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

In the Matter of the Accusation Against: **K & S OWL INC., DBA OWL HOMECARE PHARMACY;** **MAHER HALIM KALDAS, OWNER and** **ALBERT SOLIMAN, OWNER** **13851 E. Garvey Avenue Unit A** **Baldwin Park, CA 91706** **Permit No. PHY 45091** **and** **MAHER HALIM KALDAS** **19036 E. Summit Ridge Dr.** **Walnut, CA 91789** **Pharmacist-In-Charge License No. RPH 39184** **and** **ALBERT SOLIMAN** **21238 Stockton Pass Rd.** **Walnut, CA 91789** **Pharmacist License No. RPH 44883** Respondents.	Case No. 4668 **A C C U S A T I O N**

and

MINACEUTICALS WHOLESALE
ALBERT SOLIMAN, OWNER
MAHER
MAHER HALIM KALDAS, OWNER

Permit No. WLS 4527

Affiliated Party.

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 28, 2004, the Board issued Original Permit Number PHY 45091 to K and S Owl Inc. doing business as Owl Homecare Pharmacy (Respondent Owl). The permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2016, unless renewed. Respondent Owl is co-owned by Respondents Maher Halim Kaldas (Respondent Kaldas) and Albert Soliman (Respondent Soliman). Respondent Kaldas has been the Chief Executive Officer and Pharmacist-In- Charge of Respondent Owl since April 28, 2004. Respondent Soliman has been the Treasurer/Chief Financial Officer of Respondent Owl since April 28, 2004.

3. On or about March 12, 1985, the Board issued Pharmacist License Number RPH 39184 to Respondent Kaldas. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2017, unless renewed.

4. On or about September 17, 1991, the Board issued Pharmacist License Number RPH 44883 to Respondent Soliman. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2015, unless renewed.

Minaceuticals Wholesale

5. On or about December 1, 2004, the Board issued Permit Number WLS 4527 to Minaceuticals Wholesale. The permit was in full force and effect at all times relevant to the charges brought herein and will expire on December 1, 2015, unless renewed. Minaceuticals

Wholesale is co-owned by Respondent Kaldas and Respondent Soliman. Respondent Maher, has been has been the Pharmacist-In-Charge since December 1, 2004.

JURISDICTION

6. This Accusation is brought before the Board, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

7. Section 4300 of the Code states:

"(a) Every license issued may be suspended or revoked.

"(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding one year.

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

"...."

8. Section 118(b) of the Code provides, in pertinent part, that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

9. Section 4402(a) of the Code provides that any license that is not renewed within three years following its expiration may not be renewed, restored, or reinstated and shall be canceled by operation of law at the end of the three-year period.

STATUTORY PROVISIONS

10. Section 4059 of the Code states, in pertinent part, that a person may not furnish any dangerous drug except upon the prescription of a physician, dentist, podiatrist, optometrist,

veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

11. Section 4076 of the Code states:

"(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

....

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

....."

12. Section 4081 of the Code states:

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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

"(c) The pharmacist-in-charge or 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 representative-in-charge had no knowledge, or in which he or she did not knowingly participate."

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13. Section 4105 of the Code states:

"(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

"(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

"(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

"(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

"(e)(1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter."

14. Section 4127, subdivision (a), of the Code states:

"A pharmacy that compounds sterile drug products for injection, administration into the eye, or inhalation shall possess a sterile compounding pharmacy license as provided in this article."

15. Section 4169 of the Code states:

"(a)(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.

....

"(a)(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."

16. 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:

". . ."

"(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.

". . ."

17. Section 4302 of the Code 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."

18. Section 4306.5 of the Code states:

"Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the

dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

....

(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function."

19. Section 4307 of the Code states:

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

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) Manager, administrator, owner, member, officer, director, associate, or partner," as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been

given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law. "

20. Section 4332 of the Code states:

"Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor."

21. Section 4333 of the Code states, in pertinent part, that all prescriptions filled by a pharmacy and all other records required by Section 4081 shall be maintained on the premises and available for inspection by authorized officers of the law for a period of at least three years. In cases where the pharmacy discontinues business, these records shall be maintained in a board-licensed facility for at least three years.

22. Section 4342 of the Code states:

"(a) The board may institute any action or actions as may be provided by 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 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 Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

REGULATORY PROVISIONS

23. California Code of Regulations, title 16, section 1718 states in pertinent part:

"Current Inventory" as used in Section 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Section 4081 and 4332. The controlled substances inventories required by title 21, California Code of Regulations, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory."

24. California Code of Regulations, title 16, section 1735.7 states:

"(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product."

25. California Code of Regulations, title 16, section 1793.7 states, in pertinent part:

"(a) Except as otherwise provided in section 1793.8, any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.

....

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients."

26. California Code of Regulations, title 16, section 1764 states, in pertinent part:

"No pharmacist shall exhibit, discuss, or reveal the contents of any prescription, the therapeutic effect thereof, the nature, extent, or degree of illness suffered by any patient or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative, the prescriber or other licensed practitioner then caring for the patient, another licensed pharmacist serving the patient, or a person duly authorized by law to receive such information."

27. California Code of Regulations, title 22, Division 5, Chapter 3, Article 3, section 72371, states in pertinent parts:

"(c) Patient's drugs supplied by prescription which have been discontinued and those which remain in the facility after discharge of the patient shall be destroyed by the facility in the following manner:

(1) Drugs listed in Schedules II, III or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 shall be destroyed by the facility in the presence of a pharmacist and a registered nurse employed by the facility. The name of the patient, the name and strength of the drug, the prescription number, the amount destroyed, the date of destruction and the signatures of the witnesses required above shall be recorded in the patient's health record or in a separate log. Such log shall be retained for at least three years.

(2) Drugs not listed under Schedules II, III or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 shall be destroyed by the facility in the presence of a pharmacist or licensed nurse. The name of the patient, the name and strength of the drug, the prescription number if applicable, the amount destroyed, the date of destruction and the signatures of the person named above and one other person shall be recorded in the patient's health record or in a separate log. Such log shall be retained for at least three years.

(d) Unless otherwise prohibited under applicable federal or state laws, individual patient drugs supplied in sealed containers may be returned, if unopened, to the issuing pharmacy for disposition provided that:

(1) No drugs covered under the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 are returned.

(2) All such drugs are identified as to lot or control number.

(3) The signatures of the receiving pharmacist and a registered nurse employed by the facility are recorded in a separate log which lists the name of the patient, the name, strength, prescription number (if applicable), the amount of the drug returned and the date of return. The log must be retained for at least three years."

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HEALTH & SAFETY CODE SECTION PROVISIONS

28. Health and Safety Code section 11167.5 states:

"(a) An order for a controlled substance classified in Schedule II for a patient of a licensed skilled nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice may be dispensed upon an oral or electronically transmitted prescription. If the prescription is transmitted orally, the pharmacist shall, prior to filling the prescription, reduce the prescription to writing in ink in the handwriting of the pharmacist on a form developed by the pharmacy for this purpose. If the prescription is transmitted electronically, the pharmacist shall, prior to filling the prescription, produce, sign, and date a hard copy prescription. The prescriptions shall contain the date the prescription was orally or electronically transmitted by the prescriber, the name of the person for whom the prescription was authorized, the name and address of the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice in which that person is a patient, the name and quantity of the controlled substance prescribed, the directions for use, and the name, address, category of professional licensure, license number, and federal controlled substance registration number of the prescriber. The original shall be properly endorsed by the pharmacist with the pharmacy's state license number, the name and address of the pharmacy, and the signature of the person who received the controlled substances for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice. A licensed skilled nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice shall forward to the dispensing pharmacist a copy of any signed telephone orders, chart orders, or related documentation substantiating each oral or electronically transmitted prescription transaction under this section."

29. Health and Safety Code section 111255 states:

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

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30. 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."

31. 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."

32. 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."

33. Health and Safety Code section 111330 states:

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

34. Health and Safety Code section 111335 states:

"Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

35. Health and Safety Code section 111340 states:

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

(a) The name and place of business of the manufacturer, packer, or distributor.

(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."

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36. Health and Safety Code section 111380 states:

"Any drug is misbranded if it purports to be a drug that is recognized in an official compendium and it is not packaged and labeled as prescribed in the official compendium. The method of packaging, however, may be modified with the consent of the department."

37. 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."

38. Health and Safety Code section 111395 states:

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

(a) It is an imitation of another drug.

(b) It is offered for sale under the name of another drug.

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

39. 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."

40. Health and Safety Code section 111445 states:

"It is unlawful for any person to misbrand any drug or device."

41. Health and Safety Code section 111450 states:

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

COST RECOVERY

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

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CONTROLLED SUBSTANCE/DANGEROUS DRUG

43. Section 4021 of the Code states:

"Controlled substance" means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code."

44. Section 4022 of the Code states, in pertinent part:

"'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and including 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."

45. The following drugs are referenced herein:

BRAND NAME	GENERIC NAME	DANGEROUS DRUG PER Code Section 4022	CONTROLLED SUBSTANCE PER Health and Safety Code (HSC)	INDICATION FOR USE
Fosrenol	Lanthanum carbonate	Yes	No	Lower phostate in patients that have end stage kidney disease
Blocadren	Timolol	Yes	No	Migraine, hypertension, glaucoma, high blood pressure
Vancocin	Vancomycin	Yes	No	Antibiotic used to treat bacterial infections
Aricept	Donepezil	Yes	No	Used to treat dementia associated with Alzheimer's Disease
Lexapro	Escitalopram	Yes	No	Treat depression and anxiety

Renvela	Sevelamer carbonate	Yes	No	Control phosphorus levels in patients with chronic kidney disease on dialysis
Combivent	Combination of Ipratropium and Albuterol	Yes	No	Prevent bronchospasm in patients suffering from Chronic Obstructive Pulmonary Disease (COPD)
Abilify	Aripiprazole	Yes	No	Schizophrenia or Bipolar Disorder
Divalproex sodium	Depakote	Yes	No	Bipolar disorder

INVESTIGATION REPORT DATED JANUARY 29, 2013

46. On April 29, 2011, Inspector Valerie Sakamura went to Respondent Owl to perform an inspection based on an anonymous complaint. Respondent Owl is a closed door pharmacy that provides medications to skilled nursing homes or assisted living facilities. Respondent Owl dispenses medication to the nursing homes in "bubble packs." The pharmacy takes empty clear plastic pill holders, fills each section with the drugs, then heat seals the card shut with a cardboard/foil backing that seals the drugs in the cards. It dispenses these "bubble packs" to the nursing homes with the drug name, lot number, and expiration date, and other identifying information on the packs.

47. As of April 29, 2011, Respondent Owl compounded two (2) to three (3) intravenous products per day.

48. During Inspector Sakamura's April 29, 2011 inspection she found a bottle of Timolol 5 mg that appeared to be overfilled. She poured out the tablets and found that the tablets were not all the same color. The bottle stated that it contained 100 tablets. Upon counting the tablets, it was found that the bottle contained 274 tablets. All of the 274 tablets did not originally come from the bottle in which they were found. There was no way of telling where the other pills came from, what their associated lot numbers were, or when they were set to expire.

49. Per the instructions in the anonymous complaint, Inspector Sakamura proceeded to the upstairs area of the pharmacy. There was a tapestry hanging on the wall of the pharmacy as the anonymous complaint had mentioned. Behind the tapestry was a hidden locked door. Inspector Sakamura asked Respondent Kaldas to open the hidden door. Once unlocked, Inspector Sakamura went upstairs and found herself in another room. The room had another door with a white sign marked "Water heater, tools, Janitorial supplies." When Inspector Sakamura opened the janitorial supply door, she saw boxes stacked ceiling high and rows of filing cabinets. Behind those filing cabinets was another partially hidden door. This door was also locked. The inspector asked Respondent Kaldas for the key. He told her he was not sure if he could find the key. She told him that she would wait for him to find it. Respondent Kaldas left to go find the key to the room. After a while, Respondent Kaldas came back upstairs and unlocked the door. Upon unlocking this door, the inspector found a room with no lights. The inspector asked Respondent Kaldas to turn on the lights since it was pitch black and she could not see what was inside. Respondent Kaldas stated that there were no lights in the room. Using the flash from her digital camera to light her path, the inspector found plastic drug bottles that were arranged alphabetically on the shelves along the walls. She saw the room was filled with boxes piled up on the floor. The boxes contained medication cards, some of which looked unused and some of which looked used. In other boxes, she found medication cards with patient labels, which appeared to be coming back from the nursing facilities. Many of the medication cards were bagged or rubber banded together. There were also trash bags strewn across the room. Inside one of the trash bags, the inspector found food trash, as well as empty drug bottles, punch cards, and open boxes of insulin. She found some shelves contained unrefrigerated medications, when those types of medications were required to be kept refrigerated. As she walked deeper into the room, she found that there was an entrance to another dark room on the right. At the entrance to the next room, the inspector saw a table set up with a computer and drug bottles that had labels from other pharmacies. In the other dark room she found more shelves filled with pills and injectable drugs organized in an alphabetical fashion.

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50. Respondent Kaldas stated that when the drugs came back from the nursing homes, Respondent Owl would credit the account. He would then pack and return the drugs to the reverse distributors to get credit in the form of money from the reverse distributor. The reverse distributor issued credit back based on the manufacturer's return goods policy for the pills returned (these guidelines could include whether the medication bottle is returned full or not, how far out of the expiration date of the drug is, or whether Respondent Owl was the one that purchased the drugs in the first place.) The reverse distributor also charged a fee for taking back or disposing of the drugs. According to Respondent Kaldas, when he put the medication back into the original bottle, depending on the expiration date, he could get a better credit from the reverse distributor. He said he would credit the patients' accounts for the unused medications

51. When the drugs were returned from the nursing homes, Respondent Kaldas stated he would punch out the medications from the bubble packs and place the medications into the baggies located on the shelves around the hidden rooms. Inspector Sakamura saw that the baggies were arranged alphabetically on the metal shelves. The inspector found that these bags contained more than one prescription's worth of medication, and appeared to be a mix of different lot numbers and expiration dates since it contained returned medications from different time periods.

52. The inspector sealed the rooms and left for the day.

53. On May 2, 2011, Inspector Sakamura and several other Board inspectors came back to Respondent Owl to do an inspection.

54. The inspectors went back to the hidden room that Inspector Sakamura had sealed. The inspectors removed the seal to enter the room. This time there appeared to be working lights in the room. It was unclear where these lights came from since Respondent Kaldas had previously told Inspector Sakamura that the rooms contained no lights. In the pharmacy's hidden room, inspectors found many instances of pills stored in plastic bags. Each bag seemed to contain a different pill. Within each bag, it appeared that similar pills had been collected together, yet the coloring of the pills seemed to be a little different from each other. There were also boxes that were filled with only caps of bottles as well as scales with drugs littered around them.

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55. The inspectors began counting the pills in the hidden rooms. The inspectors noted the rooms were cluttered, stuffy, and warm. Nothing in the rooms suggested that the pills were being stored in a sterile manner.

56. In the hidden rooms, several blood products used for patients with bleeding disorders, which were required to be refrigerated at all times, were not kept in refrigerators. In fact, there were no refrigerators in the hidden rooms. It was unclear how long the medications requiring refrigeration were stored at room temperature. The inspectors noted that these medications were warm to the touch. There were no patient labels or labels to describe where they were supposed to go.

57. There were many sample medications found in the hidden room of the pharmacy. There were no patient labels or labels to describe where they were coming from or going to. It was unclear as to how Respondent Owl came to possess such a large quantity of sample medications.

58. The hidden room also had an iron, which was found to have prescription labels sticking to its bottom. Respondent Kaldas stated the iron was used to "remove the prescription label from the drugs." He could not explain why the labels had to be removed cleanly or at all if they were all going to be sold to a reverse distributor to be wasted. He could not explain why some boxes that were ready to be shipped to the reverse distributor still had patient names and labels on them, if he was removing the labels in the hidden rooms to ship them to the reverse distributor.

59. The hidden rooms also contained prescription bottles from other pharmacies, such as Kaiser, USC, Rite Aid, among others. Some of them still had the patients' names, the drug names, the frequency of the dosage to use the drugs and expiration dates. Some of the bottles appeared to have expired as late as 2009 – more than two (2) years prior to the date of the inspection.

60. In one of the hidden rooms, the inspectors found a "bottle room" that contained numerous empty plastic manufacturer drug bottles placed in large trash bags. Each trash bag contained a letter of the alphabet on it or the name of a drug. It appeared that the trash bags were arranged alphabetically. Within each bag were empty manufacturer drug bottles with pill names

on them. The drug bottles appeared to be arranged alphabetically.

61. In addition to the empty bottles in the trash bags, the "bottle room" had many rows of empty manufacturer bottles arranged in alphabetical order.

62. While the other inspectors inspected the contents of the hidden rooms, Board Inspector Anna Yamada conducted an inspection of the general pharmacy. During her inspection, Inspector Yamada observed two (2) bottles of Fosrenol 1000 mg tablets marked with "1/2" in black marker on the pharmacy shelves downstairs. It appeared that the bottles were ready to be dispensed to consumers. Each bottle was supposed to contain ten (10) tablets. She opened the bottles and noted they were filled with tablets that had been cut in ½. Pharmacy technician, Jessernita Jimenez (Pharmacy Technician No. 51774) counted the pills in one bottle and found that it contained 38 half-sized tablets. In the other bottle, Ms. Jimenez found 40 half-sized tablets.

63. Inspector Yamada saw licensed pharmacist, Nathan Luutuyen (Pharmacist License No. 50955) checking a prescription for an emergency kit (e-kit). Respondent Owl dispensed e-kits to the nursing homes as an emergency backup supply of drugs when the pharmacy was closed. The e-kits did not contain the date that they were prepared, or the pharmacist name who verified the preparation of the kits. Mr. Luutuyen stated there were different e-kits and each e-kit contained different drugs. All e-kits had a sheet attached to them, which listed the specific drugs in the kit, and the expiration dates for each drug. The e-kits were prepared by technicians and sealed with a tamper evident lock. The narcotic kits were not locked up. Mr. Luutuyen told the inspector that there was no one who verified the e-kit preparation prior to the tamper evident lock being placed on the kit. Mr. Luutuyen stated the only thing that pharmacists verified was that it was the proper type of e-kit to be dispensed to the facility.

64. Inspector Yamada noted several prescriptions were mislabeled with an improper expiration date; indicating a patient could be taking expired drugs. Pharmacist Joseph Haroun (Pharmacist License No. 63862) told Inspector Yamada that it was the pharmacy technician's job to check the actual expiration date and correct it if it expires earlier. In a random, small sampling search, Inspector Yamada found the following list of expired drugs:

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Prescription Number	Manufacturer expiration date	Expiration date on patient label
842219	2/12	4/24/12
920164	11/11	5/1/12
900671	11/11	4/24/12

65. Inspector Yamada also reviewed the pharmacy's Schedule II prescriptions. She found that when the nursing facilities contacted Respondent Owl, Respondent Owl took down the prescriptions orally. A review of the prescriptions revealed the transcribing pharmacists received the order from the Director of Nursing (DON) and not from the prescribing physicians. The pharmacists did not verify the new oral prescription with the physician prior to dispensing the drug for the patient. The prescriptions were not accompanied by any signed physician documentation substantiating the telephone prescription from the DON.

66. In one of the rooms in the general pharmacy area, Inspector Yamada found a large sealed box, addressed to Genco (a reverse distributor). The box appeared ready to be shipped out. Inspector Yamada opened the seal and found the box contained medications and a list with the patient names and prescription numbers. Pharmacy technician, Sandra Soriano (Pharmacy Technician No. 79132) explained the box's contents to the inspector. She stated the sheet with the patient names was an inventory of all the drugs being shipped to the reverse distributor for destruction.

67. Inspector Yamada asked Respondent Kaldas to explain the drug return process at Respondent Owl. Respondent Kaldas stated that the nursing facilities sent back the used drugs to Respondent Owl. Respondent Owl's drivers would go pick up the bags/boxes of drugs from the nursing facilities, and drop the bags/boxes in the "drug return room" of Respondent Owl. Respondent Kaldas stated he was solely responsible for the drug returns. Initially Respondent Kaldas stated that the nursing facilities did not send a list of medications they were returning to Respondent Owl. When Inspector Yamada found a drug return form sent to Respondent Owl from a nursing facility, Respondent Kaldas stated that sometimes the nursing facilities do send paperwork of the drugs they are returning to Respondent Owl. Respondent Kaldas could not provide her with logs of returns sent back from the nursing homes. On August 8, 2007, Board

inspectors had conducted an inspection and found returned medications throughout the pharmacy and on the second floor of the pharmacy. The inspectors found that even though it is the pharmacy's policy to keep records of the returns of the medication, Respondent Owl was not maintaining such records. The inspectors told Respondent Kaldas he was required to keep records of the returns from the nursing facilities and what he sent back to the reverse distributors for credit. It appeared that this still was not being done four (4) years later.

68. Inspector Yamada asked the clerk, Mina Salib, for the pharmacy's drug purchase and drug return records. Mr. Salib was the pharmacy's purchaser and accountant. Mr. Salib took Inspector Yamada to an upstairs room where all the invoices were stored. Inspector Yamada asked Mr. Salib to provide the acquisition records for three (3) randomly selected drugs. Mr. Salib was unable to obtain the information from the wholesaler's computer. Mr. Salib attempted to do a manual search, however, he could not find any of the acquisition records.

69. On May 2, 2011, Inspector Sarah Bayley conducted an inspection of Minaceuticals Pharmacy owned by Respondent Kaldas and Respondent Soliman. Respondent Soliman stated that he did not sell or purchase any drugs from Respondent Owl. Respondent Kaldas told inspectors that he did purchase drugs from Minaceuticals Pharmacy; however, Respondent Kaldas did not provide paperwork showing such acquisitions.

70. Inspector Sakamura conducted an audit of a random sample of medications found in the pharmacy. According to the paperwork, Respondent Owl bought 900 tablets of Timolol since 2008. It had dispensed 112 in the same time period. At the very least, Respondent Owl should have had 788 Timolol pills in stock. Respondent Owl only had 500 pills. Respondent Owl could not explain this discrepancy.

71. Respondent Owl had been fitted with surveillance cameras. The inspectors requested copies of the surveillance video. At one point in the video, an unknown employee of Respondent Owl, working in the downstairs portion of the pharmacy, can be seen filling bubble packs with medications. As he is filling the medications, he is not using gloves, and appears to be eating; thus, possibly contaminating the medications he is filling. On August 8, 2007, Board inspectors had conducted an inspection of Respondent Owl. At that time, the inspectors had found one of the

pharmacy technicians packaging bubble packs without gloves. Respondent Owl was advised that pharmacy technicians must wear gloves when placing medication in bubble packs. It appeared that this still was not being done four (4) years later.

72. On May 5, 2011, Inspector Sakamura questioned Respondent Kaldas. Respondent Kaldas stated that when drugs came back from the nursing homes, they were kept either: 1) next to the "IV room" behind the curtain, 2) in the upstairs "credit room", 3) in the "expired drug storage room", or 4) on the stairs near where Ms. Soriano sat. It was Respondent Owl's practice to send boxes back to the reverse distributors as often as they would accumulate. Reverse distributor, Genco, charged per pound and an extra twenty cents per cards that required disposal.

73. Respondent Kaldas stated that only Mr. Mina, "Mike," Respondent Soliman, Respondent Kaldas, and Ms. Soriano were allowed in the hidden rooms. Each pharmacist working at the pharmacy had the keys to the general pharmacy area.

74. In addition to being the owner, Respondent Soliman also worked as a pharmacist at Respondent Owl.

75. Respondent Kaldas, Mr. Mina, and a man from Mexico worked in the hidden rooms located upstairs. The man from Mexico was a day laborer from Home Depot, and only worked when Respondent Kaldas was around. Respondent Kaldas did not elaborate as to what the day laborer did in the hidden rooms.

76. Inspector Sakamura asked Respondent Kaldas why he kept insulin vials in a large plastic bag organized by date. He stated he returned them based on expiration date. In the empty bottle room, he stated he put the "skilled" medications back in the bottles and returned them for credit. He stated that putting the medication in bottles increased the chances of getting credit from the reverse distributor. Inspector Sakamura asked Respondent Kaldas why he kept refrigerated drugs outside of a refrigerator. He stated he was not planning to reuse them and was going to return them; thus, in his opinion, they did not require refrigeration.

77. Respondent Kaldas stated that the empty drug bottles found in the hidden rooms are from the nursing homes or from the pharmacy. Respondent Kaldas kept the trash and would go through it to see if someone was stealing medications. He did not elaborate as to how he would

discover stolen medications in the trash. He stated he kept the bags of bottles on the shelves so he could give them to technician schools, although he does not remember which schools he gave them to or for what purpose. Respondent Kaldas stated he would take the sticker off of the empty bottles and fill them with candies, although no such bottles were ever found by inspectors.

78. Respondent Kaldas also stated that he took prescription labels off the bottles or packs because he got credit when he returned them without labels to the reverse distributor. According to him, if the label was still on, he did not receive a credit. The iron in the room was to help him take off the labels.

79. Respondent Kaldas decided which drugs would be stored in the upstairs hidden rooms. When the drugs returned from the nursing homes, Mr. Mina and Respondent Kaldas brought the drugs to the hidden rooms. The returned medications were put in plastic bags. When they expired, they were sent back for destruction. He stated the drugs are put into clear plastic bags for cost savings. He did not elaborate as to how putting the drugs in the plastic bags saved him costs.

80. Respondent Kaldas put the drugs in the plastic bags back into the manufacturer's containers after the container expired to get credit from the reverse distributor. He stated that he has been doing this since 2007 or 2008. He used to do it in his office, but he moved the operation upstairs. He did not explain why he waited until the drug expired to return it to the reverse distributor.

81. Respondent Kaldas stated he does not know how much money he got from returning the drugs to the reverse distributor, but estimated it to be about 20%. Respondent Kaldas stated if he returned the drug within three (3) months of the expiration date on the bottle, he got 10% credit.

82. According to Respondent Kaldas, Ms. Soriano was responsible for sorting out controlled drugs versus non-controlled drugs. If the drugs were expired, they did not come to the hidden rooms. He did not elaborate as to where the expired drugs went.

83. Respondent Kaldas stated he got the sample medications from the nursing homes.

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84. Between May 2, 2011 and May 10, 2011, the inspectors took 1,675 baggies/items from Respondent Owl, which was only a small fraction of the amount of drugs in the hidden room. Upon counting the items in the plastic bags taken into evidence, Inspector Sakamura found that they had collected 207,531 pills. On the pills she could identify, she found that there were 1,010 different types of drugs in the bags the inspectors collected. When Respondent Kaldas sent the rest of the items in the hidden room to the reverse distributor, he received a total credit of $435,074.13.

FIRST CAUSE FOR DISCIPLINE

(Respondent Owl & Respondent Kaldas-Pharmacy Technician Supervision)

85. Respondents are subject to disciplinary action in violation of California Code of Regulations section, title 16, section 1793.7, subdivision (a), for not having a licensed pharmacist check the e-kits and medications in the e-kits after being filled by technicians. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraph 63, inclusive, as though set forth fully.

SECOND CAUSE FOR DISCIPLINE

(Respondent Owl & Respondent Kaldas -Unauthorized Disclosure of Prescription Information)

86. Respondents are subject to disciplinary action under section 4301, subdivision (o) of the Code, in that they failed to comply with California Code of Regulations, title 16, section 1764 by disclosing protected patient information to reverse distributors. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraph 66, inclusive, as though set forth fully.

THIRD CAUSE FOR DISCIPLINE

(Respondent Owl & Respondent Kaldas -Prescription Label Requirements)

87. Respondents are subject to disciplinary action under section 4301, subdivision (o), and under 4076, subdivision (a) of the Code, in that Board inspectors found several repackaged prescriptions with mislabeled labels on the premises. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraph 64, inclusive, as though set forth fully.

FOURTH CAUSE FOR DISCIPLINE

(Respondent Owl & Respondent Kaldas -Orally Transmitted Prescriptions)

88. Respondents are subject to disciplinary action under section 4301, subdivision (o), and 4059 of the Code, and under Health and Safety Code section 11167.5, subdivision (a), in that the pharmacists working at the pharmacy took telephone orders from non-prescribers. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraph 65, inclusive, as though set forth fully

FIFTH CAUSE FOR DISCIPLINE

(Respondent Owl & Respondent Kaldas -Drug Quality)

89. Respondents are subject to disciplinary action under section 4301, subdivision (o), and under 4342, subdivision (a), of the Code, in that there were bottles of overfilled medications found on pharmacy shelves ready to be dispensed, drugs with assigned expiration dates longer than provided by the manufacturer, and numerous baggies of unlabeled drugs kept in a non-sterile environment in the hidden rooms. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraphs 46 through 84, inclusive, as though set forth fully.

SIXTH CAUSE FOR DISCIPLINE

(Respondent Owl & Respondent Kaldas -Adulterated Drugs)

90. Respondents are subject to disciplinary action under section 4301, subdivision (o) of the Code, and Health and Safety Code section 111255 and 111260, in that there were bottles of overfilled medications found on pharmacy shelves ready to be dispensed, drugs were assigned expiration dates longer than provided by the manufacturer, and there were numerous baggies and drugs kept in a non-sterile environment in the hidden rooms. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraphs 46 through 84, inclusive, as though set forth fully.

SEVENTH CAUSE FOR DISCIPLINE

(Respondent Owl & Respondent Kaldas -Adulterated Drugs Returned for Credit)

91. Respondents are subject to disciplinary action under section 4169, subdivision (a)(2), 4301, subdivision (o) of the Code, and Health and Safety Code section 111295 and 111305, in

that Respondent Kaldas would punch out used drugs returned from nursing homes into plastic baggies, refill the drugs in random manufacturer containers, and ship them to reverse distributors for credit. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraphs 46 through 84, inclusive, as though set forth fully

EIGHTH CAUSE FOR DISCIPLINE

(Respondent Owl & Respondent Kaldas -Misbranded Drugs with False or Non-Conforming Labels)

92. Respondents are subject to disciplinary action under section 4169, subdivision (a)(3), 4301, subdivision (o), and Health and Safety Code section 111330, 111335 and 111340 in that Respondent Kaldas admitted he would take pills in the hidden room, and punch out the used drugs into plastic baggies which did not contain labels or otherwise contained non-conforming labels about the pills in the plastic baggies, refill the drugs in random manufacturer containers, and ship them to reverse distributors for credit. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraphs 46 through 84, inclusive, as though set forth fully.

NINTH CAUSE FOR DISCIPLINE

(Respondent Owl & Respondent Kaldas -Misbranded Drugs)

93. Respondents are subject to disciplinary action under section 4301, subdivision (o), and under Health and Safety Code section 111380, 111390, and 111445 in that Respondent Kaldas admitted he would take pills in the hidden room, punch out the used drugs into plastic baggies, wait until the drugs expired, and put the drugs back into manufacturer containers that had random expiration dating which did not correspond with the actual expiration dates, and send them to the reverse distributor for compensation or credit. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraphs 46 through 84, inclusive, as though set forth fully.

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TENTH CAUSE FOR DISCIPLINE

(Respondent Owl & Respondent Kaldas -Misbranded Drugs -Packaging)

94. Respondents are subject to disciplinary action under section 4301, subdivision (o), and Health and Safety Code section 111395 in that Respondent Kaldas would take pills in the hidden room, punch out the used drugs into plastic baggies, put the drugs back into manufacturer containers (without regard as to whether it had originally been dispensed from that manufacturer container), and ship the drugs to the reverse distributor for credit. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraphs 46 through 84, inclusive, as though set forth fully.

ELEVENTH CAUSE FOR DISCIPLINE

(Respondent Owl & Respondent Kaldas -Misbranded Drugs Sales to Reverse Distributor)

95. Respondents are subject to disciplinary action under section 4301, subdivision (o), and Health and Safety Code section 111440 and 111450 in that Respondent Kaldas admitted he and his employees would take pills he received back from his customers, punch the pills out of their bubble pack into plastic bags, wait until the medication expired, re-pack the pills into manufacturer's containers with random expiration dates and lot numbers which did not correspond with the pills actual expiration date or lot number, and sell them to the reverse distributor for credit. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraphs 46 through 84, inclusive, as though set forth fully.

TWELFTH CAUSE FOR DISCIPLINE

(Respondent Owl & Respondent Kaldas-Taking Back Drugs from Nursing Facilities)

96. Respondents are subject to disciplinary action under section 4301, subdivision (o), and California Code of Regulations, title 22, section 72371, subdivisions (c) and (d), in that Respondents took back controlled and non-controlled substances from nursing facilities, which should have been destroyed. Furthermore, Respondents failed to maintain proper records as to the medications received. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraphs 46 through 84, inclusive, as though set forth fully.

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THIRTEENTH CAUSE FOR DISCIPLINE

(Respondent Owl, Respondent Kaldas, & Respondent Soliman-Unprofessional Conduct)

97. Respondents are subject to disciplinary action under section 4301, subdivision (o), and 4306.5, subdivisions (a), (b), and (d) of the Code, in that Respondents took back controlled substances from nursing facilities and failed to maintain proper records as to the medications received. Respondents would then repackage these medications and send them back to reverse distributors for money. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraphs 46 through 84, inclusive, as though set forth fully.

FOURTEENTH CAUSE FOR DISCIPLINE

(Respondent Owl, Respondent Kaldas, & Respondent Soliman-Maintaining Records)

98. Respondents are subject to disciplinary action under section 4301, subdivision (o), 4081, 4105, 4332, and 4333 of the Code, in that Respondents took back controlled substances from nursing facilities and failed to maintain proper records as to the medications received. Respondents would then repackage these medications and send them back to reverse distributors for money. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraphs 46 through 84, inclusive, as though set forth fully.

FIFTEENTH CAUSE FOR DISCIPLINE

(Respondent Owl & Respondent Kaldas -Inaccurate Inventory)

99. Respondents are subject to disciplinary action under section 4301, subdivision (o), 4081, 4105, 4333 of the Code, in that Respondents could not produce records for 288 tablets of Timolol which were unaccounted for. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraph 70, inclusive, as though set forth fully.

SIXTEENTH CAUSE FOR DISCIPLINE

(Respondent Owl -Misconduct by Owner and/or Corporate Officer)

100. Respondent Owl is subject to disciplinary action under section 4302 in that a corporate officer, director and/or person holding 10 percent or more of Respondent Owl's corporate stock engaged in conduct that constitutes grounds for disciplinary action. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 46

through 84, inclusive, as though set forth fully herein.

INVESTIGATION REPORT DATED FEBRUARY 26, 2015

101. On December 15, 2014, Inspector Sakamura went back to Respondent Owl to conduct further investigation.

102. She found that the upstairs portion of the pharmacy had changed since she had last inspected the site. She found that it was more open and contained significantly less pills and bottles.

103. Inspector Sakamura spoke to two pharmacy technicians, Eric Zavala (Pharmacy Technician No. 112446) and Hami Mikhail (Pharmacy Technician No. 114748), who had worked at Respondent Owl for several years. They both stated they do intravenous (IV) compounding as part of their job duties. Mr. Zavala stated he had compounded medication as recently as December 13, 2014.

104. During the inspection, Inspector Sakamura found pharmacy technician, Jessica Oroz (Pharmacy Technician No. 109064) working at the pharmacy as a technician. Upon review of her license, the inspector found that Ms. Oroz had not renewed her license since September 30, 2014. Inspector Sakamura told Respondent Kaldas that Ms. Oroz could not work until Ms. Oroz renewed her license.

105. Inspector Sakamura came back to the pharmacy the next day, and found that Ms. Oroz had flown to Sacramento to renew her license.

106. On December 15, 2014, the inspector spoke to pharmacy technician Jocelyn Tana (Pharmacy Technician No. 82078) who told her that she makes IV compounds. She stated that in the past, the bubble packs returned from the nursing homes were recycled by someone on the night shift. She would notice that in the morning there would be more product on the shelf than the night before. She stated that the process had changed recently. Now when the driver brought the medications back from the nursing homes, someone would go through the medications and place a mis-fill sticker on the full, unused cards in the boxes returned from the nursing homes. The filling pharmacy technicians would then go through the boxes, and place the unused cards on the shelves so that they could be reused for other patients.

107. Inspector Sakamura spoke with Mr. Haroun. Mr. Haroun told her he had been working at Respondent Owl since 2009 and had been present during the last inspection. When Inspector Sakamura asked Mr. Haroun what he knew about Respondent Owl compounding medications, he appeared very hesitant to answer her questions on the subject matter. He finally told her that it was the pharmacy's policy for the pharmacist to watch over technicians if they were making IV products. He said that he did not watch them when the technicians were connecting the bags to the vials. He said he had personally witnessed technicians compound products in the hood. In a written statement, he wrote that the pharmacy: 1) attached vials to bags, 2) dispensed bags and drugs separately, 3) prepared drugs which were reconstituted and put into the final bag, and 4) TPN bags (total parenteral nutritional bags). He wrote that he has seen the pharmacy do all four (4) of these things within the last three (3) months. He told the inspector he had brought it up at the last staff meeting that the pharmacy did not have a sterile compounding license. Respondent Kaldas told him that they were reconstituting only; thus, did not need a compounding license.

108. The inspector spoke to another pharmacy technician, Adam Acosta (Pharmacy Technician No. 29410) who had been working at Respondent Owl since December 2013. The technician told her he had compounded Vancomycin almost daily, but had been told the day before not to compound anymore.

109. The inspector spoke to pharmacy technician, Vicky Thai (Pharmacy Technician No. 69956). It was Ms. Thai's responsibility to oversee technicians on the late shift. She confirmed that the medications brought back from the nursing homes were put in the closet next to the "IV room." She stated Mari Masoud (Pharmacist Technician No. 52456), the supervisor, took care of them. Ms. Thai stated that the unused full cards that come back form the nursing homes are put on the side and the technicians place the mis-fill sticker on them so the drugs can be reused. She went on to state that the pharmacy compounded in the hood Vancomycin and other drugs. About three (3) times a night, the night shift had to prepare compounded solutions. On the date of this inspection, she was told not to prepare the compounded items and send them to another pharmacy, Owl Western.

110. Inspector Sakamura spoke to pharmacist Mr. Phillip Kong (Pharmacist License No. 60275). He stated about two (2) to three (3) years ago, the staff pharmacists noticed processed prescriptions in bubble packs with contaminated items. The staff pharmacists became concerned because there were quite a few of the incidents discovered within a period of weeks. One example he remembered was an order of Aricept 5 mg tablet, which he saw was filled with Aricept 5 mg as well as a few tablets of Lexapro 5 mg. The bubble card was shown to Respondent Kaldas. On other occasions, Mr. Kong recalled bubble packs filled with the same medication, but which had slightly different shades of color. In mid-November 2014, several of the staff pharmacists, including Mr. Kong, wrote to Respondent Kaldas and Respondent Soliman, as to an incident that occurred at the pharmacy. Mr. Kong had discovered a box of ipratropium/albuterol with Respondent Owl's label on one side, and on the other side there was a prescription label from a different pharmacy for a different patient. Mr. Kong showed another pharmacist the box. Upon investigating, the other pharmacist found another box of the same drug with the same patient name and pharmacy label on it in the general pharmacy area. The staff pharmacists wrote a letter to the owners of the pharmacy to document what they had discovered.

111. Inspector Sakamura asked Respondent Kaldas if he was compounding items in the hood. He stated there may have been an oversight because they had been doing it before when they were JCAHO (Joint Commission on Accreditation of Healthcare Organization) accredited. The inspector asked Respondent Kaldas for compounding records. Respondent Kaldas told her he did not know if he had any because he did not compound many things. According to Respondent Kaldas' employees they had been keeping records of what they compounded. Inspector Sakamura pressed Respondent Kaldas to provide the compounding records. He provided only a partial printout.

112. On December 17, 2014, Inspector Sakamura returned to the pharmacy to gather up logs and other pieces of evidence. On that date she found a box filled with medication to be returned to the reverse distributor. Inside she randomly selected a bottle of Renvela to check the pills. The pills inside the bottle had different colors and the font appeared to be different; thus, appearing they had come from different bottles.

113. On December 17, 2014, the inspector asked Respondent Kaldas for compounding competencies for four (4) random members of his staff. Respondent Kaldas was able to provide only three (3) of the four (4) requested. The inspector asked Respondent Kaldas to send the competencies of all the employees to her at a later time. Respondent Kaldas sent the inspector the compounding competencies for the staff on December 23, 2014. Six (6) of his 28 staff members were missing competencies. During an August 8, 2007 inspection, Board inspectors had told Respondent Kaldas he was required to monitor the staff's competencies. During the May 2, 2011 inspection, the inspectors had asked Respondent Kaldas for the competencies of his staff for compounding. On May 2, 2011, the inspectors notified Respondent Kaldas that he had not monitored all his staff per the pharmacy's policy, and that not all of the staff were given all aspects of the training as required.

114. Inspector Sakamura went to the room next to the "IV room" and found boxes and bags of medications returned from the nursing homes. When she opened up the bags and boxes she did not find any paperwork showing the transfer of the medications. On previous occasions, Inspector Sakamura had told Respondent Kaldas that the facilities need to inventory and send paperwork as to what they are sending back to Respondent Owl.

115. Inspector Sakamura spoke to a previous employee who had worked at Owl, Mark Sabillo (Pharmacist License No. 69551). Mr. Sabillo was now a pharmacist, but worked as a pharmacy technician at Respondent Owl from 2006 to 2009. During that time frame, he knew Respondent Owl used to take back medications from the nursing facilities, punch out the medications from the bubble pack, and reuse the medications.

116. Inspector Sakamura spoke to Ms. Masoud. She stated she had been working at Respondent Owl since 2001. She became a supervisor approximately four (4) years ago.
She stated that the pharmacy was compounding medications until December 15, 2014. Inspector Sakamura asked Ms. Masoud to fill out a questionnaire, which asked the same questions Inspector Sakamura posed to her in the interview. Ms. Masoud filled out the questionnaire, but refused to sign it under penalty of perjury. Inspector Sakamura told Ms. Masoud, she could cross out the language that required her to sign the document under penalty of perjury. After crossing

out that language, Ms. Masoud signed the questionnaire.

117. On December 23, 2014, Respondent Owl sent Inspector Sakamura logs and prescriptions of sterile injectable items compounded from July 1, 2014 to December 17, 2014. The logs showed Respondent Owl had dispensed 928 sterile compounds without a sterile compounding license.

118. Inspector Sakamura spoke with pharmacy technician Maria Paguyo (Pharmacy Technician license no. 69428). She stated she had worked at Respondent Owl for about four (4) years from 2008 to 2012. During that time she stated she had made IV compounded products and worked on new admissions. She said her supervisor was Ms. Masoud. She recalled seeing overfilled bottles of medications, specifically she remember Depakote bottles being overfilled. She also recalled seeing different color pills in the same bottle. For example, she once witnessed Abilify pills in a Depakote bottle, but she does not know who did it.

119. Inspector Sakamura spoke to pharmacy technician Mayra Camargo (Pharmacy Technician No. 72577). She stated she worked at Respondent Owl from April 2008 to January 2012. She recalled seeing bottles on the shelf with overfilled medications. She suspected the bottles would show up at night because the next morning there would be more stock of drugs on the shelf. She said when she used a bottle of medication, and left it half full, the next day it would be overfilled. She also noticed different color pills come out of the same manufacturer bottle.

120. Respondent Kaldas had applied to the Board for a compounding license in May 2014.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Respondent Owl & Respondent Kaldas -Unlicensed Activity)

121. Respondents are subject to disciplinary action under section 4301, subdivision (o), and 4127, subdivision (a), of the Code, in that Respondents were performing sterile compounding without a license. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraphs 101 through 120, inclusive, as though set forth fully.

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EIGHTEENTH CAUSE FOR DISCIPLINE

(Respondent Owl, Respondent Kaldas, & Respondent Soliman-Unlicensed Activity)

122. Respondents are subject to disciplinary action under section 4301, subdivision (o), and 4306.5, subdivision (a) and (b) of the Code, in that from October 2014 to December 2014, Respondents allowed pharmacy technician Jessica Oroz to perform pharmacy technician duties with an expired license. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraph 104, inclusive, as though set forth fully.

NINETEENTH CAUSE FOR DISCIPLINE

(Respondent Owl & Respondent Kaldas –Failure to Maintain Competencies on File)

123. Respondents are subject to disciplinary action under section 4301, subdivision (o) of the Code, and California Code of Regulations 1735.7, in that on December 17, 2014, Respondent Kaldas was unable to provide the competencies of one (1) of the employees the inspector requested. When Respondent Kaldas subsequently mailed the competencies for his staff on December 23, 2014, they were incomplete. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraph 113, inclusive, as though set forth fully.

TWENTIETH CAUSE FOR DISCIPLINE

(Respondent Owl, Respondent Kaldas, & Respondent Soliman-Maintaining Records)

124. Respondents are subject to disciplinary action under section 4301, subdivision (o), 4081, 4105, 4332, and 4333 of the Code, in that Respondents took back controlled substances from nursing facilities and did not maintain proper records as to the medications received. Complainant refers to, and by this reference incorporates, the allegations set forth in above paragraph 114, inclusive, as though set forth fully.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Respondent Owl- Misconduct by Owner and/or Corporate Officer)

125. Respondent Owl is subject to disciplinary action under section 4302 in that a corporate officer, director and/or person holding 10 percent or more of Respondent Owl's corporate stock engaged in conduct that constitutes grounds for disciplinary action. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 101

through 120, inclusive, as though set forth fully herein.

DISCIPLINARY CONSIDERATIONS

126. In order to determine the degree of discipline, if any to be imposed on Respondents, Complaint alleges as follows:

a. On or about June 26, 2002, the Board filed an accusation against Respondents Kaldas and Respondent Soliman (*In the Matter of the Accusation Against Maher H. Kaldas, dba Owl Rexall Drug, Maher Halim Kaldas, Nagwa Kaldas, Albert Soliman, dba Owl Homecare Pharmacy, and Albert Soliman dba Minauceuticals Wholesale, Board Case No. 2497).* The Accusation alleged five (5) causes for discipline as to Respondent Kaldas: 1) Acting as a Wholesaler Without Proper License in violation of section 4160, subdivision (a), of the Code; 2) Failure to Maintain Records of Acquisition of Dangerous Drugs in violation of sections 4081, 4105, and 4333 of the Code and California Code of Regulations, title 16, section 1718; 3) Allowed a Person Other Than the Pharmacists to Receive Drugs in violation of section 4059.5, subdivision (a), of the Code; 4) Failure to Notify the Board of Change in Ownership in violation of sections 4300 and 4301, subdivision (o), of the Code; and 5) Furnish Large Quantities of a Dangerous Drug in violation of section 4119.5 of the Code. The Accusation alleged two (2) causes for discipline as to Respondent Soliman: 1) Unprofessional Conduct in violation of sections 4300 and 4301, subdivision (o), of the Code, and 2) Failure to Notify the Board of Change in Ownership in violation of sections 4300 and 4301, subdivision (o), of the Code. On November 13, 2004, the Board and the parties entered into a Stipulated Settlement. Under the terms of the settlement, Respondent Kaldas and Respondent Soliman's pharmacist licenses were revoked and placed on probation for one (1) year with terms and conditions.

b. Respondent Kaldas was issued a citation by the Board on March 13, 2008 (*Case No. CI 2007 3526).* Respondent Kaldas has paid the fine associated with this citation.

c. Respondent Owl was issued a citation by the Board on March 13, 2008 (*Case No. CI 2006 34139).* Respondent Owl has paid the fine associated with this citation.

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OTHER MATTERS

127. Pursuant to sections 4307, subdivision (a), if discipline is imposed on license No. 39184 issued to Respondent Kaldas, Respondent Kaldas shall be prohibited from serving as s manager, administrative, owner, member, officer, director, associate, or partner of a licensee.

128. Pursuant to sections 4307, subdivision (a), if discipline is imposed on license No. 44883 issued to Respondent Soliman, Respondent Soliman shall be prohibited from serving as s manager, administrative, owner, member, officer, director, associate, or partner of a licensee.

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 Original Pharmacy Permit Number PHY 45091 issued to K and S Owl Inc., doing business as Owl Homecare Pharmacy;

2. Revoking or suspending Pharmacist License RPH 39184 issued to Maher Halim Kaldas;

3. Revoking or suspending Pharmacist License RPH 44883 issued to Albert Soliman;

4. Ordering Respondents Maher Halim Kaldas, Albert Soliman, and Owl Homecare Pharmacy 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;

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

DATED: 1/27/16

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