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8  
9 **BEFORE THE**  
**BOARD OF PHARMACY**  
10 **DEPARTMENT OF CONSUMER AFFAIRS**  
**STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 4846

12 **CORONADO PHARMACY**  
13 **918 Orange Avenue**  
14 **Coronado, CA 92118**  
**Pharmacy Permit No. PHY 32888**

**A C C U S A T I O N**

15 **and**

16 **PHILIP HELMSTETTER**  
17 **255 Alameda Blvd.**  
**Coronado, CA 92118**  
18 **Registered Pharmacist No. 41208**

19 Respondents.

20  
21 Complainant alleges:

22 **PARTIES**

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

25 2. On or about July 1, 1986, the Board of Pharmacy issued Pharmacy Permit Number  
26 PHY 32888 to Coronado Pharmacy (Respondent Coronado). The Pharmacy Permit expired on  
27 July 1, 2011, and has not been renewed.  
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1           9.    Section 4059.5 of the Code states:

2                       (b) A dangerous drug or dangerous device transferred, sold, or delivered  
3                       to a person within this state shall be transferred, sold, or delivered only to an entity  
4                       licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's  
5                       agent.

6           10.   Section 4105 of the Code states:

7                       (a) All records or other documentation of the acquisition and disposition  
8                       of dangerous drugs and dangerous devices by any entity licensed by the board shall be  
9                       retained on the licensed premises in a readily retrievable form.

10          11.   Section 4113 of the Code states:

11                       . . . .

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

15          12.   Section 4301 of the Code states:

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

20                      . . . .

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

23                      . . . .

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

                         . . . .

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

13.   Health and safety code section 11165 provides:

                         (a) To assist law enforcement and regulatory agencies in their efforts to  
                         control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV  
                         controlled substances, and for statistical analysis, education, and research, the  
                         Department of Justice shall, contingent upon the availability of adequate funds from  
                         the Contingent Fund of the Medical Board of California, the Pharmacy Board  
                         Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund,

1 and the Osteopathic Medical Board of California Contingent Fund, maintain the  
2 Controlled Substance Utilization Review and Evaluation System (CURES) for the  
3 electronic monitoring of, and Internet access to information regarding, the prescribing  
4 and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by  
5 all practitioners authorized to prescribe or dispense these controlled substances.

6 (b) The reporting of Schedule III and Schedule IV controlled substance  
7 prescriptions to CURES shall be contingent upon the availability of adequate funds  
8 from the Department of Justice. The department may seek and use grant funds to pay  
9 the costs incurred from the reporting of controlled substance prescriptions to CURES.  
10 Funds shall not be appropriated from the Contingent Fund of the Medical Board of  
11 California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board  
12 of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic  
13 Medical Board of California Contingent Fund to pay the costs of reporting Schedule  
14 III and Schedule IV controlled substance prescriptions to CURES.

15 (c) CURES shall operate under existing provisions of law to safeguard  
16 the privacy and confidentiality of patients. Data obtained from CURES shall only be  
17 provided to appropriate state, local, and federal persons or public agencies for  
18 disciplinary, civil, or criminal purposes and to other agencies or entities, as determined  
19 by the Department of Justice, for the purpose of educating practitioners and others in  
20 lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private  
21 entities, as approved by the Department of Justice, for educational, peer review,  
22 statistical, or research purposes, provided that patient information, including any  
23 information that may identify the patient, is not compromised. Further, data disclosed  
24 to any individual or agency as described in this subdivision shall not be disclosed, sold,  
25 or transferred to any third party.

26 (d) For each prescription for a Schedule II, Schedule III, or Schedule IV  
27 controlled substance, as defined in the controlled substances schedules in federal law  
28 and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of  
Title 21 of the Code of Federal Regulations, the dispensing pharmacy or clinic shall  
provide the following information to the Department of Justice on a weekly basis and  
in a format specified by the Department of Justice:

(1) Full name, address, and the telephone number of the ultimate user or  
research subject, or contact information as determined by the Secretary of the United  
States Department of Health and Human Services, and the gender, and date of birth of  
the ultimate user.

(2) The prescriber's category of licensure and license number; federal  
controlled substance registration number; and the state medical license number of any  
prescriber using the federal controlled substance registration number of a government-  
exempt facility.

(3) Pharmacy prescription number, license number, and federal  
controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance  
dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Number of refills ordered.

1 (8) Whether the drug was dispensed as a refill of a prescription or as a  
first-time request.

2 (9) Date of origin of the prescription.

3 (10) Date of dispensing of the prescription.

4 **REGULATORY PROVISIONS**

5 14. Title 16, California Code of Regulations, Section 1708.2 provides:

6 Any permit holder shall contact the board prior to transferring or selling  
7 any dangerous drugs, devices or hypodermics inventory as a result of termination of  
8 business or bankruptcy proceedings and shall follow official instructions given by the  
board applicable to the transaction.

9 15. Title 16, California Code of Regulations, Section 1709.1 provides:

10 (a) The pharmacist-in-charge of a pharmacy shall be employed at that  
location and shall have responsibility for the daily operation of the pharmacy.

11 (b) The pharmacy owner shall vest the pharmacist-in-charge with adequate  
12 authority to assure compliance with the laws governing the operation of a pharmacy.

13 **COST RECOVERY**

14 16. Section 125.3 of the Code provides, in pertinent part, that the Board may request the  
15 administrative law judge to direct a licentiate found to have committed a violation or violations of  
16 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and  
17 enforcement of the case.

18 **FACTS SUPPORTING CAUSES FOR DISCIPLINE**

19 17. Respondent Coronado Pharmacy was licensed in 1986. The Pharmacy was owned by  
20 L. T. Helmstetter, who was also its President. Anne Helmstetter was the Vice President. When L.  
21 T. Helmstetter passed away, the ownership of the Pharmacy was bequeathed to his son, Phillip L.  
22 Helmstetter. No documentation of this transfer of ownership was ever filed with the Board which  
23 continued to list L. T. Helmstetter as the Owner and President and Anne Helmstetter as the Vice  
24 President of the Pharmacy.

25 18. Phillip L. Helmstetter, the Respondent here, was hired as the Pharmacist in Charge  
26 (PIC) of the Pharmacy as reported to the Board in 1997.  
27  
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1           19.   Sometime in April of 2011 the pharmacy closed, but it did not notify the Board of its  
2 closure, the disposition of controlled substances and dangerous drugs, or the disposition of its  
3 records.

4           20.   On May 26, 2011, based upon a complaint, the Board attempted to inspect the  
5 Pharmacy, and found it shut and under construction. The Board's inspector was unable to reach  
6 the Pharmacy by telephone.

7           21.   On June 1, 2011, a letter and notice of noncompliance was sent to the Pharmacy for  
8 failure to notify the Board of the termination of business. Further efforts to reach the Pharmacy by  
9 telephone failed.

10          22.   On July 5, 2011, the Board's inspector was able to reach Respondent Phillip  
11 Helmstetter by telephone. Respondent Helmstetter told the Board's inspector that the pharmacy  
12 closed on approximately April 30, 2011, that he was storing the controlled substances and  
13 dangerous drugs from the pharmacy at his home on 255 Alameda Blvd. in Coronado, California,  
14 and that the prescription files and invoices were stored in a storage facility.

15          23.   When Respondent Helmstetter was informed that proper procedure to close the  
16 pharmacy and store the medications and records had not been followed, he told the Board's  
17 inspector that he would transfer the medication and files to Rite Aid.

18          24.   On August 10, 2011, the Board's inspector left a notice of noncompliance at the home  
19 address of Respondent Helmstetter.

20          25.   On November 1, 2011, the Board's inspector mailed a letter with a copy of the August  
21 10, 2011 notice of noncompliance to the home address of Respondent Helmstetter directed him to  
22 contact the inspector immediately upon receipt. Respondent Helmstetter did not respond.

23          26.   On November 9, 2011, the Board's inspector called and spoke with Respondent  
24 Helmstetter who told him that the Discontinuance of Business for the pharmacy had not been  
25 completed and the controlled substances and dangerous drugs were still stored at his home  
26 address. The inspector directed Respondent to move the drugs to a licensed facility and to notify  
27 him by November 17, 2011 where they were stored.

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1 27. Through his investigation, the Board's inspector determined that on or about March  
2 16, 2012, some controlled substances and dangerous drugs were sent from 255 Alameda Ave., the  
3 address listed for Coronado Pharmacy, to a reverse distributor.

4 28. On June 1, 2012, the Board's inspector mailed a letter to L.T, Anne, and Phillip  
5 Helmstetter requesting information regarding the disposition of the pharmacy records which are  
6 required to be stored in a licensed premises.

7 29. As of June 5, 2012, the Discontinuance of Business had still not been filed by  
8 Coronado Pharmacy.

9 30. On June 8, 2012, Anne Helmstetter called the inspector and told him she would speak  
10 to Phillip Helmstetter and have her lawyer take care of any paperwork that needed to be filed.  
11 On that day, the Board's inspector sent a letter to Anne Helmstetter with a copy of the August 10,  
12 2011 noncompliance notice previously sent to Respondent Helmstetter.

13 31. Respondent Coronado had not properly reported CURES from March 30, 2007 to the  
14 date of its closure.

15 32. Because the inspector was never able to inspect the pharmacy records, and no cures  
16 reports were ever filed, the Board's inspector was never able to verify whether all of the controlled  
17 substances and dangerous drugs that Respondent was storing in his home were sent to the reverse  
18 distributor.

19 **Charges Against Respondent Coronado Pharmacy**

20 **FIRST CAUSE FOR DISCIPLINE**

21 **(Failure to Notify Board When Business Discontinued)**

22 33. Respondent Coronado Pharmacy is subject to disciplinary action under Code section  
23 4300 and 4301, subdivision (o), for violating title 16, Code of Regulations, section 1708.2 in that  
24 neither the Pharmacy nor its Pharmacist in Charge notified the Board when it discontinued its  
25 business and transferred its inventory of dangerous drugs such that the Board could give the  
26 Pharmacy official instructions applicable to the closure of the Pharmacy, as set forth more fully in  
27 paragraphs 17 to 32 above.

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1 **SECOND CAUSE FOR DISCIPLINE**

2 **(Failure to Maintain Records in Licensed Facility in Retrievable Form)**

3 34. Respondent Coronado Pharmacy is subject to disciplinary action under Code section  
4 4300 and 4301, subdivision (o), for violating section 4105(a) by failing to maintain records and  
5 other documentation of the acquisition and disposition of dangerous drugs and devices on the  
6 licensed premises in a readily retrievable form. When Coronado Pharmacy closed, the PIC stored  
7 the Pharmacy's prescription files and invoices for the purchase of dangerous drugs in a storage  
8 facility not licensed by the Board and not readily retrievable by the Board, as set forth more fully in  
9 paragraphs 17 to 32 above.

10 **THIRD CAUSE FOR DISCIPLINE**

11 **(Transferred and Delivered Dangerous Drugs to Unlicensed Facility)**

12 35. Respondent Coronado Pharmacy is subject to disciplinary action under Code section  
13 4300 and 4301, subdivision (o), for violating section 4059.5, subdivision (b), in that dangerous  
14 drugs and devices may only be transferred, sold or delivered to an entity licensed by the Board, to  
15 a manufacturer or to an ultimate user or user's agent. When Coronado Pharmacy closed, the PIC  
16 transferred the inventory of dangerous drugs from the Pharmacy to his residence located at 255  
17 Alameda Blvd., Coronado, California, an unlicensed facility, where he purportedly stored them, as  
18 set forth more fully in paragraphs 17 to 32 above.

19 **FOURTH CAUSE FOR DISCIPLINE**

20 **(Failed to File CURES Reports)**

21 36. Respondent Coronado Pharmacy is subject to disciplinary action under Code section  
22 4300 and 4301, subdivision (o), for violating Health and Safety Code section 11165, subdivision  
23 (d), for failing to file a weekly CURES report regarding the filling of prescriptions of Schedule II,  
24 III, and IV controlled substances with the Department of Justice from March 2007 to the date of  
25 its closure, as set forth more fully in paragraphs 17 to 32 above.

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1 **Charges Against Respondent Phillip Helmstetter, PIC of Coronado Pharmacy**

2 **FIFTH CAUSE FOR DISCIPLINE**

3 **(Failure to Notify Board When Business Discontinued)**

4 37. Respondent Helmstetter, PIC of Coronado Pharmacy, is subject to disciplinary action  
5 under Code section 4300 and 4301, subdivision (o), for violating title 16, Code of Regulations,  
6 section 1708.2 in that he failed to notify the Board when Coronado Pharmacy discontinued its  
7 business and transferred its inventory of dangerous drugs such that the Board could give the  
8 Pharmacy and him official instructions applicable to the closure of the Pharmacy, as set forth more  
9 fully in paragraphs 17 to 32 above. As PIC, Respondent Helmstetter was responsible for  
10 Coronado Pharmacy's compliance with Pharmacy Board rules and regulations.

11 **SIXTH CAUSE FOR DISCIPLINE**

12 **(Failure to Maintain Records in Licensed Facility in Retrievable Form)**

13 38. Respondent Helmstetter, PIC of Coronado Pharmacy, is subject to disciplinary action  
14 under Code section 4300 and 4301, subdivision (o), for violating section 4105, subdivision (a) for  
15 failing to maintain records and other documentation of the acquisition and disposition of  
16 dangerous drugs and devices on the licensed premises in a readily retrievable form. When  
17 Coronado Pharmacy closed, the PIC Helmstetter stored the Pharmacy's prescription files and  
18 invoices for the purchase of dangerous drugs and controlled substances in a storage facility not  
19 licensed by the Board and not readily retrievable by the Board, as set forth more fully in  
20 paragraphs 17 to 32 above.

21 **SEVENTH CAUSE FOR DISCIPLINE**

22 **(Transferred and Delivered Dangerous Drugs to Unlicensed Facility)**

23 39. Respondent Helmstetter, PIC of Coronado Pharmacy, is subject to disciplinary action  
24 under Code section 4300 and 4301, subdivision (o), for violating section 4059.5, subdivision (b),  
25 in that dangerous drugs and devices may only be transferred, sold or delivered to an entity licensed  
26 by the Board, to a manufacturer or to an ultimate user or user's agent. When Coronado Pharmacy  
27 closed, PIC Helmstetter transferred the inventory of dangerous drugs from the Pharmacy to his  
28

1 residence located at 255 Alameda Blvd., an unlicensed facility, where he purportedly stored them,  
2 as set forth more fully in paragraphs 17 to 32 above.

3 **EIGHTH CAUSE FOR DISCIPLINE**

4 **(Failed to File CURES Reports)**

5 40. Respondent Helmstetter, PIC of Coronado Pharmacy, is subject to disciplinary action  
6 under Code section 4300 and 4301, subdivision (o), for violating Health and Safety Code section  
7 11165, subdivision (d), for failing to file a weekly CURES report regarding Coronado Pharmacy's  
8 filling of prescriptions of Schedule II, III, and IV controlled substances with the Department of  
9 Justice from March 2007 to the date of the closure, as set forth more fully in paragraphs 17 to 32  
10 above.

11 **NINTH CAUSE FOR DISCIPLINE**

12 **(Unprofessional Conduct – Violation of Pharmacy Laws)**

13 41. Respondent Helmstetter, PIC of Coronado Pharmacy, and licensed Pharmacist is  
14 subject to disciplinary action for unprofessional conduct pursuant to Code sections 4300 and 4301,  
15 subdivisions (j), (o) and (q), for violating Pharmacy Board and other state and federal laws and  
16 regulations regarding Pharmacy. As PIC, Respondent Helmstetter was responsible for Coronado  
17 Pharmacy's compliance with Pharmacy Board rules and regulations. Respondent Helmstetter  
18 violated the law when he closed the licensed establishment without notifying the board and  
19 obtaining direction for the management of the closure, stored the inventory of controlled  
20 substances and dangerous drugs in his home, stored the Pharmacy's prescription and drug records  
21 in an unlicensed and unsecure location thus preventing the Board from being able to conduct an  
22 inspection of the facility, its inventory, and its records, as required by Pharmacy Law. Respondent  
23 Helmstetter failed to timely respond and cooperate with the Board's inspection and his conduct  
24 subverted the Board's ability to monitor the licensed facility and enforce pharmacy law, as set forth  
25 more fully in paragraphs 17 to 32 above.

26 **DISCIPLINE CONSIDERATIONS**

27 42. To determine the degree of discipline, if any, to be imposed on Respondent Phillip L.  
28 Helmstetter, Complainant alleges that on or about November 29, 2012, in a prior action, the Board

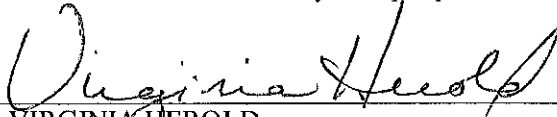
1 of Pharmacy issued Citation Number CI 2011 48883 and ordered Respondent to pay a fine of  
2 \$2,000.00. The citation arose out of an arrest and subsequent conviction for driving under the  
3 influence of drugs/alcohol, subsequently amended to reckless driving, in 2011. The citation  
4 charged a violation of Code section 4301(h) for unprofessional conduct for the use of any  
5 dangerous drug or alcoholic beverage in a dangerous manner and section 4301(l), conviction of a  
6 substantially related crime. That Citation is now final and is incorporated by reference as if fully  
7 set forth.

8 PRAYER

9 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,  
10 and that following the hearing, the Board of Pharmacy issue a decision:

- 11 1. Revoking or suspending Pharmacy Permit Number PHY 32888, issued to Coronado  
12 Pharmacy;
- 13 2. Revoking or suspending Pharmacist License Number 41208 issued to Philip  
14 Helmstetter;
- 15 3. Ordering Phillip L. Helmstetter to pay the Board of Pharmacy the reasonable costs of  
16 the investigation and enforcement of this case, pursuant to Business and Professions Code section  
17 125.3;
- 18 4. Taking such other and further action as deemed necessary and proper.

19 DATED: 6/7/14

  
20 VIRGINIA HEROLD  
21 Executive Officer  
22 Board of Pharmacy  
23 Department of Consumer Affairs  
24 State of California  
25 Complainant

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