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

In the Matter of the Accusation Against: **CABRILLO PHARMACY, ROBERT LOUIS BLOMQUIST** **146 N. Brent Street** **Ventura, CA 93003-805** **Permit No. PHY 48586** **and** **ROBERT LOUIS BLOMQUIST** **146 N. Brent Street** **Ventura, CA 93003** **Pharmacist License No. RPH 37969** Respondents.	Case No. 5729 **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 June 11, 2007, the Board of Pharmacy issued Permit Number PHY 48586 to Robert Louis Blomquist, doing business as Cabrillo Pharmacy. The Permit was in full force an

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effect at all times relevant to the charges brought herein and will expire on June 1, 2017, unless renewed.

3. On or about September 7, 1983, the Board of Pharmacy issued Pharmacist License Number RPH 37969 to Robert Louis Blomquist. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2017, unless renewed. Respondent Robert Louis Blomquist has been designated as the pharmacist-in-charge at Cabrillo Pharmacy since June 11, 2007.

JURISDICTION

4. 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.

5. Section 4300.1 of the Code states:

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

STATUTES AND REGULATIONS

6. 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:

. . .

(c) Gross negligence.

. . .

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

. . . .

7. Section 4307 of the Code states:

"(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, 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, partner, or any other person with management or control 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, partner, or in any other position with management or control 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, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such 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.

8. Section 4169, subdivision (a)(3), of the Code states that a person or entity shall not "[p]urchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code."

9. California Health and Safety Code section 111375, provides in pertinent part:

"Any drug or device is misbranded unless its labeling bears all of the following information:

. . .

"(c) Adequate warning against unsafe dosage or methods or duration of administration or application.

Warnings shall be in a manner and form as are necessary for the protection of users.

If the department determines that any requirement of subdivision (a), as applied to any drug or device, is not necessary for the protection of the public health, the department may adopt regulations exempting the drug or device from these requirements.

. . . .

10. California Health and Safety Code section 111400, provides:

"Any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling."

11. California Health and Safety Code section 111440, provides:

"It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

12. California Code of Regulations, title 16, section 1735.3, provides in part:

"(a) For each compounded drug preparation, pharmacy records shall include:

"(1) The master formula document.

"(2) A compounding log consisting of a single document containing all of the following:

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(A) Name and Strength of the compounded drug preparation.

(B) The date the drug preparation was compounded.

(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

(D) The identity of the pharmacist reviewing the final drug preparation.

(E) The quantity of each ingredient used in compounding the drug preparation.

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply. . .

(G) A pharmacy-assigned unique reference or lot number for the compounded drug preparation.

(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

(I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

"(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

"(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA- registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

"(d) 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 last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection

COST RECOVERY

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.

FACTUAL BACKGROUND

13. Domperidone is an anti-dopaminergic drug that acts as an antiemetic and prokinetic agent. It is used in some countries for the treatment of gastroparesis; however, domperidone is not FDA-approved for use in humans in the United States due to significant health and safety concerns including the potential for sudden death, cardiac arrest and cardiac arrhythmias. The FDA has warned breastfeeding women in particular not to use products containing domperidone due to its associated risks and propensity to be excreted in breast milk. Currently, no pharmacies are authorized to compound domperidone.

14. Despite these prohibitions on the use of domperidone and products containing domperidone, between April 13, 2015 and July 24, 2015, Respondent unlawfully compounded and dispensed 3,715 capsules (filling more than 30 prescriptions) of a drug containing domperidone. In illegally dispensing those capsules, Respondent failed to notify consumers of the risks associated with the drug or of its unapproved status with the FDA. In addition, although Respondent compounded and dispensed 3,715 capsules containing domperidone, Respondent failed to create or maintain compounding records for at least 1115 of those capsules as required by state law.

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FIRST CAUSE FOR DISCIPLINE

(Unlawful Manufacturing & Sale of Misbranded Drugs)

15. Respondent Robert Louis Blomquist, doing business as Cabrillo Pharmacy and individually as pharmacist-in-charge ("PIC") of Cabrillo Pharmacy (collectively "Respondent") is subject to disciplinary action under section 4301, subdivision (j), of the Code in conjunction with sections 111440, 111400 and 111375 of the Health and Safety Code in that Respondent violated state law regulating dangerous drugs by manufacturing, selling, delivering, holding, and/or offering for sale misbranded drugs. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 12 and 13, inclusive, as though set forth fully herein.

SECOND CAUSE FOR DISCIPLINE

(Unlawful Purchase, Trade Sale and/or Transfer of Misbranded Drugs)

16. Respondent is subject to disciplinary action under section 4301, subdivision (o), of the Code in conjunction with section 4169 of the Code in the Respondent violated the California Pharmacy Law by purchasing, trading, selling and/or transferring drugs that Respondent knew or reasonably should have known were misbranded. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 12 and 13, inclusive, as though set forth fully herein.

THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Records)

17. Respondent is subject to disciplinary action under section 4301, subdivision (o), of the Code in conjunction with California Code of Regulations, title 16, section 1735.3, in that Respondent violated state regulations governing the creation and maintenance of pharmacy drug compounding records. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 12 and 13, inclusive, as though set forth fully herein.

FOURTH CAUSE FOR DISCIPLINE

(Gross Negligence)

18. Respondent is subject to disciplinary action under section 4301, subdivision (c), of the Code in that Respondent exhibited gross negligence in compounding and dispensing a non-FDA

approved drug and in failing to create and maintain required records related to that compounding activity. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 12 and 13, inclusive, as though set forth fully herein.

OTHER MATTERS

19. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 48586, issued to Robert Louis Blomquist, doing business as Cabrillo Pharmacy, Robert Louis Blomquist shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 48586 is placed on probation or until Pharmacy Permit Number PHY 48586 is reinstated if it is revoked.

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 48586, issued to Robert Louis Blomquist, doing business as Cabrillo Pharmacy;

2. Revoking or suspending Pharmacist License Number RPH 37969, issued to Robert Louis Blomquist;

3. Prohibiting Robert Louis Blomquist from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee pursuant to Business and Professions Code section 4307;

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4. Ordering Robert Blomquist 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; and,

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

DATED: 7/14/17

Virginia Herold

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

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