist while on duty shall be responsible for the security
3 of the prescription department, including provisions for effective control against theft
4 or diversion of dangerous drugs and devices, and records for such drugs and devices.
5 Possession of a key to the pharmacy where dangerous drugs and controlled
6 substances are stored shall be restricted to a pharmacist.”

7
8 21. California Code of Regulations, title 16, Section 1717, states that “(a) No
9 medication shall be dispensed on prescription except in a new container which conforms with
10 standards established in the official compendia.”

11 22. California Code of Regulations, title 16, Section 1718, states:

12 “Current Inventory’ as used in Sections 4081 and 4332 of the Business
13 and Professions Code shall be considered to include complete accountability for all
14 dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

15 The controlled substances inventories required by Title 21, CFR, Section
16 1304 shall be available for inspection upon request for at least 3 years after the date of
17 the inventory.”

18 23. Health and Safety Code section 11153, subdivision (a), states in pertinent part:

19 “(a) A prescription for a controlled substance shall only be issued for a
20 legitimate medical purpose by an individual practitioner acting in the usual course of
21 his or her professional practice. The responsibility for the proper prescribing and
22 dispensing of controlled substances is upon the prescribing practitioner, but a
23 corresponding responsibility rests with the pharmacist who fills the prescription.
24 Except as authorized by this division, the following are not legal prescriptions: (1) an
25 order purporting to be a prescription which is issued not in the usual course of
26 professional treatment or in legitimate and authorized research. . .”

27 24. Health and Safety Code section 111345 provides that:

28 “Any drug or device is misbranded if any word, statement, or other
information required by or under this part to appear on the label or labeling is not
prominently placed on the label or labeling with conspicuousness, as compared with
other words, statements, designs, or devices in the labeling, and in terms as to render
it likely to be read and understood by the ordinary individual under customary
conditions of purchase and use.”

29 25. Health and Safety Code section 111430 states that “A drug or device is misbranded
30 if it was manufactured in an establishment not duly registered with the Secretary of Health,
31 Education, and Welfare of the United States.”

32 26. 21 Code of Federal Regulations, Section 1301.71, states:

33 “(a) All applicants and registrants shall provide effective controls and
34 procedures to guard against theft and diversion of controlled substances. In order to
35 determine whether a registrant has provided effective controls against diversion, the

1 Administrator shall use the security requirements set forth in sections 1301.72-
2 1301.76 as standards for the physical security controls and operating procedures
3 necessary to prevent diversion. Materials and construction which will provide a
4 structural equivalent to the physical security controls set forth in sections 1301.72,
5 1301.73 and 1301.75 may be used in lieu of the materials and construction described
6 in those sections.”

7 COST RECOVERY

8 27. Section 125.3 states, in pertinent part, that the Board may request the administrative
9 law judge to direct a licentiate found to have committed a violation or violations of the licensing
10 act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the
11 case.

12 CONTROLLED SUBSTANCES/DANGEROUS DRUGS

13 28. Ambien (generic - Zolpidem Tartrate) is a dangerous drug as defined by Section
14 4022 and a controlled substance schedule IV as listed in the Health and Safety Code Section
15 11057, subdivision (d)(32). It is used for the treatment of insomnia or abnormal sleepfulness.

16 29. Vicodin ES (generic - Hydrocodone and Acetaminophen) is a dangerous drug as
17 defined Section 4022 and is classified as a Schedule III controlled substance as listed in the
18 Health and Safety Code Section 11056, subdivision (e)(5). It is a narcotic analgesic used in the
19 treatment of moderate to severe pain.

20 30. Xanax (generic – Alprazolam) is a dangerous drug as defined in Section 4022 and is
21 classified as a Schedule IV controlled substance as listed in the Health and Safety Code Section
22 11057(d)(1).

23 31. Ultram (generic – Tramadol) is a dangerous drug as defined in Section 4022 and is
24 used to treat moderate pain.

25 SUMMARY OF FACTS

26 32. The following facts are common to all charges of the Accusation:

27 a. On or about July 7, 2009, the Board received an anonymous online complaint
28 that Respondent Pharmacy had furnished controlled substances, including Vicodin ES, Ambien,
Xanax, and Tramadol, to teenagers without a prescription. The Board’s investigation did not
substantiate this allegation, but did find that the pharmacy was short Ambien 10 mg, Vicodin ES,
Xanax 2 mg, and Ultram 50 mg, as discussed in greater detail below.

1 b. On or about December 30, 2009, the Board's inspector visited the pharmacy
2 and observed Russian products on the shelves that contained labeling only in Russian.
3 Respondent Bagdasarian told the Board's investigator that the Russian products were either
4 herbal or dietary supplements. The Board's investigation found that the pharmacy had
5 unauthorized foreign drugs on their shelves. Respondents purchased drugs from ATE Nutritional
6 Inc., located at 1571 McDonald Avenue, Brooklyn, New York 11230, which was not licensed as
7 a non-resident wholesale distributor in California, as evidenced by the following invoices:

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DANGEROUS DRUGS	INVOICE NUMBER	INVOICE DATE
Voltaren gel and Flucinar (fluocinolone acetonide)	38123	11/11/2008
Furacillin (Nitrofurantoin) and Flucinar	38953	01/16/2009
Voltaren Gel and Strepcid (Sulfanilamide)	39611	02/26/2009
Tetracycline Ophthalmic Ointment and Voltaren gel	40351	04/22/2009
Furacillin and Flucinar	41015	06/19/2009
Tetracycline Ophthalmic Ointment	42325	09/15/2009
Flucinar	43237	11/17/2009

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24 c. According to the U.S.C. Drug Information and the Internet, one of the
25 products on Respondent Pharmacy's shelves, No-Spa – Drotaverine, is an antispasmodic drug,
26 structurally related to papverine, which may have teratogenic effects on a fetus (i.e. can cause
27 birth defects.) Another product, Analgin (Metamizole) is a nonsteroidal anti-inflammatory drug.
28 Neither of these two drugs are available in this country, and they are the only drugs with English

1 on their packaging. The Board's inspector found that, on or about December 30, 2009 and exact
 2 dates unknown, the pharmacy had on its shelves for sale 40 foreign drugs or pharmaceuticals
 3 manufactured in a foreign country and labeled in a foreign language. The Board's inspector
 4 requested that Respondent Pharmacy remove all of the Russian products from their shelves, and
 5 send the inspector an inventory list regarding where these products were returned.

6 d. Commencing on December 30, 2009, a selected drug audit was performed by a
 7 Board inspector of the brand and generic forms of Vicodin ES, Ambien 10 mg, Xanax 2 mg and
 8 Ultram 50 mg. The audit period for Vicodin ES, Ambien 10 mg, Xanax 2 mg was from July 27,
 9 2006 through January 10, 2009, and the audit period for Tramadol 50 mg was from July 27, 2006
 10 through December 30, 2009. The Board's inspector requested that Respondent Lee take a "Stock
 11 in Hand" inventory of Tramadol 50 mg. The audit revealed the following drugs were short and/or
 12 unaccounted for by Respondents:

DRUG	07/27/2006 INVENTORY AMOUNT	PURCHASED AMOUNT	DISPENSED AMOUNT	01/10/2009 INVENTORY AMOUNT	AMOUNT SHORT
Ambien 10 mg	138	50,200	48,542	409	1,387
Vicodin ES	280	49,100	19,392	0	29,988
Xanax 2 mg	100	1,900	1,480	100	420
Tramadol 50 mg	0	200,900	205,095 (through 12/30/09)	1,146 (stock on hand inventory of 12/30/09)	Pharmacy did not account for at least 1,949

24 e. On or after January 8, 2010, the inspector received a letter from Respondents
 25 Bagdasarian and Lee stating that some of the Russian products were purchased from Lor Care
 26 Cosmetics, Inc., and admitting that they did not label the products correctly for sale in the U.S.
 27 Further, the letter indicated that the pharmacy could not contact the foregoing supplier, and
 28

1 therefore retained PharmEcology Services, WM Healthcare Solutions in Wauwatosa, Wisconsin,
2 a medical waste processor, to accept these medications for destruction.

3 f. Also, Respondents did not notify the Board that they had terminated a licensed
4 pharmacy technician for stealing drugs. In a letter to the Board, Respondent Lee stated that, on
5 February 11, 2009, a pharmacy technician employed at the pharmacy, Saro Khachaturian, was
6 caught in the act of stealing stock bottles of medications and was fired on the spot. Respondent
7 Lee claimed that the pharmacy technician was responsible for the huge losses of drugs.
8 Respondents did not include any evidence supporting this claim, did not report this incident to the
9 Board, and did not explain why they did not report the firing of Mr. Khachaturian to the Board.

10 g. On or about July 28, 2010, the Board received a letter from Mr. Khachaturian,
11 which stated that he had been dismissed from Respondent Pharmacy because he had requested
12 days off from work to prepare for his son's christening. The allegations of theft of drugs from
13 Respondent Pharmacy by Mr. Khachaturian could not be substantiated by the Board, due to a
14 lack of sufficient evidence.

15 **FIRST CAUSE FOR DISCIPLINE**

16 **(Failure to Maintain Complete and Accurate Records for Controlled Substances)**

17 33. Respondents Bagdasarian, Lee and Ararat Plaza Pharmacy are subject to disciplinary
18 action under Section 4300 for unprofessional conduct as defined in Section 4301, subdivisions (j)
19 and (o), in conjunction with Sections 4081, subdivision (a) and 4105, and California Code of
20 Regulations, title 16, Section 1718 for failure to maintain a complete and accurate record for all
21 controlled substances/dangerous drugs received, sold, or otherwise disposed of by them.
22 Respondents were unable to account for substantial doses of narcotics, including Ambien 10 mg,
23 Vicodin ES, Xanax 2 mg and Tramadol 50 mg, per a selected drug audit performed by a Board
24 inspector, for the audit period from July 27, 2006 to January 10, 2009, as described in Paragraph
25 32 above as though fully set forth.

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1 Section 1301.71, for failing to maintain Respondent Pharmacy's facilities, space, fixtures, and
2 equipment so that drugs are safely and properly prepared, maintained, secured. Respondents
3 failed to secure and maintain its facilities from the alleged theft of drugs by pharmacy technician
4 Mr. Khachaturian, as claimed by Respondents Bagdasarian and Lee, and/or the loss of substantial
5 amounts of drugs that were not accounted for. Complainant refers to and by this reference
6 incorporates allegations of Paragraph 32 above as though fully set forth.

7 **FIFTH CAUSE FOR DISCIPLINE**

8 **(Failure to Maintain Security of Controlled Substances)**

9 37. Respondents Bagdasarian and Lee are subject to disciplinary action under Section
10 4300 for unprofessional conduct as defined in Section 4301, subdivisions (j) and (o), in
11 conjunction with Sections 4113, subdivision (c) and 4115, subdivision (h), California Code of
12 Regulations, title 16, Section 1714, subdivisions (b) and (d), and 21 Code of Federal Regulations,
13 Section 1301.71, for failing to secure the prescription department and provide effective controls to
14 prevent theft and/or diversion of substantial amounts of controlled substances and dangerous
15 drugs, between July 27, 2006 and January 10, 2009, and maintain complete records for such
16 drugs. Complainant refers to and by this reference incorporates allegations of Paragraph 32
17 above as though fully set forth.

18 **SIXTH CAUSE FOR DISCIPLINE**

19 **(Purchase and/or Sale of Controlled Substances From An Unlicensed Entity)**

20 38. Respondents Bagdasarian, Lee and Ararat Plaza Pharmacy are subject to disciplinary
21 action under Section 4300 for unprofessional conduct as defined in Section 4301, subdivisions (j)
22 and (o), in conjunction with Sections 4076, 4113, subdivision (c), 4161, 4169, subdivision (a)(1),
23 4342, subdivision (a) and Health and Safety Code section 11153, subdivision (a), for purchasing
24 and/or selling controlled substances obtained from ATE Nutritional, Inc., an unlicensed entity.
25 Complainant refers to and by this reference incorporates allegations of Paragraph 32 above as
26 though fully set forth.

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1 **SEVENTH CAUSE FOR DISCIPLINE**

2 **(Purchase and/or Sale of Non-Compliant, Misbranded Foreign Drugs)**

3 39. Respondents Bagdasarian, Lee and Ararat Plaza Pharmacy are subject to disciplinary
4 action under Section 4300 for unprofessional conduct as defined in Section 4301, subdivisions (j)
5 and (o), in conjunction with Section 4076, subdivisions (a)(1)-(4) and (a)(8), 4342, subdivision
6 (a), and California Code of Regulations, title 16, Section 1717, and Health and Safety Code
7 sections 11153, subdivision (a), 111345 and 111430, in that the Board's investigation found non-
8 compliant, misbranded foreign drugs on the pharmacy's shelves, with foreign and/or Russian
9 labels. Complainant refers to and by this reference incorporates allegations of Paragraph 32
10 above as though fully set forth.

11 **EIGHTH CAUSE FOR DISCIPLINE**

12 **(Failure to Report Firing of A Licensed Pharmacy Technician for Theft of Drugs)**

13 40. Respondents Bagdasarian and Lee are subject to disciplinary action under Section
14 4300 for unprofessional conduct as defined in Section 4301, subdivisions (j) and (o), in
15 conjunction with Section 4104, subdivision (c)(6), and 4113, subdivision (c), in that Respondents
16 failed to report the February 11, 2009 termination of pharmacy technician Saro Khachaturian's
17 employment with the pharmacy within 30 days to the Board. Complainant refers to and by this
18 reference incorporates allegations of Paragraph 32 above as though fully set forth.

19 **PRAYER**

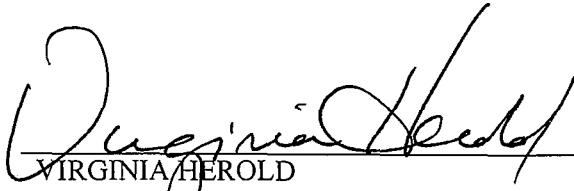
20 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
21 and that following the hearing, the Board of Pharmacy issue a decision:

- 22 1. Revoking or suspending Original Pharmacy Permit Number PHY 42130, issued to
23 Petros Bagdasarian dba Ararat Plaza Pharmacy
- 24 2. Revoking or suspending Pharmacist License No. RPH 44619, issued to Michael
25 Myung Y. Lee;
- 26 3. Ordering Ararat Plaza Pharmacy, Petros Bagdasarian and Michael Myung Y. Lee to
27 pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case,
28 pursuant to Business and Professions Code section 125.3;

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

DATED: 12/10/10



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

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