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

In the Matter of the Accusation Against: APGUARD MEDICAL, INC. 6404 Independence Avenue Woodland Hills, CA 91367 Pharmacy Permit No. PHY 43386, Respondent.	Case No. 3166 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about August 12, 1998, the Board of Pharmacy issued Pharmacy Permit Number PHY 43386 to Apguard Medical, Inc. (Respondent Apguard Medical). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2009, unless renewed.

JURISDICTION

3. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section

references are to the Business and Professions Code unless otherwise indicated.

4. Section 4300 of the Code provides, in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

5. Section 118, subdivision (b) states:

"The suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending ore revoking the license or otherwise taking disciplinary action against the licensee on any such ground."

6. Section 4113, subdivision (b) of the Code states:

"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."

7. Section 4301 of the Code states:

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

. . . .

(j) The violation of any of the statutes of this 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."

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8. Section 4081 of the Code states, in pertinent part:

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

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

9. Section 4169, subdivision (a)(1), states:

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

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

10. Section 4333 of the Code states, in pertinent part:

"(a) All prescriptions filled by a pharmacy and all other records required by Section 4081 shall be maintained on the premises and available for inspection by authorized officers of the law for a period of at least three years. In cases where the pharmacy discontinues business, these records shall be maintained in a board-licensed facility for at least three years."

11. California Code of Regulations, title 16, section 1711, states, in pertinent part:

"(a) Each pharmacy shall establish or participate in an established quality

assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

. . .

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. . . .

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created. . . ."

12. California Code of Regulations, title 16, section 1718, states:

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

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

COST RECOVERY

13. 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.

DANGEROUS DRUGS

14. Xopenex, a brand name for Levalbuterol, is classified as a dangerous drug pursuant to section 4022 of the Code and is used for bronchospasms in patients with reversible obstructive airway disease.

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FIRST CAUSE FOR DISCIPLINE

(Quality Assurance Records Not Immediately Retrievable)

15. Respondent is subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with California Code of Regulations, Title 16, section 1711, subdivisions (e) and (f), in that during an inspection of Apguard Medical on or about May 17, 2007, personnel and / or officers of Apguard Medical were unable to locate the quality assurance records and policy and procedures for medication errors.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Current Inventory)

16. Respondent is subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4081, subdivisions (a) and (b) and California Code of Regulations, Title 16, section 1718, in that Respondent failed to maintain a current and accurate inventory of Xopenex. The circumstances are as follows:

a. An audit of Apguard Medical's purchase and sales records from on or about May 1, 2004 to on or about May 17, 2007, revealed an overage of 10,859 unit-dosed vials of Xopenex 0.63 mg/3mls and 3,556 unit-dose vials of Xopenex 1.25 mg/3mls.

THIRD CAUSE FOR DISCIPLINE

(Purchased Drugs from Unlicensed Wholesaler)

17. Respondent is subject to disciplinary action under section 4301, subdivisions (j) and (o), in conjunction with Code section 4169, subdivision (a)(1), in that Respondent purchased dangerous drugs from an unlicensed wholesaler. The circumstances are as follows:

a. From on or about October 26, 2005 to on or about April 18, 2007, Respondent purchased Xopenex 0.63 mg/3mls and 1.25 mg/3mls from Letco Medical, Inc., located in Decatur, Alabama. Letco Medical was not licensed in California as a non-resident wholesaler until on or about November 1, 2007.

b. An audit of Apguard Medical's purchase records of Xopenex from on or about May 1, 2004 to on or about May 17, 2007, revealed that Apguard Medical purchased

Xopenex from Clifford Victor,[1] who was not licensed as a wholesaler. Mr. Victor worked at Savon Drug Store No. 9655 and diverted the Xopenex from Savon Drugs and sold the Xopenex to Apguard Medical.

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 43386, issued to Apguard Medical, Inc.;

2. Ordering Apguard Medical, Inc. to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

DATED: 2/2/09

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

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1. Clifford Victor was, at the time, employed as a pharamist at Savon Drug. On or about December 6, 2007, Mr. Victor's License No. RPH 41656 was revoked.