KAMALA D. HARRIS
Attorney General of California
JANICE K. LACHMAN
Supervising Deputy Attorney General
ANAHITA S. CRAWFORD
Deputy Attorney General
State Bar No. 209545
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 322-8311
Facsimile: (916) 327-8643
Attorneys for Complainant

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

In the Matter of the Accusation Against: **SIERRA COMPOUNDING PHARMACY** **ROBERT HILBERT SEIWERT, OWNER** **ANGALINE MARIE WUSSTIG, PIC** **1101 Maidu Drive, #200** **Auburn, CA 95603** **Pharmacy Permit No. PHY 49228,** **ANGALINE MARIE WUSSTIG** **3813 Rogue River Circle** **West Sacramento, CA 95691** **Pharmacist License No. RPH 69944,** **and** **KRISTEN R. GORSKI** **12188 Colfax Highway** **Grass Valley, CA 95945** **Pharmacist License No. RPH 67057** Respondents.	Case No. 5534 **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 ("Board"), Department of Consumer Affairs.

2. On or about December 29, 2008, the Board issued Pharmacy Permit Number PHY 49228 to Robert Hilbert Seiwert ("Respondent"), owner of Sierra Compounding Pharmacy. The pharmacy permit was in full force and effect at all times relevant to the charges brought herein and will expire on December 1, 2016, unless renewed.

3. On or about October 3, 2013, the Board issued Pharmacist License Number RPH 69944 to Angaline Marie Wusstig ("Respondent Wusstig"). The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2017, unless renewed.

4. On or about April 19, 2012, the Board issued Pharmacist License Number RPH 67057 to Kristen R. Gorski ("Respondent Gorski"). The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2017, unless renewed.

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 ("Code") unless otherwise indicated.

6. Code section 4300.1 states:

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

7. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

8. Code section 4300 states, in pertinent part:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

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

(4) Revoking his or her license.

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

STATUTORY PROVISIONS

Business and Professions Code (Disciplinary Provisions)

9. Code section 4301 states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . . Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

(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 . . .

10. Code section 4306.5 states, in pertinent part:

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

. . . .

(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 . . .

11. Additionally, Code section 4113, subdivision (c), states that "[t]he 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."

12. Section 4013(a) of the Code states:

> Any facility licensed by the board shall join the board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal.

13. Section 4169 of the Code states:

> (a) A person or entity shall not do any of the following:
>
> . . .
>
> (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

State and Federal Drug Codes (Misbranded Drugs)

14. Health and Safety Code section 111335 states that "[a]ny drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

15. Health and Safety Code section 111400 provides that a drug 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."

16. Title 21, United States Code, section 352 states, in pertinent part:

> A Drug or device shall be deemed to be misbranded --
>
> . . . .
>
> (f) Directions for use and warnings on label
>
> Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost . . .

Health and Safety Codes (Prohibition on Misbranded Drugs)

17. Health and Safety Code section 111440 states that "[i]t is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

18. Health and Safety Code section 111450 provides that it is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

REGULATORY PROVISIONS

19. California Code of Regulations, title 16, section 1735, subdivision (a): states in pertinent part:

> "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
>
> ...

20. California Code of Regulations, title 16, section 1735.2 states:

> ....
>
> (d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:
>
> (1) Active ingredients to be used.
>
> (2) Equipment to be used.
>
> (3) Expiration dating requirements.
>
> (4) Inactive ingredients to be used.
>
> (5) Process and/or procedure used to prepare the drug.
>
> (6) Quality reviews required at each step in preparation of the drug.
>
> (7) Post-compounding process or procedures required, if any.
>
> ...

. . .

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

COST RECOVERY

21. Code section 125.3 provides, in pertinent part, that a 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

22. "Domperidone" is an anti-dopaminergic drug that acts as an antiemetic and a prokinetic agent, and is used to relieve nausea and vomiting and to increase lactation. It is a dangerous drug under Business and Professions Code section 4022. Domperidone is not approved for use in humans in the United States by the Food and Drug Administration. Drug products compounded using domperiodone are subject to the approval requirements of the federal Food, Drug and Cosmetic Act.

FACTUAL BACKGROUND

23. On and between October 16, 2012 and April 24, 2015, Kristen R. Gorski ("Respondent Gorski") was the pharmacist-in-charge at Sierra Compounding Pharmacy. On or about April 27, 2015, Angaline Marie Wusstig ("Respondent Wusstig") replaced Respondent Gorski as the pharmacist-in-charge.

24. On June 7, 2004, the U.S. Food and Drug Administration ("FDA") issued a talk paper titled, "FDA Warns Against Women Using Unapproved Drug, Domperidone, to Increase Milk Production." The paper stated in pertinent part that domperidone is an "unapproved drug," and that it is not approved in the US for human use. It also warned breast-feeding women not to use the product because of safety concerns, and that FDA field personnel were alerted to be on the lookout for attempts to import domperidone so it could be detained. The talk paper indicated that the FDA issued six letters to pharmacies that compound products containing domperidone and firms that supply domperidone for use in compounding. The paper stated, "[t]he letters

violate the Federal Food, Drug, and Cosmetic Act (the Act)[1] because they are unapproved new drugs and misbranded. In addition, distribution within the U.S., or importation of domperidone-containing products, violates the law." Over the next several years, the FDA continued to issue and publish warning letters to laboratories and pharmacies that it identified were distributing and compounding domperidone for human use, in violation of the Act.

25. On March 18, 2011, the FDA issued an import alert for domperidone indicating the agency learned domperidone was being imported as a bulk active pharmaceutical ingredient for pharmacy compounding, which presented a public health risk and violated the Act.

26. On March 12, 2012, the FDA issued a revised import alert for domperidone. This revised import alert stated that ". . . domperidone is not appropriate for pharmacy compounding use because this bulk active ingredient is not a component of an FDA approved drug, or is a component of a drug that was withdrawn or removed from the market for safety reasons."

27. On or about April 14, 2015, the Board of Pharmacy issued a "subscriber alert" to pharmacies and pharmacists stating, "Domperidone is not FDA-approved for any use in humans in the United States. Drug products compounded using domperidone are subject to the approval requirements of the Federal Food, Drug, and Cosmetic Act."

28. Respondents did not possess any FDA approval allowing them to receive or dispense domperidone.

29. On or between April 29, 2014 and April 29, 2015, Respondents compounded 5,191 capsules of various strengths of domperidone which were dispensed on over 50 prescriptions. Respondent pharmacy stated that the pharmacy compounded domperidone pursuant to prescriptions and that the drug had been purchased from PCCA.

30. Invoices from PCCA showed that the pharmacy had purchased domperidone from PCCA on and between August 19, 2014 to April 29, 2015.

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[1] 21 U.S.C. § 301 et seq.

FIRST CAUSE FOR DISCIPLINE

(Failure to Exercise or Implement Best Professional Judgment or Corresponding Responsibility)

31. Respondent Seiwert's pharmacy permit and Respondents Gorski's and Wusstig's pharmacist licenses are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5 subdivision (b), in that Respondents failed to exercise or implement their best professional judgment or corresponding responsibility by compounding and dispensing domperidone, a drug that had not been approved for human use by the FDA and for which the FDA had issued a warning against its use, as further set forth in paragraphs 24-30, above and incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Failing to Consult Appropriate Records)

32. Respondent Seiwert's pharmacy permit and Respondents Gorski's and Wusstig's pharmacist licenses are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5 subdivision (c), in that Respondents failed to consult appropriate FDA records pertaining to the performance of pharmacy functions when they compounded and dispensed domperidone, a drug that had not been approved for human use by the FDA and for which the FDA had issued warnings against its use, as further set forth in paragraphs 24-30, above and incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Received, Delivered and/or Sold Misbranded Drugs)

33. Respondent Seiwert's pharmacy permit and Respondents Gorski's and Wusstig's pharmacist licenses are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301 subdivision (j), for violating statutes regulating dangerous drugs, in that Respondents received, sold and/or delivered misbranded drugs, as defined by Health and Safety Code sections 111335, 111400, and United States Code, title 21, section 352, subdivision (f) and in violation of Health and Safety Code section 111440 and 111450, as further set forth in paragraphs 24-30, above and incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Commission of Prohibited Acts)

34. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), in that Respondents violated or attempted to violate provisions of the pharmacy laws and/or of the applicable federal and state laws and regulations governing pharmacy, when Respondent's received, compounded, delivered and/or sold domperidone without FDA approval in violation of section 4169, subdivision (a)(3), and as more fully set forth in paragraphs 24-33, above, which are incorporated herein by reference.

MATTERS IN AGGRAVATION

35. To determine the degree of discipline to be assessed against Respondents Seiwert and Gorski, if any, Complainant alleges as follows:

Respondent Seiwert/Sierra Compounding Pharmacy

a. On or about June 30, 2011, the Board issued Citation and Fine No. CI 2010 46937 against Sierra Compounding Pharmacy for violating California Code of Regulations ("CCR"), title 16, section 1761, subdivision (a)/Health and Safety Code section 11170 (no pharmacist shall compound or dispense any prescription which contains any significant error or omission/prohibition of prescribing, etc. controlled substance for self); Health and Safety Code section 11165, subdivision (d) (for each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the Department of Justice); and section 4081, subdivision (a)/section 4105, subdivision (a) (records of dangerous drugs kept open for inspection/retaining records of dangerous drugs and devices on licensed premises; temporary removal; waivers; access to electronically maintained records). The Board ordered Respondent to pay a fine of $4,500 by July 30, 2011. The citation has been paid in full and is final.

b. On or about March 24, 2014, the Board issued Citation and Fine No. CI 2013 58024 against Sierra Compounding Pharmacy for violating Title 21, Code of Federal Regulations ("CFR"), section 1304.04, subdivisions (h)(1) and (2) (inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy/Schedules III, IV, and V shall be maintained either separately from all other records of

the pharmacy); Title 21, CFR, section 1301.75, subdivision (b) (controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet); and CCR, title 16, section 1707.5, subdivision (d) (patient-centered labels for prescription drug containers; requirements; pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label). The Board ordered Respondent to pay fines totaling $1,250 by April 23, 2014. The citation has been paid in full and is final.

Respondent Gorski

c. On or about March 24, 2014, the Board issued Citation and Fine No. CI 2013 60613 against Respondent Gorski for violating Title 21, CFR, section 1304.04, subdivisions (h)(1) and (2) (inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy/Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy); Title 21, CFR, section 1301.75, subdivision (b) (controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet); and CCR, title 16, section 1707.5, subdivision (d) (patient-centered labels for prescription drug containers; requirements; pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label) The Board ordered Respondent to pay fines totaling $1,250 by April 23, 2014. The citation has been paid in full and is final.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this Accusation, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacy Permit No. PHY 49228, issued to Robert Hilbert Seiwert, owner of Sierra Compounding Pharmacy;

2. Revoking or suspending Pharmacist License No. RPH 69944, issued to Angaline Marie Wusstig;

3. Revoking or suspending Pharmacist License No. RPH 67057, issued to Kristen R. Gorski;

4. Ordering Robert Hilbert Seiwert, owner of Sierra Compounding Pharmacy, Angaline Marie Wusstig, and Kristen R. Gorski 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: 5/4/16

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

SA2015104447