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

In the Matter of the Accusation Against: **ROXSAN PHARMACY**, **INC**.; **FARBOD MELAMED**, **Pharmacist-in-Charge**, **SHAHLA KEYVANFAR MELAMED**, **CEO**, **President**, **Secretary** 465 N. Roxbury Dr. Beverly Hills, CA 90210 **Pharmacy Permit No**. **PHY 38297**, **SHAHLA KEYVANFAR MELAMED** 465 N. Roxbury Dr. Beverly Hills, CA 90210 **Pharmacist License No**. **RPH 42096**, And **FARBOD MELAMED** 411 North Palm Dr. #11 Beverly Hills, CA 90210 **Pharmacist License No**. **RPH 68252** Respondents.	Case No. 5455 **A C C U S A T I O N** [Gov. Code, § 11503.]

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Complainant alleges:

PARTIES

1. Complainant Virginia K. Herold brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, an agency within the Department of Consumer Affairs.

2. On November 3, 1992, the Board issued Pharmacy Permit Number PHY 38297 to Shahla Keyvanfar Melamed to do business as Rox San Pharmacy. On September 30, 2003, the license holder changed its name to Roxsan Pharmacy, Inc. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2015 unless it is renewed.

3. On August 19, 1988, the Board issued Pharmacist License Number RPH 42096 to Shahla Keyvanfar Melamed. Said license was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2016 unless it is renewed. Respondent Shahla Melamed was the Pharmacist-in-Charge of Roxsan Pharmacy, formerly known as Rox San Pharmacy, from November 3, 1992 through December 2, 2012. She is and has been the President, Secretary and Chief Executive Officer of Roxsan Pharmacy since August 5, 2003.

4. On October 5, 2012, the Board issued Pharmacist License Number RPH 68252 to Farbod Melamed. Said license was in full force and effect at all times relevant to the charges brought herein and will expire on December 31, 2015 unless it is renewed. Respondent Farbod Melamed has been the Pharmacist-in-Charge of Roxsan Pharmacy since December 3, 2012. Respondent Farbod Melamed disassociated as the Pharmacist-in-Charge on January 20, 2015.

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JURISDICTION

5. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code and all regulatory references are to title 16 of the California Code of Regulations unless otherwise indicated.

6. Section 4300 relevantly states that the Board has authority to suspend or revoke any license issued under the Pharmacy Law, and that the proceedings to suspend or revoke a license must be conducted according to the Administrative Procedure Act (Gov. Code, §§ 11500, *et seq*.).

7. Section 4300.1 of the Code provides the Board with continuing jurisdiction over a license regardless of the license's expiration, cancellation, forfeiture, retirement, surrender or suspension.

STATUTORY PROVISIONS

8. Section 4036.5 states:

> 'Pharmacist-in-charge' means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

9. Section 4059.5 relevantly states:

> (e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

10. Section 4081 states:

> (a) All records of manufacture and of sale, acquisition, receipt, shipment, 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, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the

Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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

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

11. Section 4105 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) (1) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(2) In the case of a veterinary food-animal drug retailer, wholesaler, or third-party logistics provider, any records that are maintained electronically shall be maintained so that the designated representative-in-charge or the responsible manager, or the designated representative on duty or the designated representative-3PL on duty if the designated representative-in-charge or responsible manager is not on duty, shall, at all times during which the licensed place of business is open for business, be able to produce a hardcopy 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.

(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is

subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.

12. Section 4113, subdivision (c) states:

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

13. Section 4156 states:

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

14. Section 4150 relevantly states:

A pharmacy corporation means a corporation that is authorized to render professional services, as defined in Section 13401 of the Corporations Code, so long as that corporation and its shareholders, officers, directors, and employees rendering professional services who are pharmacists are in compliance with the Moscone-Knox Professional Corporation Act, this article, and all other statutes and regulations now or hereafter enacted or adopted pertaining to the corporation and the conduct of its affairs.

15. Section 4301 relevantly states:

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

…

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

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

…

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

…

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

(p) Actions or conduct that would have warranted denial of a license.

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

16. 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.

17. Section 4306 states:

It shall constitute unprofessional conduct and a violation of this chapter for any person licensed under this chapter to violate, attempt to violate, directly or indirectly, or assist in or abet the violation of, or conspire to violate, any provision or term of this article, the Moscone-Knox Professional Corporation Act, or any regulations duly adopted under those laws.

18. Section 4306.5 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.

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(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 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 4324 relevantly states:

(a) Every person who...falsely makes, alters, forges, utters, publishes, passes, or attempts to pass, as genuine, any prescription for any drugs is guilty of forgery and upon conviction thereof shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in a county jail for not more than one year.

21. Section 4342 relevantly 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).

22. Section 111400 of the Sherman Food, Drug, and Cosmetic Law (Health & Saf. Code, §§ 109875, *et seq*.) defines a misbranded drug or device as one that "is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling."

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REGULATORY PROVISIONS

23. Regulation 1716 states:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription.

24. Regulation 1735 states:

(a) 'Compounding' means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, 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 drug product from chemicals or bulk drug substances

(b) 'Compounding' does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.

(c) 'Compounding' does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

(d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.).

25. Regulation 1735.2 relevantly states:

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond-use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

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(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product…

26. Regulation 1751 relevantly states:

(a) Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.

...

(c) Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.

27. Regulation 1751.1 relevantly states:

(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.

(b) In addition to the records required by section 1735.3 and subdivision (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be made and kept by the pharmacy:

…

(2) Refrigerator and freezer temperatures.

…

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

28. Regulation 1751.7 relevantly states:

(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

…

(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

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(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

29. Regulation 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.

30. Regulation 1793.7 relevantly states:

(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.

…

(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician…

ARKANSAS PHARMACY LAW

31. At all times relevant to the charges brought herein, Arkansas Administrative Code, title 070, division 00, rule 4, section 04-04-0001 stated, in pertinent part:

Out of State pharmacies shall comply with the following qualifications to be, and remain, licensed in Arkansas by the Board.

(a)(1) The pharmacy holds a current license in good standing in the state(s) in which it is located.

(2) Each pharmacist dispensing drugs into Arkansas shall be licensed as a pharmacist in Arkansas or in the state where he practices if that state has standards of licensure at least equivalent to those of Arkansas.

…

(c) The out of state pharmacy shall apply for licensure and renewal on forms provided by the Board. The Board may require such information as reasonably necessary to carry out the provisions of A.C.A. § 17-92-401, including, without limitation, the name, address and position of each officer and director of a corporation or of the owners if the pharmacy is not a corporation.

Provided, however, the Board may grant an exemption from licensing under A.C.A. § 17-92-401 upon application by any non-resident pharmacy which confines its dispensing activity to isolated transactions…

…

(e) The pharmacy shall maintain records of drugs dispensed to Arkansas addresses in such a manner so as to be readily retrievable upon request. These records shall be made available for inspection by the Board or by Arkansas law enforcement authorities.

(f) The pharmacy shall timely respond to any request for information from the Board or law enforcement authorities.

(g) The pharmacy shall maintain an incoming toll free telephone number for use by Arkansas customers to be answered by a pharmacist with access to patient records. This service shall be available a minimum of 40 hours a week, six days per week during normal business hours. This telephone number plus others available for use shall be printed on each container of drugs dispensed into Arkansas. The toll free number shall have sufficient extensions to provide reasonable access to incoming callers.

…

(i) The facilities and records of the pharmacy shall be subject to inspection by the Board: provided, however, the Board may accept in lieu thereof satisfactory inspection reports by the licensing entity using similar standards of the state where the pharmacy is located.

(j) Each out of state pharmacy doing business in Arkansas by dispensing and delivering or causing to be delivered prescription drugs to Arkansas consumers shall designate a resident agent in Arkansas for service of process.

(k) Each out of state pharmacy doing business in Arkansas shall comply with Board of Pharmacy regulation 09-00-0001 (Patient Information, Drug Use Evaluation, and Patient Counseling).

…

The responsibility to ensure compliance with this regulation rests both with the Arkansas pharmacist in charge and with the pharmacy owner if they are not the same.

CONNECTICUT PHARMACY LAW

32. At all times relevant to the charges brought herein, section 20-601 of the Connecticut Pharmacy Practice Act stated in pertinent part:

The department shall collect the following nonrefundable fees:

…

(12) The fee for issuance of a nonresident pharmacy certificate of registration is seven hundred fifty dollars.

(13) The fee for renewal of a nonresident pharmacy certificate of registration is one hundred ninety dollars…

33. Section 20-605 of the Connecticut Pharmacy Practice Act states:

No individual may engage in the practice of pharmacy unless the individual holds a current license or temporary permit to practice pharmacy issued by the department.

34. At all times relevant to the charges brought herein, section 20-627 of the Connecticut Pharmacy Practice Act stated:[1]

> (a) As used in sections 20-627 to 20-630, inclusive, "nonresident pharmacy" means any pharmacy located outside this state which ships, mails or delivers, in any manner, legend devices or legend drugs into this state pursuant to a prescription order.
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> (b) A nonresident pharmacy shall be registered with the department, upon approval of the commission, and shall:
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> (1) Disclose annually in a report to the commission the location, names and titles of all principal corporate officers, if applicable, and all pharmacists who are dispensing drugs or devices to residents of this state. A nonresident pharmacy shall file an additional report within thirty days after any change of office, corporate officer or pharmacist.
>
> (2) Submit a statement that the nonresident pharmacy complies with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as comply with all requests for information made by the commission pursuant to this section.
>
> (3) Maintain at all times, a valid unexpired license, permit or registration to conduct such pharmacy in compliance with the laws of the state in which the nonresident pharmacy is located.
>
> (4) Before receiving a certificate of registration from the department, submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the nonresident pharmacy is located.
>
> (c) A nonresident pharmacy shall, during its regular hours of operation, but not less than six days per week, and for a minimum of forty hours per week, provide a toll-free telephone number to facilitate communication between patients in this state and a pharmacist at such nonresident pharmacy who has access to the patient's records. Such toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

35. At all times relevant to the charges brought herein, section 20-628 of the Connecticut Pharmacy Practice Act stated:

> No nonresident pharmacy shall engage in the business of shipping, mailing or delivering legend devices or legend drugs in this state unless such nonresident pharmacy has been issued a certificate of registration by the commission and has paid the fee for issuance or renewal of such certificate of registration required in section 20-601. Applications for a certificate of registration as a nonresident pharmacy shall be made on a form furnished by the commission. The commission may require such information as it deems reasonably necessary to carry out the purpose of this section.

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[1] Amended by 2014 Conn. Legis. Serv. P.A. 14-224 (H.B. 5262) (WEST)

FLORIDA PHARMACY LAW

36. At all times relevant to the charges brought herein, section 465.0156 of the Florida Pharmacy Act stated:

> (1) Any pharmacy which is located outside this state and which ships, mails, or delivers, in any manner, a dispensed medicinal drug into this state shall be considered a nonresident pharmacy, shall be registered with the board, shall provide pharmacy services at a high level of protection and competence, and shall disclose to the board the following specific information:
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> (a) That it maintains at all times a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed;
>
> (b) The location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for dispensing medicinal drugs to residents of this state. This disclosure shall be made within 30 days after any change of location, corporate officer, or pharmacist serving as the prescription department manager for dispensing medicinal drugs to residents of this state;
>
> (c) That it complies with all lawful directions and requests for information from the regulatory or licensing agency of all states in which it is licensed as well as with all requests for information made by the board pursuant to this section. It shall respond directly to all communications from the board concerning emergency circumstances arising from errors in the dispensing of medicinal drugs to the residents of this state;
>
> (d) That it maintains its records of medicinal drugs dispensed to patients in this state so that the records are readily retrievable from the other business records of the pharmacy and from the records of other medicinal drugs dispensed; and
>
> (e) That during its regular hours of operation but not less than 6 days per week, for a minimum of 40 hours per week, a toll-free telephone service shall be provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number must be disclosed on the label affixed to each container of dispensed medicinal drugs.
>
> (2) Applications for nonresident pharmacy registration under this section shall be made on a form furnished by the board. The board may require such information as the board deems reasonably necessary to carry out the purposes of this section. The board may grant an exemption from the registration requirements of this section to any nonresident pharmacy which confines its dispensing activity to isolated transactions. The board may define by rule the term isolated transactions.
>
> (3) The registration fee and the biennial renewal fee shall be the fee specified in s. 465.022.
>
> (4) The board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for failure to comply with s. 465.0158, s. 465.017(2), or s. 465.025, or with any requirement of this section in accordance with this chapter.

(5) In addition to the prohibitions of subsection (4) the board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy in accordance with this chapter for conduct which causes or could cause serious bodily or psychological injury to a human or serious bodily injury to a nonhuman animal in this state.

(6) A nonresident pharmacy is subject to s. 456.0635.

(7) It is unlawful for any nonresident pharmacy which is not registered pursuant to this section to advertise its services in this state, or for any person who is a resident of this state to advertise the pharmacy services of a nonresident pharmacy which has not registered with the board, with the knowledge that the advertisement will or is likely to induce members of the public in this state to use the pharmacy to fill prescriptions.

(8) This section does not apply to Internet pharmacies required to be permitted under s. 465.0197.

(9) Notwithstanding s. 465.003(10), for purposes of this section, the registered pharmacy and the pharmacist designated by the registered pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

LOUISIANA PHARMACY LAW

37. At all times relevant to the charges brought herein, section 1201 of the Louisiana Pharmacy Practice Act stated:

A. Except as otherwise provided in this Chapter, it shall be unlawful for any individual to engage in the practice of pharmacy unless currently licensed or registered to practice under the provisions of this Chapter.

B. Licensed practitioners authorized under the laws of this state to compound drugs and to dispense drugs to their patients in the practice of their respective professions shall meet the same standards, record keeping requirements, and all other requirements for the dispensing of drugs applicable to pharmacists.

C. It shall be unlawful for any individual to assist in the practice of pharmacy unless currently registered or certified by the board.

38. At all times relevant to the charges brought herein, section 1221 of the Louisiana Pharmacy Practice Act stated:

A. No person shall open, establish, operate, or maintain a pharmacy located within this state unless the pharmacy is issued a permit by the board.

B. No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy located out-of-state unless the pharmacy is issued a permit by the board.

C. No permit to operate a pharmacy shall be granted or renewed unless evidence satisfactory to the board ensures that a pharmacist in the state where the permit is issued and pharmacy is located will be on duty during normal hours as administratively defined.

39. At all times relevant to the charges brought herein, section 1232 of the Louisiana Pharmacy Practice Act stated:

> A. A pharmacy located outside this state which does business in this state within the meaning of this Chapter shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit".
>
> B. A nonresident pharmacy granted a nonresident pharmacy permit by the board shall disclose to the board the location, names, and titles of all principal corporate officers, as well as the owner's managing officer and pharmacist-in-charge. A report containing this information shall be made to the board on an annual basis and within thirty business days after any change of office, corporate officer, or within ten business days of the departure of the prior owner's managing officer or pharmacist-in-charge.
>
> C. The nonresident pharmacy shall maintain at all times authorization to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to seeking a permit from the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located, as well as any other state pharmacy licensing agency or any agent thereof, and any inspection reports produced by the federal Food and Drug Administration or the federal Drug Enforcement Administration. Thereafter, the nonresident pharmacy granted a permit shall submit to the board a copy of any subsequent inspection report on the pharmacy conducted by the regulatory or licensing body of the state in which it is located, or by any other state pharmacy licensing agency, or any agent thereof, or by the federal Food and Drug Administration or the federal Drug Enforcement Administration. In addition to or in lieu of an inspection by the regulatory or licensing body of the state in which it is a resident, or any agent thereof, the nonresident pharmacy shall be subject to an inspection by the board. When the board conducts an inspection of a nonresident pharmacy, the board shall recover its expenses from the nonresident pharmacy in addition to the applicable permit fee authorized by this Chapter.
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> D. A nonresident pharmacy granted a nonresident pharmacy permit by the board shall maintain records of any controlled substances or dangerous drugs or devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.
>
> E. Records for all prescriptions and products delivered into the state shall be readily retrievable from the other prescription records of the nonresident pharmacy and shall be in compliance with all federal laws and with regulations as may be required by this state.

40. At all times relevant to the charges brought herein, Louisiana Administrative Code, title 46, section 2301, entitled "Purpose," stated:

> A. Out-of-State Pharmacies shall comply with the provisions of this Chapter in order to be and remain permitted to operate in Louisiana as an out-of-state pharmacy.

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B. This Chapter applies to any place physically located outside the state of Louisiana that provides services in the state of Louisiana where prescription drugs are dispensed and/or pharmacy care is provided to residents of the state of Louisiana. This includes, but is not limited to, pharmacies providing goods and services via U.S. mail carrier, commercial carrier, the Internet, and/or directly to Louisiana residents.

41. At all times relevant to the charges brought herein, Louisiana Administrative Code, title 46, section 2303, entitled "Out-of-State Pharmacy Requirements," stated:

A. The out-of-state pharmacy shall hold a current pharmacy permit in good standing in the state(s) in which it is located and/or practicing pharmacy.

B. Each pharmacist dispensing drugs into Louisiana shall be licensed as a pharmacist in good standing in the state(s) where he practices.

C. Every out-of-state pharmacy doing business in Louisiana by dispensing and delivering prescription drugs and devices to Louisiana residents shall designate a resident agent and a registered office in Louisiana for the service of process.

42. At all times relevant to the charges brought herein, Louisiana Administrative Code, title 46, section 2305, entitled "Out-of-State Pharmacy Permit Requirements," stated:

A. The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board. The board may require such information as reasonably necessary to carry out the provisions of R.S. 37:1232, including, without limitation, the name, address, and position of each officer and director of a corporation or of the owners, if the pharmacy is not a corporation.

B. The out-of-state pharmacy shall pay an annual permit fee as defined in R.S. 37:1184.

43. At all times relevant to the charges brought herein, Louisiana Administrative Code, title 46, section 2307, entitled "Pharmacist-in-Charge," relevantly stated:

A. Designation. A pharmacist licensed by the Louisiana Board of Pharmacy shall be named in the application as the pharmacy's pharmacist-in-charge for the Louisiana permit and shall be responsible for the pharmacy permit's compliance.

B. The pharmacist-in-charge shall have an active and current license in the state in which the pharmacy is located, and further, shall not have any restrictions that prohibit the position of pharmacist-in-charge.

C. Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription

department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

44. At all times relevant to the charges brought herein, Louisiana Administrative Code, title 46, section 2309, entitled "Applicable Laws and Regulations," stated:

> A. Louisiana pharmacy laws and regulations shall be applicable to regulate the practice of pharmacy for that portion of the out-of-state pharmacy's Louisiana pharmacy practice or operation.

MARYLAND PHARMACY LAW

45. At all times relevant to the charges brought herein, section 12-401 of the Maryland Health Occupations Code stated:

> **Permit required**
> (a) A person shall hold a pharmacy permit issued by the Board before the person may establish or operate a pharmacy in this State.
>
> **Multiple permits**
> (b) A separate pharmacy permit is required for each pharmacy that a person establishes or operates.

46. At all times relevant to the charges brought herein, section 12-402 of the Maryland Health Occupations Code stated:

> To qualify for a pharmacy permit, an applicant shall satisfy the Board that the pharmacy for which the application is made will be operated in accordance with the standards specified in § 12-403 of this subtitle.

47. At all times relevant to the charges brought herein, section 12-403 of the Maryland Health Occupations Code relevantly stated:

> **Laws or regulations of state in which located**
> (b) This section does not require a nonresident pharmacy to violate the laws or regulations of the state in which it is located.
>
> **Pharmacy permit requirements**
> (c) Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:
>
> (1) Shall be operated in compliance with the law and with the rules and regulations of the Board;
>
> (2) Shall be located and equipped so that the pharmacy may be operated without endangering the public health or safety;
>
> (3) Shall ensure that a licensed pharmacist be immediately available on the premises to provide pharmacy services at all times the pharmacy is in operation;

(4) Shall be supervised by a licensed pharmacist who is responsible for the operations of the pharmacy at all times the pharmacy is in operation;

…

(17) With regard to a prescription drug that is delivered in this State by the United States mail, a common carrier, or a delivery service and is not personally hand delivered directly to a patient or to the agent of the patient at the residence of the patient or at another location designated by the patient, shall:

(i) Provide a general written notice in each shipment of a prescription drug that alerts a consumer that, under certain circumstances, a medication's effectiveness may be affected by exposure to extremes of heat, cold, or humidity; and

(ii) Provide a specific written notice in each shipment of a prescription drug that provides a consumer with a toll-free or local consumer access telephone number accessible during regular hours of operation, which is designed to respond to consumer questions pertaining to medications;

…

Licensed pharmacist on staff

(e) A nonresident pharmacy shall:

(1) Hold a pharmacy permit issued by the Board; and

(2) Have a pharmacist on staff who is:

(i) Licensed by the Board; and

(ii) Designated as the pharmacist responsible for providing pharmaceutical services to patients in the State.

Application and fee for pharmacy permit

(f)(1) In order to obtain a pharmacy permit from the Board, a nonresident pharmacy shall:

(i) Submit an application to the Board on the form that the Board requires;

(ii) Pay to the Board an application fee set by the Board;

(iii) Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the nonresident pharmacy is located; and

(iv) On the required permit application, identify the name and current address of an agent located in this State officially designated to accept service of process.

(2) A nonresident pharmacy shall report a change in the name or address of the resident agent in writing to the Board 30 days prior to the change.

Compliance with home state laws

(g) Notwithstanding subsection (b) of this section, a nonresident pharmacy shall:

(1) Comply with the requirements of subsection (c)(2), (7) through (12), and (19) of this section when:

(i) Dispensing prescription drugs or prescription devices to a patient in this State; or

(ii) Otherwise engaging in the practice of pharmacy in this State;

(2) On an annual basis and within 30 days after a change of office, corporate officer, or pharmacist, disclose to the Board the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescriptions for drugs or devices to persons in this State;

(3) Comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is located and all requests for information made by the Board pursuant to this section;

(4) Maintain at all times a valid, unexpired permit to conduct a pharmacy in compliance with the laws of the state in which it is located;

(5) Maintain its records of prescription drugs or devices dispensed to patients in this State so that the records are readily retrievable;

(6) During its regular hours of operation, but not less than 6 days a week, and for a minimum of 40 hours per week, provide toll-free telephone service to facilitate communication between patients in this State and a pharmacist or an individual who:

(i) Has access to the patient's prescription records; and

(ii) Is required to refer patients in the State to the responsible pharmacist licensed in the State, as appropriate;

(7) Disclose its toll-free telephone number on a label affixed to each container of drugs or devices;

(8) Comply with the laws of this State relating to the confidentiality of prescription records if there are no laws relating to the confidentiality of prescription records in the state in which the nonresident pharmacy is located; and

(9) Comply with the requirements of subsection (c)(17) and (20) of this section.

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COST RECOVERY

48. 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.

DRUG CLASSIFICATIONS

49. Cyanocobalmin, commonly known as vitamin B12, is a dangerous drug when in the form of an injectable solution. (Bus. & Prof. Code, § 4022.)

50. Follistim AQ is a brand name for follitropin beta, a follicle-stimulating hormone indicated primarily for female infertility and ovarian failure. Follitropin beta is a dangerous drug. (Bus. & Prof. Code, § 4022.)

51. Hylenex and Wylase are brand names for hyaluronidase, a genetically designed protein that aids in the absorption of injected medications. Hyaluronidase is a dangerous drug. (Bus. & Prof. Code, § 4022.)

52. Ketamine is a Schedule III controlled substance and dangerous drug. (Bus. & Prof. Code, § 4022; Health & Saf. Code, § 11056, subd. (g).) It functions as an anesthetic and analgesic.

53. Lupron is the brand name for leuprolide, a dangerous drug that reduces testosterone in men and estrogen in women. (Bus. & Prof. Code, § 4022.)

54. Omnitrope is the brand name for somatropin, a dangerous drug indicated for growth failure in children and adults and for treatment of HIV-related Lipodystrophy. Somatropin has an off-label use of improving female fertility. (Bus. & Prof. Code, § 4022.)

55. Progesterone is a dangerous drug and naturally occurring hormone in women that regulates ovulation and menstruation. (Bus. & Prof. Code, § 4022.)

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STATEMENT OF FACTS

56. This Accusation alleges causes for discipline stemming from nine consumer complaints.

57. The Board received the first complaint on June 9, 2011. In substance, the complainant alleged that on February 21, 2011, Roxsan Pharmacy substituted an inappropriate device for injecting a drug marketed under the name "Omnitrope." Omnitrope is indicated for growth hormone deficiency and has an off-label use of improving female fertility. The Board investigated the complaint and conducted an inspection of Roxsan Pharmacy on June 23, 2011. The relevant findings are alleged in Section A, below.

58. The second consumer complaint came to the Board on July 27, 2011. The complainant alleged that Roxsan Pharmacy dispensed Domperidone to nursing mothers to enhance breast milk production. Domperidone is approved in some countries for gastrointestinal disorders. The United States Food and Drug Administration, the federal agency responsible for reviewing new drug applications, has not approved Domperidone for any purpose in this country and has banned the drug's importation and interstate transfer except for research purposes. The Board inspected Roxsan Pharmacy on September 15, 2011. The relevant findings are alleged in Section B, below.

59. The Board received the third consumer complaint on February 21, 2013. The complainant alleged that Roxsan Pharmacy sold dangerous drugs and controlled substances to Louisiana residents without being licensed in that state, as Louisiana law requires. The Board inspected Roxsan Pharmacy on June 4, 2013. The relevant findings are alleged in Section C, below.

60. The fourth consumer complaint came to the Board on September 24, 2013. The complainant alleged that Roxsan Pharmacy dispensed prescriptions to consumers in Connecticut without being licensed in that state, as Connecticut law requires. The Board inspected Roxsan Pharmacy on November 5, 2013. The relevant findings are alleged in Section D, below.

61. The Board learned of the fifth complaint on September 25, 2013. The Arkansas State Board of Pharmacy alleged that Roxsan Pharmacy dispensed prescriptions to consumers in

Arkansas without being licensed in that state, as Arkansas law requires. The Board inspected Roxsan Pharmacy on November 5, 2013. The relevant findings are alleged in Section E, below.

62. The sixth consumer complaint came from the California State Health and Human Services Agency, Department of Health Care Services ("Department of Health Care Services"). The Board received the complaint on September 27, 2013. The Department alleged that Roxsan Pharmacy did not maintain original prescription records for certain dispensed drugs. The Board investigated the complaint and inspected the pharmacy on November 5, 2013. The relevant findings are alleged in Section F, below.

63. The seventh consumer complaint came to the Board on December 2, 2013. The complainant alleged that Roxsan Pharmacy dispensed the wrong dose of Leuprolide. The Board investigated the complaint. The relevant findings are alleged in Section G, below.

64. The Board received the eighth consumer complaint on April 16, 2014. The complainant alleged that Roxsan Pharmacy dispensed dangerous drugs to consumers in Florida and Maryland without being licensed in those states. The Board investigated the complaint. The relevant findings are alleged in Section H, below.

65. The final consumer complaint reached the Board on August 11, 2014. The Board launched an investigation, during the course of which it was revealed that Roxsan Pharmacy had applied an incorrect expiration date to a Progesterone prescription. The relevant findings are alleged in Section I, below.

A. Omnitrope Complaint and Pharmacy Inspection on June 23, 2011

66. On December 9, 2010, a San Francisco-based fertility doctor prescribed Omnitrope (somatropin) 5mg per 1.5ml to one of her patients. Omnitrope is a recombinant human growth hormone indicated for the treatment of adult onset or childhood onset growth hormone deficiency. It is dispensed in cartridges holding doses of 5mg per 1.5ml or 10mg per 1.5ml. The cartridges are designed by the manufacturer, Sandoz, to be used with its own dispensing pens, Pen 5 and Pen 10. Each pen is specific to the prescribed dose—Pen 5 for 5mg prescriptions and Pen 10 for 10mg prescriptions. Sandoz supplies the pens to patients free of charge upon the prescriber's request. In Omnitrope's published drug information, Sandoz warns against using

non-proprietary devices to dispense the medication, stating that Omnitrope cartridges "must be used with the corresponding OMNITROPE® Pen 5 and Pen 10 delivery system, respectively."

67. The Follistim Pen is a dispensing device made by Merck. It is designed to inject precise doses of Merck's Follistim AQ (follitropin beta) drug. Follistim AQ is a gonadotropin that stimulates reproductive processes in women. Follistim AQ is indicated for the induction of ovulation and pregnancy and development of multiple follicles for patients in assisted reproductive programs. Merck sells the drug in cartridges dosed in international units (IU). Follistim AQ is available in strengths of 175 IU per 0.210ml, 350 IU per 0.420ml, 650 IU per 0.780ml, and 975 IU per 1.170ml. Merck's patient information guide advises patients not to "mix any other medicines into the cartridge" and directs patients to "[u]se [the] "Follistim AQ Cartridge only with the Follistim Pen."

68. On February 21, 2011, Roxsan Pharmacy received a faxed prescription for Omnitrope. Pharmacist J.A. (not a party to this action) dispensed the Omnitrope cartridge (5mg per 1.5ml) that day and substituted a Follistim Pen for the Omnitrope Pen 5. Roxsan Pharmacy and the dispensing pharmacist did not instruct the patient on how to convert milliliters (Omnitrope Pen) into international units (Follistim Pen) or otherwise provide adequate use instructions.

69. The patient was unable to use the Follistim pen dispensed by Roxsan Pharmacy and obtained the Omnitrope Pen 5 from her fertility clinic. Roxsan Pharmacy never replaced the Follistim pen with a suitable dispensing device.

70. On June 9, 2011, the patient's partner filed a complaint with the Board over the substitution of the Follistim pen. On June 23, 2011, a Board inspector conducted a complaint inspection of Roxsan Pharmacy at its Beverly Hills location. The inspector documented the following relevant facts:

1. A Pharmacist Falsified a Prescription Record

71. As part of the inspection into the Omnitrope consumer complaint, the inspector asked for all pharmacy records related to the dispensing of the patient's Omnitrope prescription. The dispensing pharmacist, J.A., produced records that showed the prescription was written on

December 9, 2010 for "Omnitrope Pen 5 (5mg/1.5ml)" in a quantity of five with one authorized refill. The prescription was typed and contained instructions to "dispense as written." The words "Foll Pen #1 per MD" appeared, handwritten, on the right side of the prescription. The dispensing pharmacist told the inspector that the physician verbally authorized the substitution.

72. The inspector noticed that the handwritten portion of the order, which purported to reflect the physician's order for the substitution, was wet. To test her belief, she ran her finger across the ink. The order smeared. The dispensing pharmacist admitted that she wrote the order for the substitution during the inspection.

73. By letter dated July 6, 2011, the prescribing doctor denied having authorized the Follistim Pen's substitution.

2. Pharmacist-in-Charge Shahla Melamed Falsified the DEA Biennial Controlled Substance Inventory

74. Later in the inspection, the Board inspector requested the pharmacy's federal Drug Enforcement Administration biennial controlled substance inventory. Pharmacist K.B. (not a party to this action) produced a spiral notebook containing handwritten controlled substance counts. The dates of the inventories were June 7, 2007, May 6, 2009 and June 1, 2011. For the biennial periods ending in 2007 and 2009, the inventories included Schedule II through V controlled substances. For the period ending in 2011, the inventory recorded only Schedule II controlled substances; missing were drug counts for Schedule III through V controlled substances.

75. At some point during the inspection, Respondent Shahla Melamed, the Pharmacist-in-Charge, arrived at the pharmacy. The Board inspector asked her for the pharmacy's self assessment and DEA inventory. Respondent Shahla Melamed produced the same spiral notebook as before. The inspector noticed that within the 2009 inventory, the header had been changed to include the date of June 1, 2011 for Scheduled drugs not listed in the 2011 inventory. The Board inspector asked Respondent Shahla Melamed if she added the 2011 date to the 2009 inventory. After first denying the charge, Respondent Shahla Melamed admitted adding "6/1/11" to the 2009 controlled substance inventory. The modification gave the appearance that Roxsan Pharmacy

maintained a count of Schedule III through V controlled substances for the biennial reporting period ending in 2011.

3. Roxsan Pharmacy Did Not Perform End-Product Sterility and Pyrogen Testing on Sterile Injectable Products or Keep Temperature Records

76. While evaluating the pharmacy's sterile compounding practice, the Board inspector discovered that Roxsan Pharmacy compounded injectable alprostadil alcohol solution on March 30, 2011 and June 2, 2011, and also prepared mitomycin injectable solution on February 14, 2011. Roxsan Pharmacy did not conduct end-product sterility and pyrogen testing on either solution to ensure safe use. Nor did the pharmacy maintain temperature records for the freezer used to store these and other sterile injectable solutions.

4. Roxsan Pharmacy Did Not Verify All Pharmacy Technician Work, Did Not Ensure that Each Pharmacy Technician Was Wearing Identification, and Maintained 17 Expired Ingredients in Active Compounding Stock

77. In addition to having deficient practices concerning sterile injectable products, Roxsan Pharmacy comingled 17 expired compounding ingredients with active compounding stock and permitted two of its pharmacy technicians to be present in the compounding area without wearing identification badges. The Board inspector found 14 medication bubble cards prepared by pharmacy technicians that did not contain a pharmacist's initials indicating that a pharmacist had verified the technician's work.

B. <u>Domperidone Complaint and Inspection on September 15, 2011</u>

78. On July 28, 2011, the Board received a complaint alleging that Roxsan Pharmacy dispensed Domperidone. Domperidone is a galactagogue, meaning it increases breast milk production in lactating women. The drug is not approved in the United States for any purpose although it is approved in other countries for the treatment of gastrointestinal disorders. The FDA bans the importation and interstate transportation of finished products and bulk compounding ingredients containing Domperidone except for use in research and development.

79. On September 15, 2011, Board inspectors conducted a complaint inspection at Roxsan Pharmacy. They discovered compounded Domperidone in the pharmacy's inventory. The

pharmacy possessed 100 10mg capsules, 200 20mg capsules, 200 30mg capsules and 100 40mg capsules of the drug. The pharmacy dispensed 452 prescriptions containing Domperidone in these various strengths between approximately August 4, 2005 and September 2, 2011.

80. Under its authority to embargo misbranded drugs, the Board seized the pharmacy's stock of Domperidone. (Bus. & Prof. Code, § 4084.)

C. Louisiana Complaint and Pharmacy Inspection on June 4, 2013

81. On February 21, 2013, the Louisiana Board of Pharmacy complained to the Board that Roxsan Pharmacy was soliciting business from Louisiana physicians and selling dangerous drugs and controlled substances in that state without proper licensure.

82. On June 4, 2013, the Board inspected Roxsan Pharmacy. Respondent Farbod Melamed was the acting Pharmacist-in-Charge. He admitted to the inspector that Roxsan pharmacy dispensed and shipped dangerous drugs to patients in Louisiana without being licensed in that state.

83. From July 31, 2012 to June 6, 2013, Roxsan Pharmacy dispensed 22 original prescriptions and two refills to patients residing in Louisiana. All but one of the prescriptions contained ketamine, a Schedule III controlled substance.

84. The inspection further revealed that Roxsan Pharmacy established incorrect beyond-use dates for eight batch compounded drug products. In each case, the compounded drug product's expiration date exceeded the expiration date of one of its ingredients. Respondent Shahla Melamed verified the products in question and Roxsan Pharmacy dispensed prescriptions from the stale batches.

D. Connecticut Complaint and Pharmacy Inspection on November 5, 2013

85. On September 24, 2013, a Connecticut consumer complained to the Board that Roxsan Pharmacy was dispensing prescriptions to consumers in Connecticut without being licensed in that state.

86. On November 5, 2013, the Board inspected Roxsan Pharmacy. Respondent Farbod Melamed was the acting Pharmacist-in-Charge.

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87. From May 21, 2012 to June 14, 2013, Roxsan Pharmacy dispensed 230 prescriptions to patients residing in Connecticut. During this period, Respondent Roxsan Pharmacy was not licensed in the state of Connecticut.

E. Arkansas Complaint and Pharmacy Inspection on November 5, 2013

88. On September 25, 2013, the Arkansas Board of Pharmacy complained to the Board that Roxsan Pharmacy was dispensing prescriptions to consumers in Arkansas without proper licensure.

89. On November 5, 2013, the Board inspected Roxsan Pharmacy. Respondent Farbod Melamed was the acting Pharmacist-in-Charge. He admitted that Respondent Roxsan Pharmacy shipped prescriptions into Arkansas without being licensed in that state.

90. From January 7, 2013 to June 11, 2013, Roxsan Pharmacy dispensed 16 original prescriptions to patients residing in Arkansas. During this period, Respondent Roxsan Pharmacy was not licensed in the state of Arkansas.

F. Department of Health Care Services Complaint and Pharmacy Inspection on November 5, 2013

91. Responding to a complaint from the Department of Health Care Services, the Board inspected Roxsan Pharmacy on November 5, 2013. On March 28, 2014, the Board inspector asked for original prescription records for 41 prescriptions dispensed between June 1 and December 31, 2012. Roxsan Pharmacy produced six original dispensing records but did not have records for the remaining 35 prescriptions.

G. Leuprolide Complaint

92. On December 2, 2013, a patient filed a complaint with the Board after Roxsan Pharmacy filled her prescription in the wrong strength. In early 2014, the Board inspected Roxsan Pharmacy. The inspector documented the following relevant facts:

1. Variation from Leuprolide Prescription

93. On December 18, 2012, an Orange County-based fertility doctor prescribed Leuprolide acetate 40mcg/0.2ml to one of her patients undergoing in vitro fertilization ("IVF"). During an IVF cycle, different medications are used to control the menstrual cycle of the patient

to allow for optimal stimulation of the ovaries. The physician directed the patient to use Leuprolide for ten to twelve days.

94. On December 18, 2012, Roxsan Pharmacy received a faxed prescription for diluted Leuprolide. Two days later, a pharmacist who is not a party to this action dispensed *full-strength* Leuprolide 1mg/0.2ml. The dispensed drug was not diluted as the prescription required.

95. The patient injected the dispensed medication each day for nine days before she consulted her fertility doctor, who discovered the pharmacy's error. The physician ended the IVF cycle because she believed that the incorrect dosage of Leuprolide had compromised the patient's treatment.

2. Roxsan Pharmacy Did Not Perform End-Product Sterility and Pyrogen Testing on Sterile Injectable Products

96. While evaluating the pharmacy's sterile compounding practice, the Board inspector discovered that from November 2012 to February 2013, Roxsan Pharmacy compounded twenty products from non-sterile sources. The compounded products were Cyanocobalmin and several batches of (separately) Leuprolide and Hyaluronidase. Roxsan Pharmacy failed to conduct pyrogen testing on all 20 products. It also failed to conduct end-product sterility testing on 19 of the selfsame products. The one product that Roxsan Pharmacy *did* test for sterility was Leuprolide; however, the pharmacy failed to quarantine the product while it awaited test results.

97. On November 7, 14 and 19, 2012 and again on January 11, 2013, the pharmacy compounded bacteriostatic water (benzyl alcohol 0.9% injection) for use in sterile injectable solutions. The pharmacy prepared the bacteriostatic water with sodium chloride granules, a non-sterile ingredient. Roxsan Pharmacy did not conduct end-product sterility or pyrogen testing on the bacteriostatic water to ensure its sterility. It used the untested water to create injectable compounds that were sold and dispensed as sterile. Roxsan Pharmacy did not test any of the final compounds made from this untested bacteriostatic water.

98. From November 1, 2012, to March 22, 2013, Roxsan Pharmacy dispensed 474 compounded prescriptions made from non-sterile ingredients without subjecting the final product to end-product sterility and pyrogen testing.

H. Florida and Maryland Complaints

99. Roxsan Pharmacy dispensed 6,048 prescriptions for dangerous drugs to Florida residents from approximately January 10, 2012 to March 21, 2013. Of that number, 1,949 prescriptions contained ketamine, a Schedule III controlled substance. Roxsan Pharmacy also dispensed 3,516 prescriptions for dangerous drugs to Maryland residents from approximately February 9, 2012 to June 26, 2013. Of that number, 1,745 contained ketamine. Roxsan Pharmacy did not have a license in Florida or Maryland when it dispensed these prescriptions.

I. Progesterone Complaint

100. On August 11, 2014, a California consumer complained to the Board about a prescription of Progesterone 200 mg Gelatin Troche. On January 5, 2015, a Board inspector requested the master formula for the drug. From this she learned that Roxsan Pharmacy labeled the prescription with a beyond-use date greater than what the master formula supported. Roxsan Pharmacy did not conduct stability studies to justify its extended expiration date.

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FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Falsification of Pharmacy Records)

(As to Respondents Roxsan Pharmacy and Shahla Melamed)

101. Respondents Roxsan Pharmacy and Shahla Melamed are subject to discipline under section 4301, subdivision (g), for knowingly making or signing a document that falsely represents the existence or nonexistence of a state of facts. On June 23, 2011, Respondent Shahla Melamed knowingly falsified a DEA biennial controlled substance inventory during an inspection of the pharmacy. Complainant realleges paragraphs 57, 66–70 and 74–75.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Falsification of Pharmacy Records)

(As to Respondent Roxsan Pharmacy)

102. Respondent Roxsan Pharmacy is subject to discipline under section 4301, subdivision (g), in that on June 23, 2011, one of its pharmacists knowingly falsified a prescription for Omnitrope 5mg/1.5ml. Complainant realleges paragraphs 57 and 66–73.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Subverting a Board Investigation)

(As to Respondents Roxsan Pharmacy and Shahla Melamed)

103. Respondents Roxsan Pharmacy and Shahla Melamed are subject to discipline under section 4301, subdivision (q), for attempting to subvert an investigation of the Board on June 23, 2011. Complainant realleges paragraphs 57, 66–75 and 101–102.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Dishonesty, Fraud or Deceit)

(As to Respondents Roxsan Pharmacy and Shahla Melamed)

104. Respondents Roxsan Pharmacy and Shahla Melamed are subject to discipline under section 4301, subdivision (f), for committing an act on June 23, 2011 involving dishonesty, fraud, deceit or corruption. Complainant realleges paragraphs 57, 66–75 and 101–103.

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FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Violation of Pharmacy Law and Regulations)

(As to Respondent Roxsan Pharmacy)

105. Respondent Roxsan Pharmacy is subject to discipline under section 4301, subdivision (o), for violating, or assisting in or abetting the violation of or conspiring to violate a state law governing pharmacy. In particular, Respondent Roxsan Pharmacy violated Code section 4324, which section makes it a crime to falsely make or alter a prescription. On June 23, 2011, a pharmacist employed by Respondent Roxsan Pharmacy knowingly falsified a pharmacy record during an inspection of the pharmacy. The pharmacist wrote an unauthorized device substitution (Follistim Pen) on a prescription for Omnitrope 5mg/1.5ml. Complainant realleges paragraphs 57, 66–73 and 102–104.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Violation of Pharmacy Law and Regulations)

(As to Respondents Roxsan Pharmacy and Shahla Melamed)

106. Respondents Roxsan Pharmacy and Shahla Melamed are subject to discipline under section 4301, subdivision (o), for violating, or assisting in or abetting the violation of or conspiring to violate provisions of the Pharmacy Law and state laws and regulations governing pharmacy, as follows:

107. **Section 4342**: Section 4342 empowers the Board to act to prevent the sale of pharmaceutical preparations and drugs that fail to conform to the standard and tests as to quality and strength. On June 23, 2011, a Board inspection revealed that Roxsan Pharmacy stored 17 expired ingredients in its active compounding stock, as set forth in the table below. Respondent Shahla Melamed was the Pharmacist-in-Charge at the time of the acts in question and, under Code sections 4036.5 and 4113, subdivision (c), she had the responsibility of ensuring that pharmaceutical preparations and drugs dispensed by the pharmacy conformed to the standard and tests as to quality and strength. Complainant realleges paragraphs 57 and 77.

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Drug	Expiration Date	Days Expired at Time of Inspection
Sorbitol	5/2/2008	Three years, 52 days
Sorbitan Monooleate	10/10/2008	Two years, 256 days
Potassium Azelaoyl	11/19/2008	Two years, 216 days
Versabase Foam	2/26/2010	One year, 117 days
Sardine Flavor	3/1/2010	One year, 114 days
Kaolin	4/30/2010	One year, 54 days
Rapeseed Oil	6/1/2010	One year, 22 days
PCCA[2] Vanpen	10/13/2010	253 days
Cocamide DEA	10/14/2010	252 days
Dow Corning 1501 Fluid	10/17/2010	249 days
Versabase Shampoo	11/6/2010	229 days
Gelatin	11/19/2010	216 days
Arginine	11/23/2010	212 days
PCCA[2] Anhydrous Lipoderm	1/27/2011	147 days
Ascorbyl Palmitate	2/11/2011	132 days
PCCA[2] Natapres	3/26/2011	89 days
Panthenol	4/30/2011	54 days

108. **Health and Safety Code section 111400**: Health and Safety Code section 111400 defines as "misbranded" any drug that is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended or suggested in its labeling. From approximately August 4, 2005 to September 2, 2011, Respondent Roxsan Pharmacy compounded and dispensed 452 misbranded prescriptions containing Domperidone. Domperidone is not approved for any purpose in the United States and no safe dosage has been established. As the Pharmacist-in-Charge at the time of the acts in question, Respondent Shahla Melamed was responsible, under

[2] Professional Compounding Centers of America

Code sections 4036.5 and 4113, subdivision (c), for preventing the sale of a drug dangerous to human health. Complainant realleges paragraphs 58, 78–80.

109. **Regulation 1716**: Regulation 1716 prohibits deviation from the requirements of a prescription except upon the prior consent of the prescriber or in accordance with section 4073 of the Code. Section 4073 allows a pharmacist to select a generic drug that boasts the same effectiveness as the brand name drug subject to the prescriber's order not to substitute. On February 21, 2011, Respondent Roxsan Pharmacy dispensed a Follistim Pen for injecting Omnitrope 5mg per 1.5ml and failed to provide appropriate use instructions. The Follistim Pen is not designed for Omnitrope injectable medication and cannot be substituted for the Omnitrope Pen 5. Respondent Roxsan Pharmacy deviated from the requirements of the patient's prescription without prior prescriber consent and in violation of section 4073. Respondent Shahla Melamed was the Pharmacist-in-Charge at the time of the conduct in question and had the responsibility, under Code sections 4036.5 and 4113, subdivision (c), to ensure that the dispensed medication conformed to the patient's prescription. Complainant realleges paragraphs 57 and 66–70.

110. **Regulation 1751.1**, **subd. (b)**: Regulation 1751.1, subdivision (b), requires pharmacies to maintain temperature records for all refrigerators and freezers in which sterile compounded products are stored. An inspection on June 23, 2011 revealed that Respondent Roxsan Pharmacy did not maintain temperature records for the freezer it used to store sterile injectable products. As the Pharmacist-in-Charge at the time of the acts in question, Respondent Shahla Melamed was responsible, under Code sections 4036.5 and 4113, subdivision (c), for ensuring that adequate temperature readings of the freezer were recorded and maintained for inspection. Complainant realleges paragraphs 57 and 76.

111. **Regulation 1751.7**, **subd**. **(c)**: Regulation 1751.7, subdivision (c), requires a compounding pharmacy to perform end-product testing for sterility and pyrogens (bacterial toxins) whenever it compounds sterile injectable drug products from one or more non-sterile ingredients. The regulation requires the pharmacy to quarantine injectable drug products until end-product testing confirms their sterility and acceptable levels of pyrogens. Respondent Roxsan Pharmacy prepared sterile injectable drug products from non-sterile sources without subjecting

the final product to testing. Specifically, on February 14, 2011, Respondent Roxsan Pharmacy prepared mitomycin 0.2% injection solution without testing it. The pharmacy also prepared but failed to test alprostadil alcohol injection solution on March 30 and June 2, 2011. As the Pharmacist-in-Charge at the time of the acts in question, Respondent Shahla Melamed had a duty, under Code sections 4036.5 and 4113, subdivision (c), to ensure that sterile injectable products compounded from non-sterile ingredients were quarantined until end-product testing confirmed their sterility and acceptable levels of pyrogens. Complainant realleges paragraphs 57 and 76.

112. **Regulation 1793.7, subd. (a)**: Regulation 1793.7, subdivision (a), requires a pharmacist to verify every function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals. The verification must be documented in writing by the verifying pharmacist on the prescription label. Respondents Roxsan Pharmacy and Shahla Melamed failed to verify 14 bubble packs of medication that were prepared by a pharmacy technician. As the Pharmacist-in-Charge at the time of the acts in question, Respondent Shahla Melamed was responsible, under Code sections 4036.5 and 4113, subdivision (c), for ensuring that each bubble pack prepared by a pharmacy technician was verified by a pharmacist. The prescriptions and dates of preparation for which no written verification of technician work appeared on the prescription label are set forth in the table below. Complainant realleges paragraphs 57 and 77.

Date	**Rx. No.**	**Drug**	**No. of Cards Per Rx.**
2/1/2011	1238102	Atenolol 25mg	1
3/1/2011	1238102	Atenolol 25mg	1
4/1/2011	1238102	Atenolol 25mg	1
4/7/2011	1284869	Actos 30mg	1
4/11/2011	1285308	Simvastatin 20mg	1

(*cont'd...*)

Date	Rx. No.	Drug	No. of Cards Per Rx.
4/12/2011	1285427	Metoclopramide 5mg	3
4/12/2011	1285430	Omeprazole 20mg	1
4/12/2011	1285435	Hydralazine 10mg	2
4/19/2011	1285431	Isosorbide 30mg	1
4/19/2011	1285437	Aggrenox	1
5/1/2011	1238102	Atenolol 25mg	1

113. **Regulation 1793.7**, **subd. (c)**: Regulation 1793.7, subdivision (c), requires a pharmacy technician to wear identification that clearly identifies him as a pharmacy technician. During an inspection on June 23, 2011, two pharmacy technicians were not wearing identification clearly identifying them as pharmacy technicians. Respondent Shahla Melamed was the Pharmacist-in-Charge at the time of the act in question and was responsible, under Code sections 4036.5 and 4113, subdivision (c), for ensuring that pharmacy technicians were wearing proper identification. Complainant realleges paragraphs 57 and 77.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Violation of Pharmacy Law and Regulations)

(As to Respondents Roxsan Pharmacy and Farbod Melamed)

114. Respondents Roxsan Pharmacy and Farbod Melamed are subject to discipline under section 4301, subdivision (o), for violating, or assisting in or abetting the violation of or conspiring to violate provisions of the Pharmacy Law and state laws and regulations governing pharmacy, as follows:

115. **Regulation 1716**: Regulation 1716 prohibits deviation from the requirements of a prescription except upon the prior consent of the prescriber or in accordance with section 4073 of the Code. Section 4073 allows a pharmacist to select a generic drug that boasts the same effectiveness as the brand name drug subject to the prescriber's order not to substitute. On December 18, 2012, Respondent Roxsan Pharmacy dispensed full-strength Leuprolide 1mg/0.2ml instead of the prescribed Leuprolide acetate 40mcg/0.2ml. Respondent Roxsan Pharmacy

deviated from the requirements of the patient's prescription without prior prescriber consent and in violation of section 4073. Respondent Farbod Melamed was the Pharmacist-in-Charge at the time of the conduct in question and had the responsibility under Code sections 4036.5 and 4113, subdivision (c), to ensure that the dispensed medication conformed to the patient's prescription. Complainant realleges paragraphs 63, 92–95.

116. **Regulation 1735.2**, **subd**. **(h)**: Regulation 1735.2, subdivision (h), states that every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond-use date" of the compounded drug product cannot exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Respondent Roxsan Pharmacy compounded the following drug products and labeled each with an expiration date in excess of the expiration date of one of its ingredients. As the Pharmacist-in-Charge at the time of the acts in question, Respondent Farbod Melamed had the responsibility, under Code sections 4036.5 and 4113, subdivision (c), to ensure that each compounded drug product contained a correct beyond-use date. Complainant realleges paragraphs 59, 65, 81–84, and 100.

Date Compounded	**Drug**	**Ingredient or Compound with Expiration Date that is Less Than the Beyond-Use Date**	**Beyond-Use Date on Label**
1/7/2013	Cream with: Hydroquinone cream 2% Kojic acid 2% Triamcinolone 2% Retinoic acid (tretinoin) 0.025%	4/6/2013 Hydroquinone cream 2%	5/7/2013

(*cont'd*…)

Date Compounded	Drug	Ingredient or Compound with Expiration Date that is Less Than the Beyond-Use Date	Beyond-Use Date on Label
1/10/2013	Cream with: Hydroquinone cream 4% Kojic acid 4% Triamcinolone 4% Retinoic acid (tretinoin) 0.05%	3/12/2013 Hydroquinone cream 4%	5/10/2013
2/21/2013	Hydroquinone cream 8%	7/19/2013 Sodium metabisulfite	8/20/2013
2/21/2013	Hydroquinone cream 10%	7/19/2013 Sodium metabisulfite	8/20/2013
5/17/2013	Hydroquinone cream 2%	7/19/2013 Sodium metabisulfite	11/13/2013
5/20/2013	Hydroquinone cream 5%	7/19/2013 Sodium metabisulfite	11/16/2013
5/28/2013	Hydroquinone cream 5% with Salicylic acid 5% solution	7/19/2013 Sodium metabisulfite	11/24/2013
7/1/2014	Progesterone 200 mg Gelatin Troche (PCCA Special Micronized)	9/29/2014 Compound (Progesterone 200 mg Gelatin Troche [PCCA Special Micronized])	12/28/2014

117. **Section 4342**: Section 4342 empowers the Board to act to prevent the sale of pharmaceutical preparations and drugs that fail to conform to the standard and tests as to quality and strength. Inspections on June 4, 2013 and October 10, 2014 revealed that Respondent Roxsan Pharmacy compounded eight drug products and labeled them with expiration dates that exceeded the expiration dates of their ingredients, as more particularly set forth in paragraph 116, *supra*. Respondent Farbod Melamed was the Pharmacist-in-Charge at the time of the acts in question and had the responsibility, under Code sections 4036.5 and 4113, subdivision (c), to ensure that pharmaceutical preparations and drugs dispensed by the pharmacy conformed to the standard and tests as to quality and strength. Complainant realleges paragraphs 59, 65, 81–84, 100, and 116.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Violation of Pharmacy Law and Regulations)

(As to All Respondents)

118. Respondents Roxsan Pharmacy, Shahla Melamed and Farbod Melamed are subject to discipline under section 4301, subdivision (o), for violating, or assisting in or abetting the violation of or conspiring to violate provisions of the Pharmacy Law and state laws and regulations governing pharmacy, as follows:

A. Respondents Illegally Shipped Drugs Into Other States Without a License

119. **Section 4059.5**, **subdivision (e)**, prohibits the transfer, sale or delivery of dangerous drugs and devices to persons outside California unless the transfer, sale or delivery complies with California law, federal law, and the law of the state into which the dangerous drug or device is delivered. Respondents Roxsan Pharmacy, Shahla Melamed and Farbod Melamed violated Code section 4059.5, subdivision (e), by selling dangerous drugs in other states in contravention of the laws of those states and in violation of the laws of this State.

1. Louisiana Drug Sales

120. From approximately September 28, 2012 to June 6, 2013, Respondent Roxsan Pharmacy dispensed 22 prescriptions for dangerous drugs and two refills to patients in the state of Louisiana without proper licensure. Twenty-one of the twenty-two prescriptions contained ketamine, a Schedule III controlled substance.

121. Respondent Roxsan Pharmacy dispensed four of the aforementioned prescriptions from September 28, 2012 through December 2, 2012, during which time Respondent Shahla Melamed was the Pharmacist-in-Charge. The remaining 18 prescriptions were dispensed between December 3, 2012 and June 6, 2013, during which time Respondent Farbod Melamed was the Pharmacist-in-Charge.

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122. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to ensure that every prescription dispensed and sold in Louisiana complied with the Pharmacy Law, federal law and the Louisiana Pharmacy Practice Act. Complainant realleges paragraphs 59 and 81–84.

2. Connecticut Drug Sales

123. From approximately May 21, 2012 to June 14, 2013, Respondent Roxsan Pharmacy dispensed 230 prescriptions for dangerous drugs to patients in the state of Connecticut without proper licensure.

124. Respondent Roxsan Pharmacy dispensed 128 of the aforementioned prescriptions between May 21, 2012 and December 2, 2012, during which time Respondent Shahla Melamed was the Pharmacist-in-Charge. The remaining 102 prescriptions were dispensed between December 3, 2012 and June 14, 2013, during which time Respondent Farbod Melamed was the Pharmacist-in-Charge.

125. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to ensure that every prescription dispensed and sold in Connecticut complied with the Pharmacy Law, federal law and the Connecticut Pharmacy Practice Act. Complainant realleges paragraphs 60 and 85–87.

3. Florida Drug Sales

126. From approximately January 10, 2012 to March 21, 2013, Respondent Roxsan Pharmacy dispensed 6,048 prescriptions for dangerous drugs to patients in the state of Florida without proper licensure.

127. Respondent Roxsan Pharmacy dispensed 4,604 of the aforementioned prescriptions between January 10, 2012 and December 1, 2012, during which time Respondent Shahla Melamed was the Pharmacist-in-Charge. The remaining 1,444 prescriptions were dispensed between December 3, 2012 and March 21, 2013, during which time Respondent Farbod Melamed was the Pharmacist-in-Charge.

128. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to ensure that every prescription dispensed and sold in Florida complied with the Pharmacy Law, federal law and the Florida Pharmacy Act. Complainant realleges paragraphs 64 and 99.

4. Maryland Drug Sales

129. From approximately February 9, 2012 to June 26, 2013, Respondent Roxsan Pharmacy dispensed 3,516 prescriptions for dangerous drugs to patients in the state of Maryland without proper licensure.

130. Respondent Roxsan Pharmacy dispensed 1,152 of the aforementioned prescriptions between February 9, 2012 and December 1, 2012, during which time Respondent Shahla Melamed was the Pharmacist-in-Charge. The remaining 2,364 prescriptions were dispensed between December 3, 2012 and June 26, 2013, during which time Respondent Farbod Melamed was the Pharmacist-in-Charge.

131. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to ensure that every prescription dispensed and sold in Maryland complied with the Pharmacy Law, federal law and the laws of Maryland. Complainant realleges paragraphs 64 and 99.

5. Respondent Shahla Melamed Knew About the Out-of-State Drug Sales

132. When Respondent Farbod Melamed became the Pharmacist-in-Charge, Respondent Shahla Melamed remained the pharmacy's President, Chief Executive Officer and Secretary. As a corporate officer, she had knowledge that Roxsan Pharmacy dispensed dangerous drugs to residents of Connecticut, Florida, Louisiana and Maryland without being licensed in those states, even after she ceased being the Pharmacist-in-Charge. Complainant realleges paragraphs 59–60, 81–87, 99, and 118–131.

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B. Respondents Failed to Test Sterile Injectable Medication

133. **Regulation 1751**, **subdivision (c)**, requires a compounding pharmacy to perform end-product testing for sterility and pyrogens (bacterial toxins) whenever it compounds sterile injectable drug products from one or more non-sterile ingredients. The regulation requires the pharmacy to quarantine injectable drug products until end-product testing confirms the drugs' sterility and acceptable levels of pyrogens.

134. Respondent Roxsan Pharmacy prepared sterile injectable drug products from non-sterile sources without subjecting the final product to testing. Specifically, from October 2012, to February, 2013, Roxsan Pharmacy compounded twenty products (Cyanocobalmin, Leuprolide, and Hyaluronidase) prepared from non-sterile sources without testing them. The pharmacy also prepared bacteriostatic water on November 7, 14, and 19, 2012, and again on January 11, 2013, using non-sterile sources without testing it. The bacteriostatic water was then used to create other injectable compounds but these compounds were not tested for sterility.

135. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to ensure that sterile injectable products compounded from non-sterile ingredients were quarantined until end-product testing confirmed their sterility and acceptable levels of pyrogens. Complainant realleges paragraphs 2–4, 63, and 92–98.

C. Respondents Failed to Keep Records of Sale and Disposition of Dangerous Drugs

136. **Sections 4081**, **subdivision (a)**, **and 4105**, require a pharmacy to maintain all records of sale, acquisition, receipt, shipment, or disposition of dangerous drugs for three years from the date of making. The records must be open to inspection during the pharmacy's business hours. On March 28, 2014, the Board requested original prescription records for 41 prescriptions dispensed between June 1 and December 31, 2012. Roxsan Pharmacy produced six original dispensing records but did not produce records for the remaining 35 prescriptions. Respondents failed to keep and maintain records of sale, acquisition, receipt, shipment and disposition for those 35 prescriptions, all of which were dangerous drugs.

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137. Respondent Roxsan Pharmacy dispensed 33 of the undocumented prescriptions prior to December 3, 2012, during which time Respondent Shahla Melamed was the Pharmacist-in-Charge. The remaining two undocumented prescriptions were dispensed on December 17 and 26, 2012, during which time Respondent Farbod Melamed was the Pharmacist-in-Charge.

138. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to maintain all records of sale, acquisition, receipt, shipment and disposition of dangerous drugs. Complainant realleges paragraphs 62 and 91.

NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Violation of Pharmacy Law and Regulations)

(As to Respondents Roxsan Pharmacy and Farbod Melamed)

139. Respondents Roxsan Pharmacy and Farbod Melamed are subject to discipline under section 4301, subdivision (o), for violating, or assisting in or abetting the violation of or conspiring to violate provisions of the Pharmacy Law and state laws and regulations governing pharmacy, in particular Code section 4059.5, subdivision (e).

140. **Section 4059.5**, **subdivision (e)**, prohibits the transfer, sale or delivery of dangerous drugs and devices to persons outside of California unless the transfer, sale or delivery complies with California law, federal law, and the law of the state into which the dangerous drug or device is delivered. Respondents Roxsan Pharmacy and Farbod Melamed violated Code section 4059.5, subdivision (e) by dispensing medications to patients in the state of Arkansas in contravention of California and Arkansas law.

141. From approximately January 7, 2013 to June 11, 2013, Respondent Roxsan Pharmacy dispensed 16 prescriptions to patients in the state of Arkansas without proper licensure.

142. During that time period, Respondent Farbod Melamed was the Pharmacist-in-Charge and had a duty to ensure that every prescription dispensed and sold in Arkansas complied with the Pharmacy Law, federal law and Arkansas law. Complainant realleges paragraphs 61, 88–90.

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143. Respondent Shahla Melamed, as Roxsan Pharmacy's President, Chief Executive Officer and Secretary, had knowledge of the out-of-state drug sales. Complainant realleges paragraph 132.

TENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Violation of State and Federal Statutes Regulating Controlled Substances and Dangerous Drugs)

(As to All Respondents)

144. Respondents Roxsan Pharmacy, Shahla Melamed and Farbod Melamed are subject to discipline under section 4301, subdivision (j), for violating statutes of this State and other states regulating controlled substances and dangerous drugs. Complainant realleges paragraphs 57–143.

ELEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Conduct Which Would Warrant Denial of an Application)

(As to All Respondents)

145. Respondents Roxsan Pharmacy, Shahla Melamed and Farbod Melamed are subject to discipline under section 4301, subdivision (p), for engaging in conduct that would have warranted denial of a license. Complainant realleges paragraphs 57–144.

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DISCIPLINARY CONSIDERATIONS

Complainant alleges as a disciplinary consideration the following prior violations:

Section Violated	Offense	Cited Person, Citation Number and Date of Issuance
Code Fed. Regs., tit. 21, § 1304.04 (f)	Failure to maintain separate inventories and records of controlled substances	Roxsan Pharmacy CI 2007 35352 (6/5/08) PIC Shahla Melamed CI 2007 36251 (6/5/08)
Code Fed. Regs., tit. 21, § 1304.11 (c)	Failure to maintain complete inventory of controlled substances	Roxsan Pharmacy CI 2001 22642 (3/3/03) CI 2004 27776 (10/26/04) PIC Shahla Melamed CI 2001 22642 (3/3/03) CI 2004 27776 (10/26/04)
Code, § 4052 (a)	Scope of practice	Roxsan Pharmacy CI 2002 24424 (9/8/03)
Code, § 4059	Furnishing dangerous drug or device other than upon the prescription of a person authorized to prescribe dangerous drugs and devices	Roxsan Pharmacy CI 2002 24424 (9/8/03) PIC Shahla Melamed CI 2002 24424 (9/8/03)
Code, § 4076	Failure to dispense prescription in a container that meets the requirements of state and federal law and is correctly labeled	Roxsan Pharmacy CI 2001 22642 (3/3/03) PIC Shahla Melamed CI 2001 22642 (3/3/03)

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Section Violated	Offense	Cited Person, Citation Number and Date of Issuance
Code, § 4076 (a) Code, § 4076 (a)(11)(A)	Mislabeling of physical description of the dispensed medication	Roxsan Pharmacy CI 2007 35352 (6/5/08) CI 2007 36248 (10/1/09) CI 2009 41104 (6/4/10) PIC Shahla Melamed CI 2007 36251 (6/5/08) CI 2009 41471 (10/1/09) CI 2009 44011 (6/24/10)
Code, § 4077 (d)	Failure of pharmacist to affix warning label on products containing dimethyl sulfoxide	Roxsan Pharmacy CI 2007 36248 (10/1/09) PIC Shahla Melamed CI 2009 41471 (10/1/09)
Code, § 4081 (a)	Failure of pharmacy to maintain a current inventory of dangerous drugs and to have that inventory available for inspection	Roxsan Pharmacy CI 2004 27776 (10/26/04) CI 2007 35352 (6/5/08) PIC Shahla Melamed CI 2004 27776 (10/26/04) CI 2007 36251 (6/5/08)
Code, § 4104 (a)	Failure to have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally or physically impaired to the extent it affects his ability to practice the profession or is discovered to have engaged in the theft, diversion or self-use of dangerous drugs	Roxsan Pharmacy CI 2007 35352 (6/5/08) PIC Shahla Melamed CI 2007 36251 (6/5/08)

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Section Violated	Offense	Cited Person, Citation Number and Date of Issuance
Code, § 4115 (g)	Failure of pharmacist to supervise pharmacy technician in reviewing work completed during pharmacist's temporary absence	Roxsan Pharmacy CI 2001 22642 (3/3/03) PIC Shahla Melamed CI 2007 36251 (6/5/08)
Code, § 4125 (a) Regulation 1711 (e)	Failure of pharmacy to complete and maintain quality assurance review following medication error	Roxsan Pharmacy CI 2002 24424 (9/8/03) CI 2009 41104 (6/4/10) PIC Shahla Melamed CI 2002 24424 (9/8/03) CI 2009 44011 (6/24/10)
Code, § 4342 Regulation 1716.2 (a)(3)	Failure to ensure pharmaceutical preparations and drugs dispensed by the pharmacy conform to the standard and tests as to quality and strength	Roxsan Pharmacy CI 2001 22642 (3/3/03) CI 2002 24424 (9/8/03) CI 2004 27776 (10/26/04) CI 2007 35352 (6/5/08) CI 2007 36248 (10/1/09) CI 2009 41104 (6/24/10) PIC Shahla Melamed CI 2001 22642 (3/3/03) CI 2002 24424 (9/8/03) CI 2004 27775 (10/26/04) CI 2007 36251 (6/5/08) CI 2009 41471 (10/1/09) CI 2009 44011 (6/24/10)
Regulation 1707.3	Failure of pharmacist to review patient's drug therapy and medication record before dispensing prescription	Roxsan Pharmacy CI 2009 41104 (6/4/10) PIC Shahla Melamed CI 2009 44011 (6/24/10)

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Section Violated	Offense	Cited Person, Citation Number and Date of Issuance
Regulation 1714 (c)	Failure to maintain pharmacy and fixtures and equipment in clean and orderly condition	Roxsan Pharmacy CI 2001 22642 (3/3/03) PIC Shahla Melamed CI 2001 22642 (3/3/03)
Regulation 1715 (a)	Failure of pharmacy to maintain current pharmacy self-assessment form	Roxsan Pharmacy CI 2007 35352 (6/5/08) PIC Shahla Melamed CI 2007 36251 (6/5/08)
Regulation 1716.2 (a)(4)	Failure of pharmacy to maintain records that include the signature or initials of the pharmacists performing the compounding	Roxsan Pharmacy CI 2004 27776 (10/26/04) CI 2007 35352 (6/5/08) CI 2009 41104 (6/24/10) PIC Shahla Melamed CI 2004 27776 (10/26/04) CI 2007 36251 (6/5/08) CI 2009 44011 (6/24/10)
Regulation 1718	Failure to maintain complete inventory of all dangerous drugs	Roxsan Pharmacy CI 2001 22642 (3/3/03) PIC Shahla Melamed CI 2007 36251 (6/5/08)
Regulation 1761 (a) Regulation 1716	Variation from prescription	Roxsan Pharmacy CI 2004 27776 (10/26/04) CI 2007 35352 (6/5/08) CI 2009 41104 (6/4/10) PIC Shahla Melamed CI 2004 27776 (10/26/04) CI 2007 36251 (6/5/08) CI 2009 44011 (6/24/10)

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Section Violated	Offense	Cited Person, Citation Number and Date of Issuance
Regulation 1793.7	Failure to have policies and procedures and a job description for pharmacy technicians in place in the pharmacy	Roxsan Pharmacy CI 2004 27776 (10/26/04) PIC Shahla Melamed CI 2004 27776 (10/26/04)
Regulation 1793.7 (a)	Failure of pharmacist to verify and document work of pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals	Roxsan Pharmacy CI 2004 27776 (10/26/04) CI 2009 41104 (6/24/10) PIC Shahla Melamed CI 2004 27776 (10/26/04) CI 2009 44011 (6/24/10)
Regulation 1793.7 (a), (c), (d)	Pharmacy technician not wearing identification	Roxsan Pharmacy CI 2007 35352 (6/5/08) CI 2007 36248 (10/1/09) PIC Shahla Melamed CI 2007 36251 (6/5/08) CI 2009 41471 (10/1/09)

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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 Pharmacy Permit Number PHY 38297, issued to Roxsan Pharmacy, Inc. with Shahla Keyvanfar Melamed as its CEO and President;

2. Revoking or suspending Pharmacist License Number RPH 42096, issued to Shahla Keyvanfar Melamed;

3. Revoking or suspending Pharmacist License Number RPH 68252, issued to Farbod Melamed;

4. Prohibiting Shahla Keyvanfar Melamed from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee during the period in which discipline is imposed on Pharmacy Permit Number PHY 38297, issued to Roxsan Pharmacy, Inc. with Shahla Keyvanfar Melamed as its CEO and President.

5. Ordering Roxsan Pharmacy, Inc., Shahla Keyvanfar Melamed and Farbod Melamed to pay the reasonable costs of the investigation and enforcement of this case pursuant to Business and Professions Code section 125.3; and

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

DATED: April 15, 2015

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