

**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

OAH No. 2016061130

**STIPULATED SETTLEMENT AND  
DISCIPLINARY ORDER**

**DECISION AND ORDER**

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 1, 2017.

It is so ORDERED on January 30, 2017.

BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA



By

\_\_\_\_\_  
Amy Gutierrez, Pharm.D.  
Board President

1 KAMALA D. HARRIS  
Attorney General of California  
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Supervising Deputy Attorney General  
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7 *Attorneys for Complainant*

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**BOARD OF PHARMACY**  
9 **DEPARTMENT OF CONSUMER AFFAIRS**  
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18 Pharmacist License No. RPH 69944,

19 and

20 **KRISTEN R. GORSKI**  
12188 Colfax Highway  
21 Grass Valley, CA 95945

22 Pharmacist License No. RPH 67057

23 Respondents.  
24

25  
26 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-  
entitled proceedings that the following matters are true:

27 //  
28



1 documents; the right to reconsideration and court review of an adverse decision; and all other  
2 rights accorded by the California Administrative Procedure Act and other applicable laws.

3 8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and  
4 every right set forth above.

5 CULPABILITY

6 9. Respondent admits the truth of each and every charge and allegation in Accusation  
7 No. 5534.

8 10. Respondent agrees that her Pharmacist License is subject to discipline and she agrees  
9 to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

10 CONTINGENCY

11 11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent  
12 understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may  
13 communicate directly with the Board regarding this stipulation and settlement, without notice to  
14 or participation by Respondent or her counsel. By signing the stipulation, Respondent  
15 understands and agrees that he may not withdraw her agreement or seek to rescind the stipulation  
16 prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation  
17 as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or  
18 effect, except for this paragraph, it shall be inadmissible in any legal action between the parties,  
19 and the Board shall not be disqualified from further action by having considered this matter.

20 12. The parties understand and agree that Portable Document Format (PDF) and facsimile  
21 copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile  
22 signatures thereto, shall have the same force and effect as the originals.

23 13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an  
24 integrated writing representing the complete, final, and exclusive embodiment of their agreement.  
25 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,  
26 negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary  
27 Order may not be altered, amended, modified, supplemented, or otherwise changed except by a  
28 writing executed by an authorized representative of each of the parties.

1 14. In consideration of the foregoing admissions and stipulations, the parties agree that  
2 the Board may, without further notice or formal proceeding, issue and enter the following  
3 Disciplinary Order:

4 **DISCIPLINARY ORDER**

5 IT IS HEREBY ORDERED that Pharmacist License Number RPH 67057 issued to Kristen  
6 R. Gorski is revoked. However, the revocation is stayed and Respondent is placed on probation  
7 for two (2) years on the following terms and conditions.

8 1. **Obey All Laws**

9 Respondent shall obey all state and federal laws and regulations.

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

- 12 • an arrest or issuance of a criminal complaint for violation of any provision of the  
13 Pharmacy Law, state and federal food and drug laws, or state and federal controlled  
14 substances laws
- 15 • a plea of guilty or nolo contendere in any state or federal criminal proceeding to any  
16 criminal complaint, information or indictment
- 17 • a conviction of any crime
- 18 • discipline, citation, or other administrative action filed by any state or federal agency  
19 which involves respondent's Pharmacist License or which is related to the practice of  
20 pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging  
21 for any drug, device or controlled substance.

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

23 2. **Report to the Board**

24 Respondent shall report to the board quarterly, on a schedule as directed by the board or its  
25 designee. The report shall be made either in person or in writing, as directed. Among other  
26 requirements, respondent shall state in each report under penalty of perjury whether there has  
27 been compliance with all the terms and conditions of probation. Failure to submit timely reports  
28 in a form as directed shall be considered a violation of probation. Any period(s) of delinquency

1 in submission of reports as directed may be added to the total period of probation. Moreover, if  
2 the final probation report is not made as directed, probation shall be automatically extended until  
3 such time as the final report is made and accepted by the board.

4 **3. Interview with the Board**

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

10 **4. Cooperate with Board Staff**

11 Respondent shall cooperate with the board's inspection program and with the board's  
12 monitoring and investigation of respondent's compliance with the terms and conditions of her  
13 probation. Failure to cooperate shall be considered a violation of probation.

14 **5. Continuing Education**

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

17 **6. Notice to Employers**

18 During the period of probation, respondent shall notify all present and prospective  
19 employers of the decision in case number 5534 and the terms, conditions and restrictions imposed  
20 on respondent by the decision, as follows:

21 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of  
22 respondent undertaking any new employment, respondent shall cause her direct supervisor,  
23 pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's  
24 tenure of employment) and owner to report to the board in writing acknowledging that the listed  
25 individual(s) has/have read the decision in case number 5534, and terms and conditions imposed  
26 thereby. It shall be respondent's responsibility to ensure that her employer(s) and/or supervisor(s)  
27 submit timely acknowledgment(s) to the board.

28

1 If respondent works for or is employed by or through a pharmacy employment service,  
2 respondent must notify her direct supervisor, pharmacist-in-charge, and owner at every entity  
3 licensed by the board of the terms and conditions of the decision in case number 5534 in advance  
4 of the respondent commencing work at each licensed entity. A record of this notification must be  
5 provided to the board upon request.

6 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen  
7 (15) days of respondent undertaking any new employment by or through a pharmacy employment  
8 service, respondent shall cause her direct supervisor with the pharmacy employment service to  
9 report to the board in writing acknowledging that he has read the decision in case number 5534  
10 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure  
11 that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

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

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

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

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

25 **8. Probation Monitoring Costs**

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

3 **9. Status of License**

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

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

11 **10. License Surrender While on Probation/Suspension**

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

19 Upon acceptance of the surrender, respondent shall relinquish her pocket and wall license to  
20 the board within ten (10) days of notification by the board that the surrender is accepted.

21 Respondent may not reapply for any license from the board for three (3) years from the effective  
22 date of the surrender. Respondent shall meet all requirements applicable to the license sought as  
23 of the date the application for that license is submitted to the board, including any outstanding  
24 costs.

25 **11. Notification of a Change in Name, Residence Address, Mailing Address or**  
26 **Employment**

27 Respondent shall notify the board in writing within ten (10) days of any change of  
28 employment. Said notification shall include the reasons for leaving, the address of the new



1 employer, the name of the supervisor and owner, and the work schedule if known. Respondent  
2 shall further notify the board in writing within ten (10) days of a change in name, residence  
3 address, mailing address, or phone number.

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

6 **12. Tolling of Probation**

7 Except during periods of suspension, respondent shall, at all times while on probation, be  
8 employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any  
9 month during which this minimum is not met shall toll the period of probation, i.e., the period of  
10 probation shall be extended by one month for each month during which this minimum is not met.  
11 During any such period of tolling of probation, respondent must nonetheless comply with all  
12 terms and conditions of probation.

13 Should respondent, regardless of residency, for any reason (including vacation) cease  
14 practicing as a pharmacist for a minimum of 40 hours per calendar month in California,  
15 respondent must notify the board in writing within ten (10) days of the cessation of practice, and  
16 must further notify the board in writing within ten (10) days of the resumption of practice. Any  
17 failure to provide such notification(s) shall be considered a violation of probation.

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

21 "Cessation of practice" means any calendar month during which respondent is  
22 not practicing as a pharmacist for at least 40 hours, as defined by Business and  
23 Professions Code section 4000 et seq. "Resumption of practice" means any calendar  
24 month during which respondent is practicing as a pharmacist for at least 40 hours as a  
25 pharmacist as defined by Business and Professions Code section 4000 et seq.

26 **13. Violation of Probation**

27 If a respondent has not complied with any term or condition of probation, the board shall  
28 have continuing jurisdiction over respondent, and probation shall automatically be extended, until

1 all terms and conditions have been satisfied or the board has taken other action as deemed  
2 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and  
3 to impose the penalty that was stayed.

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

11 **14. Completion of Probation**

12 Upon written notice by the board or its designee indicating successful completion of  
13 probation, respondent's license will be fully restored.

14 **15. Remedial Education**

15 Within thirty (30) days of the effective date of this decision, respondent shall submit to the  
16 board or its designee, for prior approval, an appropriate program of remedial education related to  
17 compounding drugs. The program of remedial education shall consist of at least 10 hours, which  
18 shall be completed within 30 months at respondent's own expense. All remedial education shall  
19 be in addition to, and shall not be credited toward, continuing education (CE) courses used for  
20 license renewal purposes.

21 Failure to timely submit or complete the approved remedial education shall be considered a  
22 violation of probation. The period of probation will be automatically extended until such  
23 remedial education is successfully completed and written proof, in a form acceptable to the board,  
24 is provided to the board or its designee.

25 Following the completion of each course, the board or its designee may require the  
26 respondent, at her own expense, to take an approved examination to test the respondent's  
27 knowledge of the course. If the respondent does not achieve a passing score on the examination,

28 //

1 this failure shall be considered a violation of probation. Any such examination failure shall  
2 require respondent to take another course approved by the board in the same subject area.

3 ACCEPTANCE

4 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully  
5 discussed it with my attorney, Natalia Mazina. I understand the stipulation and the effect it will  
6 have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order  
7 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the  
8 Board of Pharmacy.

9  
10 DATED: 11.17.2016   
11 KRISTEN R. GORSKI  
Respondent

12 I have read and fully discussed with Respondent Sierra Compounding Pharmacy; Robert  
13 Hilbert Seiwert, Owner; Angaline Marie Wusstig, PIC the terms and conditions and other matters  
14 contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and  
15 content.

16 DATED: Nov. 17, 2016   
17 NATALIA MAZINA  
18 KELLY, HOCKEL, & KLEIN P.C.  
Attorney for Respondent

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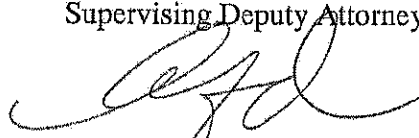
ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated: 11.17.16

Respectfully submitted,

KAMALA D. HARRIS  
Attorney General of California  
JANICE K. LACHMAN  
Supervising Deputy Attorney General



ANAHITA S. CRAWFORD  
Deputy Attorney General  
*Attorneys for Complainant*

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**Exhibit A**

**Accusation No. 5534**

1 KAMALA D. HARRIS  
Attorney General of California  
2 JANICE K. LACHMAN  
Supervising Deputy Attorney General  
3 ANAHITA S. CRAWFORD  
Deputy Attorney General  
4 State Bar No. 209545  
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6 Telephone: (916) 322-8311  
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7 *Attorneys for Complainant*

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**ACCUSATION**

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19 and

20 **KRISTEN R. GORSKI**  
12188 Colfax Highway  
21 Grass Valley, CA 95945

22 Pharmacist License No. RPH 67057

23 Respondents:

24  
25 Complainant alleges:

26 **PARTIES**

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



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- (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."



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

2           Any facility licensed by the board shall join the board's e-mail notification list within  
3           60 days of obtaining a license or at the time of license renewal.

4           13.       Section 4169 of the Code states:

5           (a) A person or entity shall not do any of the following:

6           ...

7           (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or  
8           reasonably should have known were misbranded, as defined in Section 111335 of  
9           the Health and Safety Code.

9           State and Federal Drug Codes (Misbranded Drugs)

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

13          15.       Health and Safety Code section 111400 provides that a drug is misbranded if it is  
14          dangerous to "health when used in the dosage, or with the frequency or duration prescribed,  
15          recommended, or suggested in its labeling."

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

17          A Drug or device shall be deemed to be misbranded --

18          .....  
19          (f) Directions for use and warnings on label

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

27          Health and Safety Codes (Prohibition on Misbranded Drugs)

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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.
- ...

1  
2 (i) The pharmacist performing or supervising compounding is responsible  
3 for the proper preparation, labeling, storage, and delivery of the compounded drug  
4 product.

#### 5 COST RECOVERY

6 21. Code section 125.3 provides, in pertinent part, that a Board may request the  
7 administrative law judge to direct a licentiate found to have committed a violation or violations of  
8 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and  
9 enforcement of the case.

#### 10 DRUG

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

#### 17 FACTUAL BACKGROUND

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

22 24. On June 7, 2004, the U.S. Food and Drug Administration ("FDA") issued a talk  
23 paper titled, "FDA Warns Against Women Using Unapproved Drug, Domperidone, to Increase  
24 Milk Production." The paper stated in pertinent part that domperidone is an "unapproved drug,"  
25 and that it is not approved in the US for human use. It also warned breast-feeding women not to  
26 use the product because of safety concerns, and that FDA field personnel were alerted to be on  
27 the lookout for attempts to import domperidone so it could be detained. The talk paper indicated  
28 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

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

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

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

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

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

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

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

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28 <sup>1</sup> 21 U.S.C. § 301 et seq.

1 **FIRST CAUSE FOR DISCIPLINE**

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

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

11 **SECOND CAUSE FOR DISCIPLINE**

12 **(Failing to Consult Appropriate Records)**

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

20 **THIRD CAUSE FOR DISCIPLINE**

21 **(Received, Delivered and/or Sold Misbranded Drugs)**

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

1 **FOURTH CAUSE FOR DISCIPLINE**

2 **(Commission of Prohibited Acts)**

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

9 **MATTERS IN AGGRAVATION**

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

12 **Respondent Seiwert/Sierra Compounding Pharmacy**

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

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

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

8 **Respondent Gorski**

9 c. On or about March 24, 2014, the Board issued Citation and Fine No. CI 2013  
10 60613 against Respondent Gorski for violating Title 21, CFR, section 1304.04, subdivisions  
11 (h)(1) and (2) (inventories and records of all controlled substances listed in Schedules I and II  
12 shall be maintained separately from all other records of the pharmacy/Schedules III, IV, and V  
13 shall be maintained either separately from all other records of the pharmacy); Title 21, CFR,  
14 section 1301.75, subdivision (b) (controlled substances listed in Schedules II, III, IV, and V shall  
15 be stored in a securely locked, substantially constructed cabinet); and CCR, title 16, section  
16 1707.5, subdivision (d) (patient-centered labels for prescription drug containers; requirements;  
17 pharmacy shall have policies and procedures in place to help patients with limited or no English  
18 proficiency understand the information on the label) The Board ordered Respondent to pay fines  
19 totaling \$1,250 by April 23, 2014. The citation has been paid in full and is final.

20 **PRAYER**

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

- 23 1. Revoking or suspending Pharmacy Permit No. PHY 49228, issued to Robert Hilbert  
24 Seiwert, owner of Sierra Compounding Pharmacy;
- 25 2. Revoking or suspending Pharmacist License No. RPH 69944, issued to Angaline  
26 Marie Wusstig;
- 27 3. Revoking or suspending Pharmacist License No. RPH 67057, issued to Kristen R.  
28 Gorski;

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4. Ordering Robert Hilbert Seiwert, owner of Sierra Compounding Pharmacy, Angeline 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*  
VIRGINIA HEROLD  
Executive Officer  
Board of Pharmacy  
Department of Consumer Affairs  
State of California  
*Complainant*

SA2015104447