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,
Pharmacy Permit No. PHY 45091;

MAHER HALIM KALDAS
Pharmacist License No. RPH 39184;

and

ALBERT SOLIMAN
Pharmacist License No. RPH 44883

Respondents and Sterile Compounding Pharmacy License Applicants

and

MINACEUTICALS WHOLESALE; ALBERT SOLIMAN, Owner and MAHER HALIM KALDAS, Owner
Wholesale Permit No. WLS 4527

Agency Case No. 4668; OAH No. 2016120241

DECISION AFTER REMAND

On January 27, 2016, the Complainant served an accusation alleging 21 causes for discipline against respondent K&S Owl Inc., dba Owl Homecare Pharmacy (Owl) and 19 causes for discipline against Maher Halim Kaldas (Kaldas). On June 13, 2016, the Complainant filed a Statement of Issues against Owl and Kaldas in connection with an application filed for a sterile compounding license. The Accusation and the Statement of Issues were consolidated for hearing. The consolidated matters were heard from January 23, 2017 to January 26, 2017. On July 31, 2017, the California State Board of Pharmacy ("Board") issued an Order adopting the April 21, 2017 Proposed Decision of the Administrative Law Judge in the above-entitled matter. The decision, which became effective on August 30, 2017, concluded that the Complainant had established 13 causes for discipline against Owl, and 11 causes of discipline against Kaldas.

The Board's decision denied the sterile compounding pharmacy license, revoked the licenses of Owl and Kaldas, with revocation stayed and Owl and Kaldas were placed on five years of probation with conditions. On September 29, 2017, Owl surrendered its pharmacy license. On November 22, 2017, Respondents Owl and Kaldas filed a petition for writ of mandamus pursuant to California Code of Civil Procedure section 1094.5 in the Sacramento County Superior Court challenging the legal conclusions as to seven of the causes for discipline but conceding the remaining causes of discipline. On November 16, 2018, the superior court granted Respondent's petition as to one cause of discipline, the fifth cause for poor drug quality. The superior court concluded that the remaining challenged causes for discipline were substantiated. The superior court remanded the matter to the Board to determine the appropriate discipline in light of the court's finding that the fifth cause for discipline was unsubstantiated.

On October 29, 2020, the Board issued an order fixing the date for submission of written argument on remand with a due date of November 25, 2020. The Board sought written argument on 1) what discipline was appropriate in light of the superior court's determination

that the fifth cause for discipline was unsubstantiated, and 2) the impact of Owl's license surrender on the decision. Both parties filed timely written briefs. A brief was filed for Respondent Kaldas only.

The Board, having reviewed and considered the superior court's decision and the written arguments, now issues this this decision.

The April 21, 2017, Proposed Decision is adopted as the Board's Decision and Order in this matter, with the revisions as follows:

A. The Legal Conclusions section on pages 13-14, paragraphs 14 through 17 are amended to read:

LEGAL CONCLUSIONS

14. Complainant did not establish this cause for discipline. Under the Sherman Food, Drug, and Cosmetic Law, "[i]t is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated." (Health & Saf. Code, § 111295.) "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." (Health & Saf. Code, § 111255.) A drug or device is also 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." (Health & Saf. Code, § 111260.)

15. The drugs in the upstairs rooms were adulterated. Many drugs requiring refrigeration were unrefrigerated, and pills were found on a plastic plate, in a plastic cup, and on shelves in clear plastic bags, including bags of mixed pills, and bags with multiple

returned prescriptions of the same pills mixed together. The rooms lacked air-conditioning and were not well-cleaned, with bags of trash on the floor. (Factual Findings 14-16.)

16. Owl and Kaldas assert these storage methods were permissible, because the drugs were to be shipped to reverse distributors, and the requirements for storing and labeling drugs in pharmacies relate solely to drugs held for dispensing to patients. Owl and Kaldas cited no authority establishing an exception for drugs destined for reverse distributors, which their counsel characterized as "inactive stock."

17. The Fifth Cause for Discipline also alleges the prescriptions with incorrect expiration dates and overfilled medication bottles found downstairs violated drug quality requirements. Complainant did not establish that these drugs also violated the Sherman Food, Drug, and Cosmetic Law, because their labels were false and misleading, making them "misbranded." (Health & Saf. Code, § 111330).

B. The Order section beginning on page 22 of the proposed decision is not amended in any way. The discipline imposed was appropriate given the multiple and serious violations of pharmacy law in the other causes of discipline that were established. Owl's surrender of its pharmacy license in 2017 is not impacted by the Board's decision on remand.

The remainder of the Proposed Decision is adopted as written.

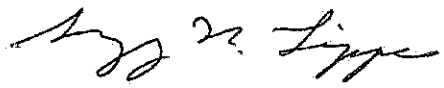
This Decision shall become effective at 5:00 p.m. on April 2, 2021.

It is so ORDERED on March 3, 2021.

BOARD OF PHARMACY

DEPARTMENT OF CONSUMER AFFAIRS

STATE OF CALIFORNIA



By

Greg Lippe
Board President

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

APPLICATION FOR VOLUNTARY SURRENDER OF PREMISES LICENSE

PLEASE PRINT IN BLACK OR BLUE INK OR TYPE YOUR RESPONSES

Name: OWL HOMECARE PHARMACY	Case No. 4668, 5511
Address of Record: 13851 GARVEY AVE STE C4 BALDWIN PARK, CA 91706	

Pursuant to the terms and conditions of probation against my premises license with the California State Board of Pharmacy (Board) in Case No. 4668, 5511, I hereby request to surrender my premises license, License No. PHY45091. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, the premises will no longer be subject to the terms and conditions of probation. I understand that this surrender constitutes a record of discipline and shall become a part of the premises license history with the Board.

Upon the acceptance of the surrender, I shall relinquish my premises license to the Board within ten (10) days of notification by the Board that the surrender is accepted. I understand that I shall, among other things, submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer. I may not reapply for any new licensure from the board for three (3) years from the effective date of the surrender. I further understand that I shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board.

PLEASE BE ADVISED THAT YOU ARE NOT RELIEVED OF THE REQUIREMENTS OF YOUR PROBATION UNLESS THE BOARD NOTIFIES YOU THAT YOUR REQUEST TO SURRENDER YOUR LICENSE HAS BEEN ACCEPTED.

Applicant's Signature — Date: 9/19/2017

Executive Officer's Approval — Date: 9/29/17

All items on this application are mandatory in accordance with your probationary order and the Board's Disciplinary Guidelines as authorized by Title 16, California Code of Regulations section 1760. Failure to provide any of the requested information or providing unreadable information will result in the application being rejected as incomplete. The information provided on this form will be used to determine eligibility for surrender. The official responsible for information maintenance is the Executive Officer, telephone (916) 574-7900, 1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834. The information you provide may also be disclosed in the following circumstances: (1) in response to a Public Records Act request; (2) to another government agency as required by state or federal law; or, (3) in response to a court or administrative order, a subpoena, or a search warrant. Each individual has the right to review the files or records maintained on them by our agency, unless the records are identified as confidential information and exempted by Section 1798.40 of the Civil Code.

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 Permit No. PHY 45091 and MAHER HALIM KALDAS Pharmacist-in-Charge License No. RPH 39184 and ALBERT SOLIMAN Pharmacist License No. RPH 44883 Respondents. and MINACEUTICALS WHOLESALE ALBERT SOLIMAN, Owner MAHER HALIM KALDAS, Owner Permit No. WSL 4527 Affiliated Party.	Case No. 4668 OAH No. 2016050596

In the Matter of the Statement of Issues Against: K& S OWL INC., dba OWL HOMECARE PHARMACY; MAHER HALIM KALDAS, Owner ALBERT SOLIMAN, Owner Pharmacy Permit No. PHY 45091; and MAHER HALIM KALDAS Pharmacist-in-Charge, Pharmacist License No. RPH 39184; and ALBERT SOLIMAN Pharmacist License No. RPH 44883; Sterile Compounding Pharmacy License Applicant. and MINACEUTICALS WHOLESALE ALBERT SOLIMAN, Owner MAHER HALIM KALDAS, Owner Permit No. WSL 4527; Affiliated Party.	Case No. 5511 OAH No. 2016120241

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on August 30, 2017.

It is so ORDERED on July 31, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____

Amy Gutierrez, Pharm.D.
Board President

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 Permit No. PHY 45091 and MAHER HALIM KALDAS Pharmacist-in-Charge License No. RPH 39184 and ALBERT SOLIMAN, Pharmacist License No. RPH 44883 Respondents. and MINACEUTICALS WHOLESALE ALBERT SOLIMAN, Owner MAHER HALIM KALDAS, Owner Permit No. WLS 4527 Affiliated Party.	Case No. 4668 OAH No. 2016050596

In the Matter of the Statement of Issues Against: K & S OWL INC., dba OWL HOMECARE PHARMACY, MAHER HALIM KALDAS, Owner, ALBERT SOLIMAN, Owner, Pharmacy Permit Number PHY 45091; and MAHER HALIM KALDAS, Pharmacist-In-Charge, Pharmacist License Number RPH 39184; and ALBERT SOLIMAN, Pharmacist License Number RPH 44883; Sterile Compounding Pharmacy License Applicant. and MINACEUTICALS WHOLESALE, MAHER HALIM KALDAS, Owner, ALBERT SOLIMAN, Owner, Permit Number WLS 4527; Affiliated Party.	Case No. 5511 OAH No. 2016120241

PROPOSED DECISION

Administrative Law Judge Thomas Heller, State of California, Office of Administrative Hearings, heard these consolidated matters in Los Angeles, California on January 23-26, 2017. At complainant's request, a single proposed decision is being issued for both cases. (Cal. Code Regs., tit. 1, § 1016, subd. (d).)

Sheronda L. Edwards and Gillian E. Friedman, Deputy Attorneys General, represented complainant Virginia Herold, Executive Officer, Board of Pharmacy (Board), Department of Consumer Affairs.

Herbert L. Weinberg, Esq., Fenton Law Group LLP, and Noah Jussim, Esq., Hinshaw & Culbertson LLP, represented respondents K & S Owl Inc., dba Owl Homecare Pharmacy (Owl), Maher Halim Kaldas (Kaldas), Albert Soliman (Soliman), and affiliated party Minaceuticals Wholesale (Minaceuticals).

At the end of the hearing, the record was held open until February 10, 2017, for closing briefs. Before the briefs were due, respondents moved to admit additional documents into evidence as Exhibits W-1 through W-11. Complainant objected to the admission of Exhibit W-9, but not the other additional exhibits. The objections to Exhibit W-9 are sustained, and the other additional exhibits are admitted.

Complainant's and respondents' closing briefs were marked as Exhibits 138 and EE, respectively, for identification purposes only. By order dated March 6, 2017, the record was reopened, and oral argument was set to address points set forth in the order. After oral argument, the matter was submitted on March 17, 2017.

SUMMARY

Complainant requests that the Board revoke respondents' licenses and deny Owl's application for a sterile compounding pharmacy license. Respondents assert license discipline is unwarranted, and that the sterile compounding application should be granted. The evidence established causes for license discipline and denial of the application, justifying revocation, stayed, with five years' probation and a 90-day suspension for Owl and Kaldas, a public reproval for Soliman, denial of the sterile compounding pharmacy license, and an award of some of the Board's investigation and enforcement costs.

FACTUAL FINDINGS

Parties and Jurisdiction

1. On April 28, 2004, the Board issued Original Permit Number PHY 45091 to Owl. The permit was set to expire on April 1, 2017, unless renewed.

2. Kaldas is a licensed pharmacist (RPH 39184), and has been Owl's Pharmacist-in-Charge and Chief Executive Officer since its formation. He co-owns Owl with Soliman, another licensed pharmacist (RPH 44883), who is its Treasurer and Chief Financial Officer.

3. On December 1, 2004, the Board issued Original Wholesale Permit Number WLS 4527 to Minaceuticals. Board records state that Minaceuticals is another fictitious

business name for K & S Owl Inc. (see exhibit 6), and was previously a fictitious business name for Soliman (see exhibit 137).

4. On May 16, 2014, the Board received Owl's application for a new sterile compounding pharmacy license.

5. The Board denied the application on April 17, 2015, citing a pending investigation of Owl as the reason for denial. On a date not established, Owl appealed the denial.

6. On February 11, 2016, complainant served an Accusation on Owl, Kaldas, and Soliman, alleging 21 causes to discipline Owl's permit and/or Kaldas's license, four of which also alleged cause to discipline Soliman's license. The Accusation listed Minaceuticals as an "Affiliated Party," but did not request any relief against its wholesale permit.

7. Owl, Kaldas, and Soliman submitted a Notice of Defense to the Accusation, dated February 16, 2016.

8. On July 7, 2016, the Board served a Statement of Issues on respondents and Minaceuticals, alleging that the denial of Owl's sterile compounding pharmacy license should be upheld.

Factual Background

9. Owl is a "closed door" pharmacy in Baldwin Park, California, which means it does not serve walk-in customers. Instead, it serves nursing homes, providing medications to patients at those facilities. It employs about 12 pharmacists, 30 technicians, 40 clerks, and 30 to 35 drivers.

10. Much of Owl's business involves dispensing "bubble packs" of medication. Bubble packs are pill holders with clear plastic "bubbles" for individual pills. Owl fills the bubbles, seals them into a cardboard holder, and delivers the bubble packs to the nursing homes, with the patient name, drug name, lot number, expiration date, and other identifying information on them.

11. Owl also dispenses liquid medications (e.g., injectable drugs), and supplies emergency kits (e-kits) of drugs to nursing homes. E-kits contain emergency backup supplies of drugs for nursing homes to use when the pharmacy is closed. Before July 1, 2014, Owl was also authorized to perform sterile compounding of drugs by virtue of its accreditation with the Joint Commission, an independent certifying organization for health care professionals. "'Compounding' means any of the following activities occurring in a licensed pharmacy . . . pursuant to a prescription: [¶] (1) Altering the dosage form or delivery system of a drug [¶] (2) Altering the strength of a drug [¶] (3) Combining components or active ingredients [¶] (4) Preparing a compounded drug preparation from chemicals or bulk drug substances." (Cal. Code Regs., tit. 16, § 1735, subd. (a).) After July 1, 2014, Owl had

to obtain a Board license to continue sterile compounding. (See Bus. & Prof. Code, div. 2, ch. 9, art. 7.5.)[1]

12. Soliman works as a pharmacist at Owl, in addition to co-owning it. Minaceuticals occupies office space at the same location, but the relationship of that wholesale business to Owl's pharmacy business was not established.

Inspection in 2011

13. In April 2011, Board Inspector Valerie Sakamura (Sakamura), a licensed pharmacist, visited Owl to investigate an anonymous complaint that the pharmacy was reusing drugs returned from nursing homes. Sakamura met with Kaldas, and started her inspection by looking for overfilled pill bottles as possible evidence of drug reuse. She found one 100-tablet bottle of Timolol Maleate 5 mg (a blood pressure medication) that seemed unusually heavy, and determined there were 274 tablets in the bottle, not 100. She also noticed the tablets were varying shades of green, which in her experience indicated that the tablets came from more than one manufacturer lot of the drug.

UPSTAIRS ROOMS

14. The anonymous complaint stated a wall tapestry in the front office concealed a door leading to a "secret" upstairs room containing returned drugs that Owl was reusing. Sakamura found the door and had Kaldas open it, revealing stairs to the second floor. Sakamura went upstairs and entered another room, which had another door with a sign reading "Water heater, Tools, Janitorial supplies" on it. Sakamura opened that door, and saw storage boxes and rows of filing cabinets, behind which was another door. Kaldas unlocked it, and Sakamura entered a room with no working lights. Using a digital camera flash, she observed mostly empty plastic drug bottles arranged alphabetically on shelves along the walls, and boxes piled up on the floor containing both used and unused bubble packs, many of which were bagged or rubber banded together. She also saw drugs requiring refrigeration being stored at room temperature on the shelves. In addition, there were trash bags on the floor, including one containing empty drug bottles, empty bubble packs, open insulin boxes, and food trash.

15. As she walked further into the room, Sakamura saw an entrance to a second unlit room. Entering that room, she saw more shelves filled with prescription pills and injectable drugs organized alphabetically, many of them in clear plastic bags. When asked to explain, Kaldas told Sakamura that when drugs came back from nursing homes, Owl staff would punch out medications from their bubble packs, place them in the clear plastic bags, and later pack them in empty bottles – not necessarily the originals – for delivery to "reverse distributors" for monetary credit. According to Kaldas, by putting the drugs back into bottles, Owl could get more credit from the reverse distributor, depending on the expiration date on the container. One of the rooms also contained an iron, which was found to have

[1] Undesignated statutory references are to the Business and Professions Code.

prescription labels sticking to its bottom. Kaldas stated the iron was used to remove such labels from the drugs.

16. Sakamura returned a few days later with other Board inspectors. This time, the room lights were working. From May 2 through May 10, 2011, the inspectors collected over 207,000 pills from the rooms, which were only some of the drugs there. Among other items, inspectors found bags of "Schedule II" controlled substances (e.g., narcotics – see Health & Saf. Code, § 11055), sample medications, prescription bottles from other pharmacies, and mixed pills on an open plate, in bags, and in a plastic cup. The pills in most bags appeared to be more than one prescription's worth of medication, and a combination of different manufacturer lots of the pills, judging from their color variations. Most of the drugs were not in their original packaging, and the bags of pills generally did not contain pill counts or expiration dates. Many drugs requiring refrigeration were being stored at room temperature, and the rooms themselves were not air-conditioned or well-cleaned.

GENERAL PHARMACY INSPECTION

17. While other inspectors were in the upstairs rooms, Board Inspector Anna Yamada (Yamada), a licensed pharmacist, inspected the pharmacy downstairs. Among other concerns, she observed two overfilled 10-tablet bottles of Fosrenol 1000 mg (a kidney disease medication) marked "1/2" on a shelf, apparently ready to be dispensed. One bottle was overfilled with 38 half-sized tablets, and the other was overfilled with 40 half-sized tablets.

18. Yamada also saw staff pharmacist Nathan Luutuyen (Luutuyen) checking an e-kit, and observed other e-kits on shelves. None of the e-kits she observed listed the date they were prepared, or the name of a pharmacist who verified their preparation. Luutuyen stated that technicians prepared and sealed the mostly clear plastic e-kits with a tamper-evident lock, and that pharmacists did not verify their preparation before sealing. Instead, a pharmacist would only verify a specific e-kit was the proper type to dispense to a facility.

19. In addition, Yamada reviewed a small number of prescriptions being dispensed from the pharmacy, and found three labeled with the wrong expiration dates, as follows:

Prescription No.	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

She also reviewed some Schedule II prescriptions, and found Owl accepted some oral or electronically transmitted orders for such drugs from non-physicians, without verifying the orders with the prescriber before dispensing the drugs. Complainant presented evidence of

six such oral or electronically transmitted Schedule II orders, none of which included a confirming signature or other verification from the prescriber. (Exhibits 31-36.)

20. In one downstairs room, Yamada found a large sealed box addressed to Genco Pharmaceutical Services (Genco), a reverse distributor. She opened it and observed medications and a list with patient names and prescription numbers, information ordinarily protected from disclosure to third parties. Pharmacy technician Sandra Soriano stated the sheet with the patient names was an inventory of the drugs being shipped for destruction.

21. Kaldas could not provide Yamada with logs of returns of drugs from nursing homes. Yamada also asked an Owl clerk for acquisition records for three randomly selected drugs, but the clerk could not provide them either. In addition, Sakamura audited a random sample of medications, and determined the pharmacy was missing 288 Timolol tablets. However, evidence presented at the hearing established that the number of missing tablets was 14, not 288.

Inspection in 2014

22. Sakamura returned to Owl in December 2014, and found that the upstairs rooms contained significantly fewer pills and bottles than in 2011. The pharmacy was keeping better track of drugs returned from nursing homes, and provided eight boxes of records that included acquisition and disposition documents for such drugs.

23. Owl had applied for a sterile compounding license in May 2014, and Sakamura interviewed several staff members about Owl's compounding practices. Several pharmacy technicians stated they performed sterile compounding after July 1, 2014, the date after which a sterile compounding pharmacy license was required. Several also stated that Owl had compounded intravenous medications until a day or two before the inspection. Sakamura asked Kaldas if this was true, and he replied Owl may have done so as an oversight because it had been compounding items while it was Joint Commission accredited. (Exhibit 18 at p. AG-5322.) He later sent Sakamura logs and prescriptions of sterile injectable items compounded between July 1 and December 17, 2014, showing that Owl dispensed over 900 sterile compounds during that period, including prescriptions for intravenous Vancomycin (an antibiotic), and other intravenous medications.

24. Sakamura asked Kaldas for compounding "competencies," first for four random staff members, and then for all staff members. "A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating [they] . . . are trained in all aspects of policies and procedures." (Cal. Code Regs., tit. 16, § 1735.7, subd. (a).) Kaldas provided six different competencies for most employees, but did not provide one or more of them for five employees (Emilie Perez, Kaldas, Lam Hoang, Samy Habib, Mari Masoud, and Joseph Haroun), or any for Luutuyen, who acknowledged checking sterile compounding work performed at Owl within the last three months.

25. In a downstairs room used for drug returns, Sakamura also found boxes and bags of medications returned from nursing homes. Opening the boxes and bags, she did not find any paperwork showing the transfer of the medications. It was not established what the medications were.

26. In addition, Sakamura observed pharmacy technician Jessica Oroz (Oroz) working at the pharmacy, and determined Oroz's license had expired on September 30, 2014, and had not been renewed. Sakamura told Kaldas that Oroz could not work as a technician until she renewed her license, which Oroz did the next day. Oroz persuasively testified she was unaware before the inspection that her license had expired.

Respondents' Evidence

27. Kaldas denied Owl re-dispensed drugs returned from nursing homes, and testified the drugs in the upstairs rooms were destined solely for reverse distributors. Complainant presented insufficient evidence to prove otherwise, and complainant's counsel acknowledged the Accusation does not allege re-dispensing of returned drugs. Kaldas also disputed the upstairs rooms were "secret," pointing to a Board inspection in 2007 that mentions one of them. He and others also testified Owl's return practices have improved significantly, with better recordkeeping of returned drugs.

28. Staff pharmacist Haroun disputed Luutuyen's statement that no pharmacist checked the contents of Owl's e-kits. Haroun testified he and other Owl pharmacists supervised their packing, and checked the contents at the time of dispensing. Kaldas testified the box addressed to Genco that Yamada found (Factual Finding 20) would not have been shipped with confidential patient information in it, because he would have inspected it again before sending it. However, this assertion seems unlikely, since the box was already sealed. Kaldas also offered into evidence an undated Genco policy memorandum stating that the reverse distributor would attempt to make any patient health information it received from its clients unidentifiable.

29. Regarding the three prescriptions with wrong expiration dates (Factual Finding 19), Kaldas testified the errors arose from a since-fixed computer program, and the drugs were to be used well before the actual expiration date, and thus posed no risk of harm. Regarding the oral or electronically transmitted Schedule II drug orders (*ibid.*), Kaldas and others testified to obtaining prescriber confirmation for such orders; however, no such confirmation was documented for the six orders at issue. Kaldas also testified the Schedule II controlled substances in the upstairs rooms (Factual Finding 16) were expired medications removed from Owl's own active stock for delivery to reverse distributors for credit, not prohibited returns of those drugs from nursing homes. He further testified that if a nursing home attempted to return controlled substances to Owl, Owl would send the drugs back to the nursing home.

30. Kaldas also testified he was unaware of Oroz's expired license (Factual Finding 26), and had Oroz correct the issue immediately. He also asserted the Board

unreasonably delayed approval of Owl's sterile compounding application, which was timely, and that he never received an indication Owl had to stop sterile compounding until Sakamura's inspection in December 2014. Kaldas also produced a few of the missing compounding competencies, including two of the missing six for Luutuyen (see exhibit Z), and asserted the other missing competencies were not required, because the affected staff performed other duties and did not need them. Soliman did not testify.

Prior Discipline and Citations

31. In 2004, Kaldas and Soliman stipulated to settlement of an accusation alleging five causes for discipline as to Kaldas, and two as to Soliman. Under the stipulation, Kaldas admitted he acted as a drug wholesaler without a proper license, failed to maintain records of acquisition of dangerous drugs, allowed a person other than a pharmacist to receive drugs, failed to notify the Board of changes in pharmacy ownership, and furnished unreasonably large quantities of a dangerous drug (Viagra) to prescribers. Soliman admitted he acted unprofessionally by failing to maintain records of acquisition and disposition of dangerous drugs, failing to maintain a permitted facility in a clean and sanitary condition, and failing to notify the Board of changes in pharmacy ownership. Under the settlement, the Board revoked the licenses of Kaldas and Soliman, stayed the revocations, and placed them on probation for one year with terms and conditions. (Decision and Order, Case Nos. 2497, 2522 & 2523, effective April 18, 2004.)

32. The Board also issued citations to Owl and Kaldas on March 13, 2008. (Case Nos. CI 2006 34139 & CI 2007 3526). The underlying offenses included a sterile compounding quality assurance violation, a recordkeeping violation, and a violation for failure to prevent sale of drugs lacking quality, among others. The dollar amounts for the two citations were not established.

Costs

33. Complainant presented certifications stating that the Board incurred $119,219.50 in costs investigating the matters alleged in the Accusation (Case No. 4668), and that the Department of Justice has billed the Board an additional $72,070 concerning that case. Board inspectors billed 1160.25 hours on the investigation, and five Deputy Attorneys General, four Supervising Deputy Attorneys General, and three paralegals at the Department of Justice worked on the case for over 420 hours through mid-January 2017.

LEGAL CONCLUSIONS

Legal Standards

1. The Board may suspend, revoke, or refuse to issue any license or permit for unprofessional conduct. (§§ 4032, 4300, subds. (a), (c), 4301; see *Hoang v. California State Board of Pharmacy* (2014) 230 Cal.App.4th 448, 456.) Unprofessional conduct includes

"[v]iolating 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." (§ 4301, subd. (o).)

2. Kaldas's and Soliman's pharmacist licenses are professional licenses. (*Murphy v. E. R. Squibb & Sons, Inc.* (1985) 40 Cal.3d 672, 678-679.) To impose discipline on a professional license, complainant must prove cause for discipline by clear and convincing evidence to a reasonable certainty. (*Sternberg v. California State Board of Pharmacy* (2015) 239 Cal.App.4th 1159, 1171; *Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) Clear and convincing evidence "requires a finding of high probability," and has been described as "requiring that the evidence be ' "so clear as to leave no substantial doubt"; "sufficiently strong to command the unhesitating assent of every reasonable mind." ' [Citation.]" (*In re Angelia P.* (1981) 28 Cal.3d 908, 919.)

3. In contrast, Owl's pharmacy permit is a nonprofessional license, because it does not have extensive educational, training, or testing requirements akin to a professional license. (See *Mann v. Dept. of Motor Vehicles* (1999) 76 Cal.App.4th 312, 319; *San Benito Foods v. Veneman* (1996) 50 Cal.App.4th 1889, 1894.) An applicant for a pharmacy permit need not be a pharmacist; instead, the applicant must designate a pharmacist-in-charge with the requisite education, training, and licensure. (§§ 4110, subd. (a), 4113, subd. (a).) To impose discipline on Owl's nonprofessional pharmacy permit, complainant must prove cause for discipline by a preponderance of the evidence, which is a lower standard of proof than clear and convincing evidence. (*Imports Performance v. Dept. of Consumer Affairs, Bureau of Automotive Repair* (2011) 201 Cal.App.4th 911, 916-917; Evid. Code, §115.) A preponderance of the evidence means "'evidence that has more convincing force than that opposed to it.' [Citation.]" (*People ex rel. Brown v. Tri-Union Seafoods, LLC* (2009) 171 Cal.App.4th 1549, 1567.)

4. On Owl's application for a sterile compounding pharmacy license, Owl bears the burden of proving it meets all prerequisites necessary for that license. (See *Martin v. Alcoholic Beverage Control Appeals Board* (1959) 52 Cal.2d 259, 265; *Breakzone Billiards v. City of Torrance* (2000) 81 Cal.App.4th 1205, 1221.) This burden also requires proof by a preponderance of the evidence. (See Evid. Code, § 115.)

Accusation

FIRST CAUSE FOR DISCIPLINE (OWL AND KALDAS – PHARMACY TECHNICIAN SUPERVISION)

5. The First Cause for Discipline alleges Owl and Kaldas did not have a pharmacist check Owl's e-kits after technicians filled them, in violation of California Code of Regulations, title 16, section 1793.7, subdivision (a). "Except as otherwise provided in section 1793.8 [for hospitals with clinical pharmacy programs], 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. . . ." (Cal. Code Regs., tit. 16, § 1793.7, subd. (a).)

6. Complainant did not establish cause to discipline Owl and Kaldas under this regulatory subdivision. The phrase "dispensing of a prescription" in the subdivision means "the furnishing of drugs or devices" upon "an oral, written, or electronic transmission order that is . . . [g]iven individually for the person or persons for whom ordered" by a physician or other authorized medical professional. (§§ 4024, 4040, subd. (a).) Owl provided e-kits to nursing homes for general emergency use (Factual Finding 11), not under an order "[g]iven individually for [any] person or persons" by a physician or other authorized medical professional. Therefore, providing the e-kits did not involve "dispensing of a prescription" under the regulatory subdivision alleged in the Accusation. Furthermore, while subdivision (b) of the same regulation requires technicians to work under the "direct supervision of a pharmacist," the First Cause for Discipline does not allege a violation of that subdivision. (Cal. Code Regs., tit. 16, § 1793.7, subd. (b).) Even if it did, Haroun testified Owl pharmacists supervised the preparation of the e-kits and checked them before dispensing (Factual Finding 28), rebutting Luutuyen's contrary statement to Yamada during the 2011 inspection (Factual Finding 18).

SECOND CAUSE FOR DISCIPLINE (OWL AND KALDAS – UNAUTHORIZED DISCLOSURE OF PRESCRIPTION INFORMATION)

7. The Second Cause for Discipline alleges Owl and Kaldas disclosed protected patient information in violation of California Code of Regulations, title 16, section 1764. Under that regulation, "[n]o 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." (Cal. Code Regs., tit. 16, § 1764.)

8. Complainant did not establish this cause for discipline. Yamada found one sealed box addressed to Genco containing protected information, but it was still at Owl's facility, not at Genco. (Factual Finding 20.) The regulation prohibits actual disclosure of patient information, not a near-disclosure. Moreover, even if Owl had already sent the box, Genco's policies adequately protected any inadvertently disclosed patient information. (Factual Finding 28; see 45 C.F.R. § 164.502(e)(1)(i) ["A covered entity [e.g., a health care provider] may disclose protected health information to a business associate . . . if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information. . . ."].)

THIRD CAUSE FOR DISCIPLINE (OWL AND KALDAS – PRESCRIPTION LABEL REQUIREMENTS)

9. The Third Cause for Discipline alleges Owl mislabeled prescriptions in violation of section 4076, subdivision (a). A pharmacist may not dispense any prescription with an incorrect expiration date. (§ 4076, subd. (a)(9).)

10. Complainant established this cause for discipline. Yamada found three prescriptions at Owl with incorrect expiration dates. (Factual Finding 19.) Both Owl and Kaldas are responsible for the violations, and Kaldas's testimony that the errors were computer-related and posed no risk of harm does not negate the violations. (See § 4113, subd. (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."].)

FOURTH CAUSE FOR DISCIPLINE (OWL AND KALDAS – ORALLY TRANSMITTED PRESCRIPTIONS)

11. The Fourth Cause for Discipline alleges Owl pharmacists improperly accepted telephone orders for Schedule II controlled substances from non-physicians. "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. . . ." (Health & Saf. Code, § 11167.5, subd. (a).)

12. Complainant established this cause for discipline, proving that Owl accepted six oral or electronically transmitted orders for Schedule II controlled substances from non-physicians, without the prescriber's signature or other verification prior to dispensing. (Factual Finding 19.) Owl's conduct violated Health and Safety Code section 11167.5, subdivision (a), because the orders were not orally or electronically transmitted or confirmed "by the prescriber . . . ." Kaldas is also responsible for the violation as a pharmacist-in-charge. (§ 4113, subd. (c).) The testimony of Kaldas and others that Owl obtained prescriber verification (Factual Finding 29) lacked documentary support as to the six orders.

FIFTH CAUSE FOR DISCIPLINE (OWL AND KALDAS – DRUG QUALITY)

13. The Fifth Cause for Discipline alleges Owl and Kaldas "are subject to disciplinary action under section 4301, subdivision (o), and section 4342, subdivision (a)," due to poor drug quality at Owl. Section 4342, subdivision (a) states: "[t]he 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)."

14. Complainant established this cause for discipline. Under the Sherman Food, Drug, and Cosmetic Law, "[i]t is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated." (Health & Saf. Code, § 111295.) "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." (Health & Saf. Code, § 111255.) A drug or device is also 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." (Health & Saf. Code, § 111260.)

15. The drugs in the upstairs rooms were adulterated. Many drugs requiring refrigeration were unrefrigerated, and pills were found on a plastic plate, in a plastic cup, and on shelves in clear plastic bags, including bags of mixed pills, and bags with multiple returned prescriptions of the same pills mixed together. The rooms lacked air-conditioning and were not well-cleaned, with bags of trash on the floor. (Factual Findings 14-16.)

16. Owl and Kaldas assert these storage methods were permissible, because the drugs were to be shipped to reverse distributors, and the requirements for storing and labeling drugs in pharmacies relate solely to drugs held for dispensing to patients. But under Health and Safety Code section 111295, no person may hold any adulterated drug, regardless of whether it is intended for dispensing to patients. Owl and Kaldas cited no authority establishing an exception for drugs destined for reverse distributors, which their counsel characterized as "inactive stock." Therefore, complainant proved Owl and Kaldas violated drug quality requirements as to the drugs in the upstairs rooms.

17. The Fifth Cause for Discipline also alleges the prescriptions with incorrect expiration dates and overfilled medication bottles found downstairs violated drug quality requirements. Complainant established that these drugs also violated the Sherman Food, Drug, and Cosmetic Law, because their labels were false and misleading, making them "misbranded." (Health & Saf. Code, § 111330.) The labeled drug quantities were incorrect

on the overfilled bottles, some of those drugs necessarily came from other bottles, and it was highly probable some of the Timolol tablets came from a manufacturer lot not listed on the bottle, judging from the overfilling and color variations of the tablets. (Factual Findings 13, 17.) The prescriptions with incorrect expiration dates were also misleading about how long the drugs could be used.

SIXTH CAUSE FOR DISCIPLINE (OWL AND KALDAS – ADULTERATED DRUGS)

18. The Sixth Cause for Discipline alleges the drugs in the upstairs rooms were adulterated in violation of Health and Safety Code sections 111255 and 111260, as were the prescriptions with incorrect expiration dates and overfilled pill bottles downstairs. Complainant established this cause for discipline as to the drugs in the upstairs rooms, as described above. (See Legal Conclusions 14-16.) The prescriptions with incorrect expiration dates and overfilled pill bottles found downstairs were misbranded, but it was not established they were also adulterated. Complainant did not prove they were contaminated, expired, or held under conditions similar to the drugs upstairs.[2]

SEVENTH CAUSE FOR DISCIPLINE (OWL AND KALDAS – ADULTERATED DRUGS RETURNED FOR CREDIT)

19. The Seventh Cause for Discipline alleges Owl and Kaldas returned adulterated drugs for credit. "A person or entity shall not . . . [¶] . . . [¶] (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." (§ 4169, subd. (a)(2).)

20. Complainant established this cause for discipline. Owl and Kaldas transferred adulterated drugs from the upstairs rooms to reverse distributors for credit. (See Factual Findings 14-16; Legal Conclusions 14-16.)

EIGHTH CAUSE FOR DISCIPLINE (OWL AND KALDAS – MISBRANDED DRUGS WITH FALSE OR NON-CONFORMING LABELS)

21. The Eighth Cause for Discipline alleges Owl and Kaldas shipped misbranded drugs to reverse distributors. "A person or entity shall not . . . [¶] . . . [¶] (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. (§ 4169, subd. (a)(3).) Under Health and Safety Code section 111335, "[a]ny drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing

[2] Complainant's closing brief asserts that other drugs found downstairs in 2011 and 2014 were also adulterated (Complainant's Closing Argument at pp. 5-8), but the Sixth Cause for Discipline includes no allegations about those other drugs. (Accusation at p. 25, ¶ 90.)

with Section 110290)," which sets standards for fair packaging and labeling of products. A drug or device is also 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." (Health & Saf. Code, § 111340.)

22. Complainant established this cause for discipline. Drugs in the upstairs rooms were placed in plastic bags without a numerical count, and then placed back in bottles – not necessarily the originals – for shipment to reverse distributors for credit. (Factual Findings 14-16.) Owl's and Kaldas's assertion that misbranding laws do not apply to "inactive stock" is unpersuasive, for the same reasons stated in Legal Conclusion 16.

NINTH CAUSE FOR DISCIPLINE (OWL AND KALDAS – MISBRANDED DRUGS)

23. The Ninth Cause for Discipline largely repeats the allegations in the Eighth Cause for Discipline, and asserts the same conduct also violates Health and Safety Code sections 111380, 111390, and 111445. Under those provisions, "[i]t is unlawful for any person to misbrand any drug or device," and "[a]ny 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;" or "if its container is so made, formed, or filled as to be misleading." (Health & Saf. Code, §§ 111380, 111390 & 111445.)

24. Complainant established this cause for discipline. The drugs in the upstairs rooms were misbranded, to the same extent described in Legal Conclusions 21-22.

TENTH CAUSE FOR DISCIPLINE (OWL AND KALDAS – MISBRANDED DRUGS – PACKAGING)

25. The Tenth Cause for Discipline also repeats the allegations in the Eighth Cause for Discipline, and alleges Owl's returns to reverse distributors violated Health and Safety Code section 111395, which 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."

26. Complainant established this cause for discipline. Owl and Kaldas returned misbranded drugs to reverse distributors, because the drugs were not returned in their original bottles. (See Factual Finding 15.) Thus, the contents of those original bottles had been removed and replaced with other material. (Health & Saf. Code, § 111395.).

ELEVENTH CAUSE FOR DISCIPLINE (OWL AND KALDAS – MISBRANDED DRUG SALES TO REVERSE DISTRIBUTORS)

27. The Eleventh Cause for Discipline alleges the same returns to reverse distributors violated Health and Safety sections 111440 and 111450, which make it 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," or "to alter, mutilate, destroy, obliterate, or remove the label or any part of the labeling of any drug or device if the act results in the drug or device being misbranded."

28. Complainant established this cause for discipline. Owl and Kaldas delivered misbranded drugs to reverse distributors, in violation of Health and Safety Code section 111440. (See Factual Findings 14-16; Legal Conclusions 21-22.) Part of the return process involved removing prescription labels with an iron (Factual Finding 15), which contributed to the misbranding, in violation of Health and Safety Code section 111450.

TWELFTH CAUSE FOR DISCIPLINE (OWL AND KALDAS – TAKING BACK DRUGS FROM NURSING FACILITIES)

29. The Twelfth Cause for Discipline alleges Owl and Kaldas violated California Code of Regulations, title 22, section 72371, by accepting controlled (e.g., Schedule II) and non-controlled substances from nursing facilities, which should have been destroyed at the facilities themselves, without maintaining proper records. That regulation requires a skilled nursing facility to destroy prescription drugs that have been discontinued or that remain after discharge of a patient, but permits it to return non-controlled individual patient drugs to the issuing pharmacy in sealed and unopened containers, provided that the drugs are identified by lot or control number, and "[t]he 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." (Cal. Code Regs., tit. 22, § 72371, subds. (c), (d).) Controlled substances may not be returned. (See *id.*, subd. (d)(1).)

30. Complainant did not establish cause to discipline Owl and Kaldas under this regulation. As to non-controlled substances, Owl and Kaldas accepted returns from skilled nursing facilities, but this is allowed if the drugs are returned in sealed and unopened containers, identified by lot or control number. Bubble packs from Owl satisfied these requirements (see Factual Finding 10), and thus returning them was not prohibited.

31. Kaldas could not produce a log of the returns, and Owl's recordkeeping regarding the returns appeared deficient. (See Factual Finding 21.) But California Code of Regulations, title 22, section 72371 is a skilled nursing facility regulation, not a pharmacy regulation, and directs skilled nursing facilities to keep a log. The Twelfth Cause for Discipline does not reference any pharmacy recordkeeping law or regulation that Owl and Kaldas allegedly violated.

32. As to controlled substances, Sakamura also found Schedule II drugs in the upstairs rooms. But Kaldas testified those drugs were expired medications removed from Owl's own active stock, not returns from nursing homes (Factual Finding 29), and complainant presented insufficient evidence to prove otherwise. No employee of Owl testified they came from nursing facilities, and the mere fact the controlled drugs were in the

same rooms as drugs returned from nursing facilities is insufficient to prove the controlled drugs also came from those facilities.

THIRTEENTH AND FOURTEENTH CAUSES FOR DISCIPLINE (OWL, KALDAS, AND SOLIMAN -- UNPROFESSIONAL CONDUCT, AND MAINTAINING RECORDS)

33. The Thirteenth and Fourteenth Causes for Discipline allege Owl, Kaldas and Soliman committed various violations by taking back controlled substances from nursing homes and failing to maintain proper records of those medications, thereafter repackaging them to send to reverse distributors. Both refer specifically to allegations concerning the Board's inspection in 2011.

34. Complainant did not establish these causes for discipline. The evidence did not prove the controlled substances in the upstairs rooms were returns from nursing homes, as described above. (Legal Conclusion 32.).

FIFTEENTH CAUSE FOR DISCIPLINE (OWL AND KALDAS – INACCURATE INVENTORY)

35. The Fifteenth Cause for Discipline alleges Owl and Kaldas violated sections 4081, 4105, and 4333, because they could not produce records for 288 missing pills of Timolol. Those statutes generally require a pharmacy to keep records of the acquisition and disposition of dangerous drugs and devices for three years, and make them available for inspection by authorized officers of the law. (§§ 4081, 4105, 4333.)

36. Complainant established this cause for discipline, but only as to 14 missing Timolol pills, not 288. Evidence presented at the hearing established that there were just 14 missing Timolol pills. (Factual Finding 21.)

SIXTEENTH CAUSE FOR DISCIPLINE (OWL – MISCONDUCT BY OWNER AND/OR CORPORATE OFFICER)

37. The Sixteenth Cause for Discipline is against Owl under section 4302, which states the Board may "deny, suspend, or revoke any license where conditions exist in relation to any person holding 10 percent or more of the ownership interest or where conditions exist in relation to any officer, director, or other person with management or control of the license that would constitute grounds for disciplinary action against a licensee." (§ 4302.) It refers specifically to allegations concerning the Board's inspection in 2011.

38. Complainant established this cause for discipline. Kaldas is an officer and equal co-owner of Owl (Factual Finding 2), and he engaged in conduct discovered during the 2011 inspection that is grounds for disciplinary action against his own license. (See Legal Conclusions 9-28, 35-36.) Therefore, Owl is also subject to discipline under section 4302 for that conduct.

SEVENTEENTH CAUSE FOR DISCIPLINE (OWL AND KALDAS – UNLICENSED ACTIVITY)

39. The Seventeenth Cause for Discipline alleges Owl and Kaldas engaged in sterile compounding in violation of section 4127, subdivision (a), which requires a pharmacy to possess a sterile compounding pharmacy license before performing such activity.

40. Complainant established this cause for discipline. Owl's records indicate its personnel engaged in sterile compounding on over 900 occasions between July 1 and December 17, 2014, without a sterile compounding pharmacy license. (Factual Finding 23.) Owl needed that license to perform sterile compounding after July 1, 2014, despite Owl's prior Joint Commission accreditation. (See Factual Finding 11.) As the pharmacist-in-charge, Kaldas is also responsible for this violation. (§ 4113, subd. (c).) His assertion that the Board delayed in processing Owl's sterile compounding application (Factual Finding 30) does not excuse the unlicensed activity.

EIGHTEENTH CAUSE FOR DISCIPLINE (OWL, KALDAS, AND SOLIMAN – UNLICENSED ACTIVITY)

41. The Eighteenth Cause for Discipline alleges Owl, Kaldas, and Soliman engaged in unprofessional conduct under section 4301, subdivision (o), and section 4306.5, subdivisions (a) and (b), by allowing Oroz to work as a pharmacy technician for several months with an expired license. Section 4306.5, subdivisions (a) and (b), state that unprofessional conduct for a pharmacist includes: [¶] (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."

42. Complainant established this cause for discipline. Oroz worked as a pharmacy technician at Owl with an expired license (Factual Finding 26), and it was an inappropriate exercise of Kaldas's and Soliman's education, training, and experience as pharmacists to allow an unlicensed person to work at a pharmacy they co-owned. (§ 4306.5, subd. (a).) No evidence suggested they were aware of the violation, but there is no express knowledge requirement in section 4306.5, subdivision (a), and language may not be inserted into a statute that the Legislature has omitted. (*Sternberg v. California State Board of Pharmacy*, *supra*, 239 Cal.App.4th at p. 1168 [section 4081, regarding pharmacy recordkeeping, does not require knowledge to impose license discipline]; see also *Arenstein v. California State Board of Pharmacy* (1968) 265 Cal.App.2d 179, 192-93, overruled on another point as stated in *Barber v. Long Beach Civil Service Com.* (1996) 45 Cal.App.4th 652, 658.) Owl itself is also subject to discipline for Oroz's unlicensed activity. (*Ibid.*; see also *California Assn. of Health Facilities v. Dept. of Health Services* (1997) 16 Cal.4th 284, 296 ["[A] licensee will be held liable for the acts of its agents . . . ."].)

NINETEENTH CAUSE FOR DISCIPLINE (OWL AND KALDAS – FAILURE TO MAINTAIN COMPETENCIES ON FILE)

43. The Nineteenth Cause for Discipline alleges Owl and Kaldas failed to maintain compounding competencies on file, in violation of California Code of Regulations, title 16, section 1735.7.

44. Complainant established this cause for discipline. Owl did not have complete compounding competencies on file for six employees, at least one of whom (Luutuyen) was involved in sterile compounding for Owl. (Factual Finding 24.) As the pharmacist-in-charge, Kaldas is responsible along with Owl for this violation. (§ 4113, subd. (c).)

TWENTIETH CAUSE FOR DISCIPLINE (OWL, KALDAS, AND SOLIMAN – FAILURE TO MAINTAIN RECORDS)

45. The Twentieth Cause for Discipline alleges Owl, Kaldas, and Soliman committed various violations by taking back controlled substances from nursing facilities and failing to maintain proper records of those medications. It is similar to the Thirteenth and Fourteenth Causes for discipline, but refers specifically to returned controlled substances that Sakamura allegedly found in a downstairs room during her 2014 inspection. (See Factual Finding 25; Accusation at p. 32, ¶ 114.)

46. Complainant did not establish this cause for discipline. No evidence established what returned medications Sakamura found, or whether they were controlled substances as alleged. Furthermore, Kaldas denied Owl accepted returns of controlled substances from nursing homes. (Factual Finding 29.)

TWENTY-FIRST CAUSE FOR DISCIPLINE (OWL – MISCONDUCT BY OWNER AND/OR CORPORATE OFFICER)

47. The Twenty-First Cause for Discipline, like the Sixteenth, is against Owl under section 4302, but refers specifically to allegations concerning the Board's inspection in 2014, not its inspection in 2011.

48. Complainant established this cause for discipline. Kaldas and Soliman both engaged in conduct in 2014 that is grounds for disciplinary action against their licenses. (See Legal Conclusions 39-44.) Therefore, Owl is also subject to discipline under section 4302 for that conduct. (See Legal Conclusions 37-38.)

Discipline on Accusation

49. Complainant requests revocation of Owl's permit and the licenses of Kaldas and Soliman, but outright revocation is unwarranted, for several reasons. First, many of the violations at issue are from 2011, and none occurred later than 2014. Second, respondents presented evidence Owl has improved its drug return process, which was a primary focus of

the Board's investigation. (Factual Finding 27.) Third, complainant did not allege or prove Owl re-dispensed drugs returned from nursing homes. Fourth, there was no evidence of actual harm to patients.

50. At the same time, the violations were not limited to the drug return process; some involved drugs and prescriptions to be dispensed to patients, and presented the potential for harm. Owl also engaged in a significant amount of unlicensed sterile compounding activity, despite Kaldas knowing Owl needed a license to do so after July 1, 2014. Furthermore, the Board has previously disciplined both Kaldas and Soliman, Owl's co-owners, and also cited Owl and Kaldas for a sterile compounding quality assurance violation, a recordkeeping violation, and a violation for failure to prevent sale of drugs lacking quality, among other offenses. (Factual Findings 31-32.)

51. Considering these factors and the Board's Disciplinary Guidelines (rev. 10/07) (Guidelines), a stayed revocation with five years' probation and a 90-day suspension is appropriate for Owl and Kaldas. This is within the range of recommended discipline for "Category II" violations, and on the low end of the recommended discipline for "Category III" violations. (Guidelines at pp. 11, 15.) Most of the proven violations fall into one of those two categories. Owl and Kaldas committed enough violations of sufficient severity to merit Board probation and monitoring over a five-year period, including a 90-day suspension. Respondents' mitigation and rehabilitation evidence were insufficient to justify a departure from the recommended level of discipline in the Guidelines.

52. The Guidelines list 15 standard conditions "that shall appear in all probation cases." (Guidelines at p. 5.) Condition seven prevents Kaldas from serving as a pharmacist-in-charge unless otherwise specified in the order. This is appropriate, given the nature and extent of the violations, and Owl will be ordered to identify a new pharmacist-in-charge within 90 days of the effective date of this decision. The last sentence of condition eight is modified so it does not prejudge how bankruptcy would affect the order for payment of costs, which is described below. Optional condition 32 is also included, to prohibit Owl and Kaldas from acquiring any new ownership of licensed premises during the probation period. Where appropriate, language has been modified to reflect that probation is imposed on both Owl as an entity and Kaldas as an individual.

53. As to Soliman, complainant proved only one cause for discipline, concerning an expired pharmacy technician license of which the technician herself was unaware. (See Factual Finding 26.) Unlicensed activity is serious, but Oroz corrected it immediately upon discovery. In addition, no evidence suggested Owl employed other unlicensed technicians. Therefore, the public interest would be best served by issuing Soliman a public reproval under section 495, rather than restricting his license.

54. "Affiliated Party" Minaceuticals occupies office space at the same property as Owl, but the relationship of the Minaceuticals wholesale business to Owl's business was not established. (Factual Finding 12.) Minaceuticals was not identified as a respondent or mentioned in any of the causes for discipline, and the Accusation includes no prayer for

relief against the Minaceuticals wholesale permit. Therefore, no discipline of that permit is appropriate.

Statement of Issues

55. The First Cause for Denial in the Statement of Issues alleges the Board should deny Owl's application for a sterile compounding pharmacy license because Owl has "[d]one . . . act[s] that if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license." (§ 480, subd. (a)(3).) The Second Cause for Denial alleges Owl engaged in unprofessional conduct, warranting denial under section 4300, subdivision (c). The Third Cause for Denial alleges the Board should deny Owl's application under section 4302, because Kaldas and Soliman, its co-owners, engaged in conduct that was grounds to discipline their pharmacy licenses.

56. The evidence established each of these causes for denial, to the extent it established the causes for discipline alleged in the Accusation, as described above. The established causes for discipline included unprofessional conduct, and conduct of Owl's officers and co-owners that is cause to discipline Owl under section 4302.

57. One established cause for discipline was Owl's unlicensed sterile compounding activity on over 900 occasions between July 1 and December 14, 2014. (See Legal Conclusions 39-40.) This unlicensed activity was not excused by alleged Board delays in processing Owl's application, and cannot be characterized as an oversight, as Kaldas told Sakamura. (Factual Finding 23.) Owl and Kaldas also committed a variety of other violations that warrant a stayed revocation and probation for five years (including a 90-day suspension). Compliance during that probationary period is an appropriate prerequisite to Owl receiving an additional license from the Board. Under these circumstances, Owl failed to prove by a preponderance of the evidence that it met the requirements for issuance of a sterile compounding pharmacy license, and its application was properly denied.

Costs

58. Complainant also requests an award of investigative and enforcement costs. "Except as otherwise provided by law, in any order issued in resolution of a disciplinary proceeding before any board within the [Department of Consumer Affairs] . . ., upon request of the entity bringing the proceeding, the administrative law judge may 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." (§ 125.3, subd. (a).)

59. Complainant presented evidence of over $190,000 in costs (Factual Finding 33), but the Board must not assess its full costs if doing so would unfairly penalize a licensee "who has committed some misconduct but used the hearing process to obtain dismissal of other charges or a reduction in the severity of the discipline imposed." (*Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, 45.) The Board must also consider

respondents' "'subjective good faith belief in the merits of [their] position;'" and whether [they] raised a "'colorable challenge'" to the proposed discipline. (*Ibid.* [quoting *California Teachers Assn. v. State of California* (1999) 20 Cal.4th 327, 342, 345].) Furthermore, the Board must determine respondents "will be financially able to make later payments," and "may not assess the full costs . . . when it has conducted a disproportionately large investigation to prove that [a licensee] engaged in relatively innocuous misconduct." (*Ibid.*)

60. Respondents presented no evidence of inability to pay the Board's costs, but prevailed on some causes for discipline, and avoided outright revocation of their licenses. Thus, they used the hearing process to obtain dismissal of some charges, and a reduction in the severity of the discipline imposed. (*Zuckerman v. State Board of Chiropractic Examiners, supra,* 29 Cal.4th at p. 45.) Furthermore, much of the Board's investigation concerned alleged re-dispensing of returned drugs, but complainant did not prove, or even allege, that violation. (Factual Finding 27.) In addition, complainant did not adequately explain why the total number of hours spent preparing the case was so high. The case was not simple, but the number of hours spent preparing it appears disproportionate to the evidence complainant presented at the hearing. The number of different attorneys and paralegals working on the case also suggests there were likely duplicate costs associated with multiple people reviewing the same investigations and evidence.

61. Considering these factors, an award of $63,000, or roughly one-third of the Board's total costs, is reasonable. Owl and Kaldas will be ordered to pay this amount. Since the evidence only established one cause for discipline against Soliman based upon facts that were resolved quickly, Soliman will not be ordered to pay those costs personally.

ORDER

Owl and Kaldas

Pharmacist License number RPH 39184, issued to respondent Maher Halim Kaldas (Kaldas), and Pharmacy Permit number PHY 45091, issued to respondent K & S Owl Inc., dba Owl Homecare Pharmacy (Owl) (together, Respondents) are revoked; however, the revocations are stayed and Respondents are placed on probation for five years upon the following terms and conditions:

1. Obey All Laws

Respondents shall obey all state and federal laws and regulations.

Respondents shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws

- a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment

- a conviction of any crime

- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondents shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondents shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent Kaldas and an officer of respondent Owl shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondents shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. Continuing Education

Respondent Kaldas shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

6. Notice to Employers

During the period of probation, respondent Kaldas shall notify all present and prospective employers of the decision in case number 4668 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent Kaldas undertaking any new employment, he shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during his tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4668, and terms and conditions imposed thereby. It shall be respondent Kaldas's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

If respondent Kaldas works for or is employed by or through a pharmacy employment service, he must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the Board of the terms and conditions of the decision in case number 4668 in advance of commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent Kaldas undertaking any new employment by or through a pharmacy employment service, he shall cause his direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that he has read the decision in case number 4668 and the terms and conditions imposed thereby. It shall be respondent Kaldas's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the Board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, respondent Kaldas shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the Board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

Respondent Owl must designate a new pharmacist-in-charge within 90 days of the effective date of this decision.

8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondents shall jointly and severally pay to the Board its costs of investigation and prosecution in the amount of $63,000. Respondents shall make monthly payments according to a schedule approved by the Board.

There shall be no deviation from the approved schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

Whether the filing of bankruptcy by either respondent relieves their responsibility to reimburse the Board its costs of investigation and prosecution is a matter to be decided by a court of competent jurisdiction.

9. Probation Monitoring Costs

Respondents shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

10. Status of License

Respondents shall, at all times while on probation, maintain an active, current license with the Board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If either respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should either respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, that respondent may tender his or its license to the Board for surrender. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the Board.

Upon acceptance of the surrender, respondent shall relinquish his or its pocket and wall license to the Board within ten (10) days of notification by the Board that the surrender is accepted. That respondent may not reapply for any license from the Board for three (3) years from the effective date of the surrender. That respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

12. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent Kaldas shall notify the Board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondents shall further notify the Board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the Board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. Tolling of Probation

Except during periods of suspension, respondent Kaldas shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 80 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, he must nonetheless comply with all terms and conditions of probation.

Should respondent Kaldas, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 80 hours per calendar month in California, he must notify the Board in writing within ten (10) days of the cessation of practice, and must further notify the Board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent Kaldas's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent Kaldas is not practicing as a pharmacist for at least 80 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 80 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

14. Violation of Probation

If Respondents have not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondents, and probation shall automatically be extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If Respondents violate probation in any respect, the Board, after giving Respondents notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. Completion of Probation

Upon written notice by the Board or its designee indicating successful completion of probation, Respondents' licenses will be fully restored.

16. Suspension

As part of probation, respondent Kaldas is suspended from the practice of pharmacy for 90 days, and respondent Owl's permit is suspended for 90 days, beginning the effective date of this decision.

During suspension, respondent Owl shall cease all pharmacy operations.

During suspension, respondent Kaldas shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the Board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent Kaldas shall not practice pharmacy nor do any act involving drug selection, selection of stock,

manufacturing, compounding, dispensing or patient consultation; nor shall respondent Kaldas manage, administer, or be a consultant to any licensee of the Board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent Kaldas shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent Kaldas shall not direct or control any aspect of the practice of pharmacy. Respondent Kaldas shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the Board.

Subject to the above restrictions, Respondents may continue to own or hold an interest in any licensed premises in which they hold an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

17. No New Ownership of Licensed Premises

Respondents shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the Board. If Respondents currently own or have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the Board, Respondents may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

Soliman

Albert Soliman, Pharmacist License number RPH 44883, is hereby publicly reproved under Business and Professions Code section 495.

Minaceuticals Wholesale Permit

No discipline is imposed against Permit number WLS 4527 issued to Minaceuticals Wholesale.

Application for Sterile Compounding Pharmacy License

The application of K & S Owl Inc., dba Owl Homecare Pharmacy for a sterile compounding pharmacy license is denied.

DATED: April 21, 2017

DocuSigned by:
Thomas Heller
CFDEA0142171A4...

THOMAS HELLER
Administrative Law Judge
Office of Administrative Hearings

KAMALA D. HARRIS
Attorney General of California
LINDA L. SUN
Supervising Deputy Attorney General
BORA S. MCCUTCHEON
Deputy Attorney General
State Bar No. 276475
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-2674
Facsimile: (213) 897-2804
Attorneys for Complainant

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

In the Matter of the Statement of Issues Against: **K & S OWL INC., DBA OWL HOMECARE PHARMACY, MAHER HALIM KALDAS, OWNER, ALBERT SOLIMAN, OWNER,** **Pharmacy Permit Number PHY 45091;** and **MAHER HALIM KALDAS,** **Pharmacist-In-Charge, Pharmacist License Number RPH 39184;** and **ALBERT SOLIMAN,** **Pharmacist License Number RPH 44883;** Sterile Compounding Pharmacy License Applicant. and **MINACEUTICALS WHOLESALE, MAHER HALIM KALDAS, OWNER, ALBERT SOLIMAN, OWNER,** **Permit Number WLS 4527;** Affiliated Party.	Case No. 5511 **STATEMENT OF ISSUES**

Complainant alleges:

PARTIES

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

K and S Owl Inc., doing business as (dba) Owl Homecare Pharmacy

2. On or about March 12, 1985, the Board issued Pharmacist License Number RPH 39184 to Maher Halim Kaldas. Pharmacist License Number 39184 will expire on February 28, 2017, unless renewed.

3. On or about September 17, 1991, the Board issued Pharmacist License Number RPH 44883 to Albert Soliman. Pharmacist License Number RPH 44883 will expire on August 31, 2017, unless renewed.

4. On or about April 28, 2004, the Board issued Original Permit Number PHY 45091 to K and S Owl Inc., dba Owl Homecare Pharmacy. The permit will expire on April 1, 2017, unless renewed. K and S Owl Inc., dba Owl Homecare Pharmacy, is co-owned by Maher Halim Kaldas and Albert Soliman. Kaldas has been the Chief Executive Officer and Pharmacist-In-Charge of K and S Owl Inc., dba Owl Homecare Pharmacy, since April 28, 2004. Soliman has been the Treasurer and Chief Financial Officer of K and S Owl Inc. dba Owl Homecare Pharmacy, since April 28, 2004.

5. On or about May 16, 2014, the Board received an application for a new licensed sterile compounding license filed by Applicant K and S Owl Inc., dba Owl Healthcare Pharmacy, Pharmacy Permit number PHY 45091, with Kaldas, Pharmacist License number RPH 39184, as the Pharmacist-In-Charge (Applicant). On or about May 1, 2014, Kaldas certified that the policies and procedures of the sterile compounding are consistent with California Code of Regulations, title 16, section 1735 et seq. and 1751 et seq.

6. The Board denied the application on April 17, 2015.

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Minaceuticals Wholesale

7. On or about December 1, 2004, the Board issued Permit Number WLS 4527 to Minaceuticals Wholesale. The permit will expire on December 1, 2016, unless renewed.

8. Minaceuticals Wholesale is co-owned by Kaldas and Soliman. Kaldas has been the designated representative-in-charge since December 1, 2004.

JURISDICTIONAL AND STATUTORY PROVISIONS

9. This Statement of Issues is brought before the Board, under the authority of the following laws.

10. Business and Professions Code section 4300[1] 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.
>
> (c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. The board may issue the license subject to any terms or conditions not contrary to public policy, including, but not limited to, the following:
>
> (1) Medical or psychiatric evaluation.
>
> (2) Continuing medical or psychiatric treatment.
>
> (3) Restriction of type or circumstances of practice.
>
> (4) Continuing participation in a board-approved rehabilitation program.

[1] All further statutory references are to the Business and Professions Code unless otherwise indicated.

(5) Abstention from the use of alcohol or drugs.

(6) Random fluid testing for alcohol or drugs.

(7) Compliance with laws and regulations governing the practice of pharmacy.

(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions.

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

11. Section 4300.1 states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

12. Section 4402, subdivision (a), 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.

13. Section 4302 states:

The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee.

14. Section 480 states, in pertinent part:

(a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:

. . .

(3) (A) Done any act that if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.

(B) The board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions, or duties of the business or profession for which application is made.

15. Section 4342 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).

16. Section 4127, subdivision (a), 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."

17. Section 4307 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.

REGULATIONS

18. California Code of Regulations, title 16, section 1770, states:

For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare.

19. 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.

FACTS

20. On January 27, 2016, the Board filed Accusation number 4668 against K & S Owl Inc., dba Owl Homecare Pharmacy, Kaldas, and Soliman. The Accusation alleged 21 causes for discipline and disciplinary considerations for acts warranting discipline on K & S Owl Inc., dba Owl Homecare Pharmacy's, Kaldas', and Soliman's licenses. Accusation number 4668 is attached as exhibit A and is incorporated by reference herein.

FIRST CAUSE FOR DENIAL OF APPLICATION

(Acts Warranting Revocation of Licensure: Accusation No. 4668)

21. Applicant's application for a new licensed sterile compounding license is subject to denial under section 480, subdivision (a)(3), in that while holding Pharmacy Permit Number PHY 45091, Pharmacist License Number RPH 39184, Pharmacist License Number RPH 44883, and Permit Number WLS 4527, Applicant committed acts that warrant revocation of licensure. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraph 20, above, and all of the statutory and regulatory violations and factual allegations in Accusation number 4668.

///

SECOND CAUSE FOR DENIAL OF APPLICATION

(Unprofessional Conduct)

22. Applicant's application for a new licensed sterile compounding license is subject to denial under section 4300, subdivision (c), in that Applicant is guilty of unprofessional conduct in running its business K & S Owl Inc., dba Owl Homecare Pharmacy. Complainant refers to, and by this reference incorporates the allegations set forth in paragraph 20, above, and Accusation number 4668, paragraphs 46–99 and 101–124.

THIRD CAUSE FOR DENIAL OF APPLICATION

(Existing Conditions in Relation to Officer or Director that Constitute Grounds for Disciplinary Action)

23. Applicant's application for a new licensed sterile compounding license is subject to denial under section 4302, in that Applicant's corporate officer or director or person holding 10 percent or more of the corporate stock of K & S Owl Inc. engaged in conduct that constitutes grounds for disciplinary action. Complainant refers to, and by this reference incorporates the allegations set forth in paragraph 20, above, and all of the statutory and regulatory violations and factual allegations in Accusation number 4668.

PRAYER

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

1. Denying Applicant's application, which was signed and dated by Maher Halim Kaldas on May 1, 2014, for a new licensed sterile compounding pharmacy license;

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

DATED: 6/13/16

Virginia Herold

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

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KAMALA D. HARRIS
Attorney General of California
THOMAS L. RINALDI
Supervising Deputy Attorney General
KRITHTHIKA VASUDEVAN
Deputy Attorney General
State Bar No. 247590
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-2540
Facsimile: (213) 897-2804
Attorneys for Complainant

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 **ACCUSATION**

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