

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

In the Matter of the Accusation Against:

CORONADO PHARMACY,

Pharmacy Permit No. PHY 32888,

and

PHILIP L. HELMSTETTER,

Registered Pharmacist No. 41208

Respondents.

Case No. 4846

OAH No. 2015020391

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective on December 4, 2015.

It is so ORDERED on November 4, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

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PROPOSED DECISION

Adam L. Berg, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter in San Diego, California, on September 10, 2015.

Diane De Kervor, Deputy Attorney General, Office of the Attorney General, State of California, represented complainant, Virginia Herold, Executive Officer, Board of Pharmacy, Department of Consumer Affairs, State of California.

Philip L. Helmstetter, respondent, represented himself and Coronado Pharmacy.

The matter was submitted on September 10, 2015.

FACTUAL FINDINGS

License Background

1. On July 1, 1986, the board issued original permit number PHY 32888 to L.T. Helmstetter Inc. to do business as Coronado Pharmacy.

L.T. Helmstetter and Anne P. Helmstetter are listed in board records as joint owners of Coronado Pharmacy.

Respondent, Philip Helmstetter, has been listed as the Pharmacist-in Charge (PIC) since October 7, 1997

The permit expired on July 1, 2011. There is no history of discipline against Coronado Pharmacy.

2. On September 26, 1987, the board issued original pharmacist license number RPH 41208 to respondent. The license was in full force and effect at all times relevant to this proceeding.

On November 29, 2012, the board issued citation number CI 2011 48883 against respondent, for use of an alcoholic beverage in a manner as to be dangerous to oneself or others, and for conviction of a substantially related crime. The citation arose out of an arrest and conviction on November 3, 2011, for "wet" reckless driving, in violation of Vehicle Code section 23103. The board assessed a fine of \$2,000.

Jurisdictional Matters

3. On June 7, 2014, complainant signed the accusation seeking the revocation or suspension of Coronado Pharmacy's permit and respondent's pharmacist license.

The accusation alleged that Coronado Pharmacy and respondent individually: failed to notify the board when Coronado Pharmacy discontinued its business; failed to maintain records and documentation of the disposition of dangerous drugs and devices;¹ transferred dangerous drugs and devices to an entity not licensed by the board; and failed to file weekly Controlled Substance Utilization Review and Evaluation System (CURES) reports with the Department of Justice (DOJ). Additionally, the accusation alleged that respondent committed unprofessional conduct based on the above allegations.

On July 14, 2014, the board received respondent's Notice of Defense.

4. At the hearing, respondent claimed that he did not receive notice of the hearing until the deputy attorney general contacted him several days before. On February 27, 2015, the Attorney General's Office sent the hearing notice by certified mail to Coronado Pharmacy's and respondent's addresses of record. Respondent conceded that he moved and did not notify the board of his new address until after the hearing notice was mailed.

Respondent requested a continuance in order to seek legal representation. Respondent stated that he did not seek representation when he received the accusation

¹ Under Business and Professions Code section 4022, a "dangerous drug" or "dangerous device" includes the following: any drug or device that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import; or any other drug or device that by federal or state law can be lawfully dispensed only on prescription.

because "he did not know any attorneys." Respondent's motion was denied for failure to show good cause. Respondent was served with the accusation on July 1, 2014. Accordingly, he had ample opportunity to seek representation and prepare a defense. Although respondent claimed he did not receive the hearing notice, respondent failed to update his address as required.

5. At the hearing, complainant's counsel amended the accusation without objection, by changing the sentence, on page 5, lines 20 and 21: "When L. T. Helmstetter passed away, the ownership of the Pharmacy was bequeathed to his son, Phillip L. Helmstetter" to read "The ownership of the Pharmacy was transferred to Philip L. Helmstetter."

The Closure of Coronado Pharmacy

6. On March 9, 2011, the board received a consumer complaint against Coronado Pharmacy relating to its dispensing practices. The board assigned the complaint to Ben Rustia, Pham. D., a board inspector since 2008. Mr. Rustia has been a licensed pharmacist since 1980 and has worked in a variety of retail and hospital pharmacies.

7. On May 26, 2011, Mr. Rustia attempted to conduct an inspection of Coronado Pharmacy. When Mr. Rustia went to Coronado Pharmacy he found the building vacant and under construction. On June 1, 2011, Mr. Rustia sent a letter and written notice of noncompliance to Coronado Pharmacy and to respondent, Coronado Pharmacy's PIC. In that letter, Mr. Rustia notified respondent that a pharmacy permit holder is required by regulation to contact the board prior to transferring or selling any dangerous drugs or devices as a result of termination of a business. Mr. Rustia asked that respondent submit the disposition of the inventory of dangerous drugs within 14 days.

8. Mr. Rustia did not receive a response from respondent or Coronado Pharmacy. After numerous attempts at calling respondent, Mr. Rustia spoke to respondent by phone on July 5, 2011. Respondent told Mr. Rustia that Coronado Pharmacy had closed on or about April 30, 2011. Respondent told Mr. Rustia that he was storing the inventory of dangerous drugs and devices at his home. Respondent stated that the prescription files and invoices were being held in a storage facility.

Mr. Rustia informed respondent that dangerous drugs and devices, as well as records, must be stored at a board-licensed facility. Respondent stated that he was not sure where he could store the inventory. Mr. Rustia suggested that respondent contact another pharmacy to see if they would store Coronado Pharmacy's drug inventory and records.

9. On August 10, 2011, Mr. Rustia and another board inspector went to respondent's residence in order to serve a written notice of noncompliance. An adult at the residence said she was the housekeeper and that respondent was not presently at home. Mr. Rustia gave the adult the notice of noncompliance with instructions to give it to respondent. Respondent did not contact Mr. Rustia.

10. On November 1, 2011, Mr. Rustia sent a letter by certified mail to respondent. The letter notified respondent that as PIC, he was required to comply with regulations relating to the discontinuance of business. Mr. Rustia requested that respondent contact him within 48 hours of receipt. Mr. Rustia included with the letter the August 10, 2011, notice of noncompliance. Respondent did not contact Mr. Rustia.

11. On November 9, 2011, Mr. Rustia called respondent. Respondent said that he had not completed the discontinuance of business form. Respondent said that the dangerous drugs and devices were still being stored at his residence. Mr. Rustia advised respondent that the discontinuance of business form was available from the board's website. Mr. Rustia instructed respondent to move the dangerous drugs to a licensed premises and notify Mr. Rustia where the drugs were being stored by November 17, 2011. Again, Mr. Rustia did not receive a response.

12. On March 12, 2012, Mr. Rustia met with Drug Enforcement Administration (DEA) officials to discuss Coronado Pharmacy's storage of controlled substances at respondent's residence. On April 21, 2012, the DEA sent Mr. Rustia a copy of a manifest from a board-licensed return distributor listing the drugs and controlled substances respondent had returned on or about March 30, 2012. A reverse distributor is a facility licensed to receive returned drugs.

13. On June 1, 2012, Mr. Rustia sent a letter to respondent requesting information regarding the disposition of Coronado Pharmacy's records, which are required to be stored at board-licensed premises. Mr. Rustia sent copies of this letter to L.T. Helmstetter and Anne Helmstetter, who were listed in board records as the owners of Coronado Pharmacy.

14. On June 8, 2012, Mr. Rustia spoke to Anne Helmstetter. Mrs. Helmstetter explained that L.T. Helmstetter had passed away, and respondent was the sole owner of Coronado Pharmacy. Mrs. Helmstetter said that she thought respondent had changed the ownership information with the board, and she would contact her attorney.

On July 3, 2012, Janet McDonough, Attorney at Law, sent Mr. Rustia a letter stating that respondent and his wife, Catherine Helmstetter, purchased L.T. Helmstetter, Inc. and Coronado Pharmacy in 2005. Ms. McDonough noted that L.T. Helmstetter passed away on April 17, 2009.

15. On July 17, 2012, Mr. Rustia wrote respondent in his capacity as owner of Coronado Pharmacy. Mr. Rustia again asked that respondent provide the board with information on the location of the records of acquisition and disposition of drugs. Mr. Rustia also requested that respondent submit a discontinuance of business form.

16. The board never received a discontinuance of business form for Coronado Pharmacy.

17. For approximately 11 months after Coronado Pharmacy had closed, respondent stored controlled substances and dangerous drugs and devices at his home.

18. Respondent never responded to any of Mr. Rustia's requests to provide information on the disposition of the pharmacy's drug inventory and records.

19. Mr. Rustia requested a CURES report for Coronado Pharmacy. Mr. Rustia testified that a pharmacy dispensing controlled substances is required to submit CURES data to the DOJ weekly. The report showed that from January 2005 to when Coronado Pharmacy closed in April 2011, Coronado Pharmacy submitted CURES data on only four occasions: February 2005, January 2006, March 2007, and May 2007.

Respondent's Testimony

20. Respondent testified that he became the PIC of Coronado Pharmacy in 1997. In 2005, he and his wife purchased the pharmacy from his parents. Respondent testified that the landlord raised the pharmacy's rent. Respondent had difficulty paying bills and employees. Respondent stopped taking a salary. With the increase in rent, Coronado Pharmacy could not stay afloat. The pharmacy was served with a 30-day eviction notice. However, respondent believed that he could save the pharmacy from closure. At the end of April 2011, Coronado Pharmacy was evicted from the building.

Respondent believed that he could keep the pharmacy open so he was unprepared when he was evicted. He transferred the entire inventory of drugs to his residence and stored them in the garage. He stored the pharmacy's records in a rented storage facility. He testified that the paper files have since been destroyed because he could not afford to pay rent on the storage facility. His electronic records are held at another community pharmacy. Around this time, his wife filed for divorce. Respondent testified that he was extremely stressed and did the best he could. He attempted to call other pharmacies to see if they would hold his inventory but he received no response. Respondent testified that he did receive notice from the board requesting information about the pharmacy's closure and the disposition of the drug inventory, although he claimed that he did not receive every letter. Respondent said that he sent his entire inventory of drugs to the reverse distributor.

Respondent blamed the board for not helping him with his situation. He questioned why the board did not take possession of the drugs when it knew he was storing them at his residence. He testified that he was overwhelmed by the situation and distraught about the closure of his family business. He conceded that he "put his head in the sand" about the situation and ignored the board's requests because he thought the situation would "just go away." Even when he received notice that the pharmacy was being evicted, he thought he could salvage the situation. He did not think that the pharmacy would close and did not make a plan.

21. Respondent testified about his failure to file CURES reports. He testified that he did not understand the CURES reporting process even though Coronado Pharmacy did

dispense controlled substances. He testified that CURES was not in place when he studied to be a pharmacist. Respondent's testimony indicated that he had little knowledge about a pharmacy's responsibilities regarding CURES reporting. He said that he was the only pharmacist at Coronado Pharmacy, and he became overwhelmed with the responsibility. For a long time, the pharmacy did not have a pharmacy technician. He said the pharmacy did not have the software or technology needed to file CURES reports. He did not know where to turn for help. He could not afford to join the local pharmacy association. He said compliance with CURES would have put him out of business as Coronado Pharmacy simply could not have afforded it.

22. Respondent said that he is a safe pharmacist. He has worked as a staff pharmacist for a retail chain establishment since 2012. He has no desire to ever work as a PIC. He said that working for a chain pharmacy has provided him access to information that he was unaware of when he was working at Coronado Pharmacy.

23. Respondent did not wish to retain Coronado Pharmacy's registration as the business has been closed. Respondent testified that the corporation has been dissolved and has no assets. He thought that his former wife had taken care of the change in ownership paperwork with the board. He felt that she left him "holding the bag" to deal with the pharmacy's closure.

24. Respondent expressed great concern that his license may be revoked. He said that he has two children in college whom he supports and needs his job. He has no idea what kind of work he could do if he were to lose his license. Respondent said that he would comply with any terms of probation required by the board.

25. Respondent has not taken any classes or continuing education relating to pharmacy law or controlled substances.

26. Respondent did not think the board should revoke his license for what he described as a "paperwork issue." He said that if Mr. Rustia had done more to help respondent transfer the drug inventory, the situation could have been avoided. He likened his delay in transferring the drugs to a licensed facility to Mr. Rustia's delay in conducting an inspection following the receipt of a consumer complaint. Respondent admitted that he made mistakes but contended that he "did the best that he could" given the situation. Respondent stated that he kept the drugs secure in his garage and that, ultimately, he transferred all of them to a licensed-facility. Respondent reiterated the stress of losing his family business and the pressure he was under during that time.

Respondent's Evidence

27. Respondent submitted a completed discontinuance of business form. Respondent testified that he faxed this form to the board on an unknown date. Respondent did not have fax confirmation. The signatures on the form were dated May 1, 2011. Respondent said he did not sign the form on that date, rather it was the date Coronado

Pharmacy closed. The form reflected that respondent performed an inventory of the drugs on February 28, 2012. Respondent submitted no other evidence establishing that he submitted the form to the board.

The board has no record of having received this form. Even if respondent did submit the form to the board, it was after February 28, 2012, ten months after the pharmacy closed.

Cost Recovery

28. Complainant submitted a certification of costs and requested cost recovery pursuant to Business and Professions Code section 125.3. The certification contained information related to services provided by the Office of the Attorney General and included costs of prosecution that totaled \$6,605.00. An additional certification contained information related to investigative costs that totaled \$3,495.00. The evidence established that those costs were reasonably incurred. The certification complied with the requirements of California Code of Regulations, title 1, section 1042, subdivision (b).

Respondent's ability to pay costs is dependent on his ability to continue work as a pharmacist.

LEGAL CONCLUSIONS

Burden and Standard of Proof

1. Complainant bears the burden of proof of establishing that the charges in the accusation are true. (Evid. Code § 115.) The standard of proof in an administrative action seeking to suspend or revoke a professional license is "clear and convincing evidence." (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) Clear and convincing evidence requires a finding of high probability, or evidence so clear as to leave no substantial doubt; it requires sufficiently strong evidence to command the unhesitating assent of every reasonable mind. (*Katie V. v. Superior Court* (2005) 130 Cal.App.4th 586, 594.)

Relevant Statutory Authority

2. Business and Professions Code section 4300, subdivision (a), states that every license issued may be suspended or revoked.

3. Business and Professions Code section 4301 provides that the board may take action against any holder of a license who is guilty of unprofessional conduct. Unprofessional conduct includes 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.

[¶] . . . [¶]

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

4. Under Business and Professions Code section 4059.5, subdivision (b): “A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user’s agent.”

5. Under Business and Professions Code section 4105, subdivision (a): “All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.”

6. Under Business and Professions Code section 4113, subdivision (c), the pharmacist-in-charge shall be responsible for a pharmacy’s compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

7. Health and Safety Code section 11165, subdivision (d), requires a pharmacy to report to the DOJ information relating to the dispensing of Schedule II, III, and IV controlled substances, not more than seven days after the date the controlled substance is dispensed.

8. California Code of Regulations, title 16, section 1708.2, provides: “Any permit holder shall contact the board prior to transferring or selling any dangerous drugs, devices or hypodermics inventory as a result of termination of business or bankruptcy proceedings and shall follow official instructions given by the board applicable to the transaction.”

Evaluation

9. Respondent, as PIC of Coronado Pharmacy, was responsible for the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. (Bus. & Prof. Code, § 4113, subd. (c); *Sternberg v. Board of Pharmacy* (2015) 239 Cal.App.4th 1159.) It is undisputed that respondent and Coronado Pharmacy, in violation of California Code Regulations, title 16, section 1708.2, failed to notify the board prior to transferring dangerous drugs or devices as a result of the pharmacy's termination of business. Despite numerous requests by the board for respondent and Coronado Pharmacy to provide this information, respondent and Coronado Pharmacy failed to comply with the regulation. Respondent and Coronado Pharmacy transferred the pharmacy's inventory of dangerous drugs to respondent's home, an unlicensed facility, in violation of Business and Professions Code, section 4059.5, subdivision (b). Respondent and Coronado Pharmacy transferred the pharmacy's records relating to the acquisition and disposition of dangerous drugs to a storage locker, an unlicensed facility, in violation of Business and Professions Code section 4105, subdivision (a).

Between March 2007 and Coronado Pharmacy's closure in April 2011, Coronado Pharmacy and respondent submitted to the DOJ CURES reports on only four occasions. Despite the fact that Coronado Pharmacy was dispensing controlled substances, respondent and Coronado Pharmacy failed to submit weekly CURES reports as required by Health and Safety Code section 11165, subdivision (d).

Respondent stored controlled substances and dangerous drugs at his home. He stored his drug records in an unlicensed storage facility. Respondent's actions prevented the board from being able to conduct an inspection of Coronado Pharmacy's records and inventory as required by law. Respondent failed to respond to the board's numerous requests for information. The board directed respondent to immediately transfer his inventory of drugs and records to a licensed facility. Respondent failed to comply with these requests. Not until the DEA intervened, did respondent send his inventory to a licensed reverse-distributor. Respondent's failure to comply with the board's directions subverted the board's ability to monitor the licensed facility and enforce the pharmacy laws. Respondent's actions constituted unprofessional conduct. (Bus. & Prof. Code, § 4301, subs. (o) & (q).)

Cause Exists to Impose Discipline

10. Cause exists to revoke or suspend Coronado Pharmacy's permit and respondent's license, pursuant to Business and Professions Code sections 4300 and 4301, subdivision (o), on the grounds that Coronado Pharmacy, and respondent as PIC, failed to notify the board when the pharmacy discontinued business and transferred its inventory of dangerous drugs as required under California Code of Regulations, title 16, section 1708.2.

11. Cause exists to revoke or suspend Coronado Pharmacy's permit and respondent's license, pursuant to Business and Professions Code sections 4300 and 4301, subdivision (o), on the grounds that Coronado Pharmacy, and respondent as PIC, failed to

maintain records and other documentation of the acquisition and disposition of dangerous drugs and devices in a licensed premises in a readily retrievable form as required under Business and Professions Code section 4105, subdivision (a).

12. Cause exists to revoke or suspend Coronado Pharmacy's permit and respondent's license, pursuant to Business and Professions Code sections 4300 and 4301, subdivision (o), on the grounds that Coronado Pharmacy, and respondent as PIC, transferred its inventory of dangerous drugs and devices from the pharmacy to an unlicensed facility, in violation of Business and Professions Code section 4059.5, subdivision (b).

13. Cause exists to revoke or suspend Coronado Pharmacy's permit and respondent's license, pursuant to Business and Professions Code sections 4300 and 4301, subdivision (o), on the grounds that Coronado Pharmacy, and respondent as PIC, failed to file CURES reports with the Department of Justice regarding the filling of prescriptions of controlled substances as required under Health and Safety Code section 11165, subdivision (d).

14. Cause exists to revoke or suspend respondent's license, pursuant to Business and Professions Code section 4301, subdivision (q), on the grounds that respondent committed unprofessional conduct by subverting the board's ability to monitor a licensed facility and enforce pharmacy laws.

Measure of Discipline

15. The purpose of an administrative proceeding seeking the revocation or suspension of a professional license is not to punish the individual; the purpose is to protect the public from dishonest, immoral, disreputable or incompetent practitioners. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.)

16. Under California Code of Regulations, title 16, section 1760, in imposing discipline on a license, the board shall consider the disciplinary guidelines. Under the disciplinary guidelines, in determining the level of discipline, the following factors should be considered: actual or potential harm to the public; actual or potential harm to any consumer; prior disciplinary record, including level of compliance with disciplinary order(s); prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s); number and/or variety of current violations; nature and severity of the act(s), offense(s) or crime(s) under consideration; aggravating evidence; mitigating evidence; rehabilitation evidence; time passed since the act(s) or offense(s); whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct; and financial benefit to the respondent from the misconduct.

17. The disciplinary guidelines have established three categories of violations and grouped statutes and regulations where violations would typically merit the recommended

range of minimum to maximum penalties for that category. The categories are one through three, with category three violations being the most serious. For multiple violations, the appropriate penalty shall increase accordingly. If violations are committed in more than one category, the minimum and maximum penalties shall be recommended in the highest category.

A violation of Business and Professions Code sections 4059.5 (transfer of dangerous drugs and devices) and 4301, subdivision (o) (unprofessional conduct), are category three violations. The minimum recommended discipline is a 90 day suspension with three to five years' probation. The maximum recommended discipline is revocation.

CORONADO PHARMACY'S PERMIT

18. Respondent testified that Coronado Pharmacy remains closed and that he has no intention of reopening. Respondent did not wish to maintain Coronado Pharmacy's permit. Based on the evidence of multiple violations, Coronado Pharmacy's permit is revoked.

RESPONDENT'S LICENSE

19. Rehabilitation is a state of mind. The law looks with favor on one who has achieved reformation and regeneration. (*Hightower v. State Bar* (1983) 34 Cal.3d 150, 157.) The absence of a prior disciplinary record is a mitigating factor. (*Chefsky v. State Bar* (1984) 36 Cal.3d 116, 132, fn. 10.) Remorse and cooperation are mitigating factors. (*In re Demergian* (1989) 48 Cal.3d 284, 296.) While a candid admission of misconduct and full acknowledgment of wrongdoing may be a necessary step in the rehabilitation process, it is only a first step. A truer indication of rehabilitation is presented if an individual demonstrates by sustained conduct over an extended period of time that he is once again fit to practice. (*In re Trebilcock* (1981) 30 Cal.3d 312, 315-316.)

20. The disciplinary guidelines provide a non-exhaustive list of the evidence a respondent may submit to demonstrate his rehabilitative efforts and competency. Relevant to this matter, are recent written statements or performance evaluations from persons in position of authority who have on-the-job knowledge of respondent's current competence in the practice of pharmacy. Respondent provided no such evidence.

Respondent's testimony demonstrated a failure to comprehend the nature of the proceedings and the board's concern about respondent's ability to safely practice. Respondent showed a lack of knowledge of a pharmacist's responsibilities with regard to CURES. He admitted failing to comply with the rules and regulations governing pharmacists and suggested that costs of compliance would have forced him out of business because Coronado Pharmacy did not have the necessary software. Respondent noted that he was running a solo pharmacy, that his pharmacy training predated CURES, and that he was overwhelmed by other responsibilities. When respondent was questioned about his yearly

certifications required as the PIC, where respondent certified that he was compliant with CURES, respondent suggested that he was too busy to read the certifications.

Although the closure of his family business was no doubt stressful and upsetting to respondent, respondent chose to ignore his responsibilities. Storing dangerous drugs and controlled substances in his home garage was reckless and dangerous. Respondent failed to appreciate the seriousness of his actions, and instead, referred to it as a "paperwork" issue. Respondent claimed that he did the best he could under the circumstances. However, when the board informed respondent that he was non-compliant, he failed to take appropriate action. Instead, of taking responsibility, he blamed the board for not assisting him with the transfer of the drug inventory to a licensed facility. Instead of reaching out to the board for assistance, respondent simply chose to ignore the board's requests.

After he was served with the accusation, respondent ignored the pending disciplinary charges as well. He failed to update his address with the board after moving, which caused him not to receive the hearing notice. Respondent insisted that he is safe to practice as a pharmacist. However, despite receiving the accusation approximately 14 months earlier, respondent has not demonstrated an understanding for why the board was seeking discipline. By casting this as a "paper work issue," respondent clearly failed to appreciate the seriousness of his conduct and the potential danger to the public. Moreover, respondent repeatedly deflected his conduct on to others: his former wife, who was a co-owner of the pharmacy who "left him holding the bag;" the board inspector who could have assisted him more with the situation; and other pharmacies that would not accept his inventory of drugs. Respondent's conduct did not establish that he is an appropriate candidate for probation.

Pharmacists must be able to perform competently in a stressful work environment. Mistakes made by a pharmacist can have serious, significant consequences to patients, including death. Respondent presented no evidence of rehabilitation or that he is safe to practice as a pharmacist. Respondent's conviction for wet reckless driving is a further aggravating factor. In light of the multiple violations, and applying the board's disciplinary guidelines, revocation is the only measure of discipline that can protect the public.

Costs of Investigation and Enforcement

21. Business and Professions Code section 125.3, subdivision (a), authorizes an administrative law judge to direct a licensee who has violated the applicable licensing act to pay a sum not to exceed the reasonable costs of investigation and prosecution. The reasonable costs in this matter were \$10,100.00.

22. In *Zuckerman v. Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, 45, the California Supreme Court set forth five factors to be considered in determining whether a particular licensee should be ordered to pay the reasonable costs of investigation and prosecution under statutes like Business and Professions Code section 125.3. Those factors are: whether the licensee has been successful at hearing in getting charges dismissed or reduced, the licensee's subjective good faith belief in the merits of his or her position,

whether the licensee has raised a colorable challenge to the proposed discipline, the financial ability of the licensee to pay, and whether the scope of the investigation was appropriate in light of the alleged misconduct. (*Ibid.*)

23. Applying the *Zuckerman* factors to this case leads to the following conclusions: respondent was not successful in getting any of the charges dismissed or reduced; although he might have exhibited a subjective good faith belief in the merits of his position, he did not raise a colorable challenge to the proposed discipline; and the scope of the investigation was appropriate in light of the alleged misconduct. Finally, respondent's ability to pay costs is limited because of his ability to obtain employment other than as a pharmacist. Coronado Pharmacy has been dissolved and has no assets.

24. In light of the revocation of respondent's license, he will not be ordered to pay costs at this time. Should respondent, or Coronado Pharmacy, petition for reinstatement, and should the board grant the petition, the board may order respondent or Coronado Pharmacy to pay the \$10,100.00 in costs as a condition of reinstatement.

ORDER

Pharmacy Permit Number PHY 32888 issued to Coronado Pharmacy is revoked.

Registered Pharmacist Number RPH 41208 issued to respondent, Philip Helmstetter, is revoked.

Respondent shall relinquish his wall license and pocket renewal license to the board within 10 days of the effective date of this decision. Respondent may not reapply or petition the board for reinstatement of his revoked license for three years from the effective date of this decision.

DATED: October 9, 2015

DocuSigned by:



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ADAM L. BERG
Administrative Law Judge
Office of Administrative Hearings

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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.
28

1 3. On or about September 26, 1987, the Board of Pharmacy issued Registered
2 Pharmacist License Number 41208 to Philip Helmstetter (Respondent Helmstetter). The license
3 will expire on December 31, 2014, if it is not renewed. Respondent Helmstetter was the
4 Pharmacist in Charge of Coronado Pharmacy from July 1, 2011 until it closed.

5 JURISDICTION

6 4. This Accusation is brought before the Board of Pharmacy (Board), Department of
7 Consumer Affairs, under the authority of the following laws. All section references are to the
8 Business and Professions Code unless otherwise indicated.

9 5. Section 4300, subdivision (a) of the Code states "Every license issued may be
10 suspended or revoked."

11 6. Section 4300.1 states:

12 The expiration, cancellation, forfeiture, or suspension of a board-issued
13 license by operation of law or by order or decision of the board or a court of law, the
14 placement of a license on a retired status, or the voluntary surrender of a license by a
15 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.

16 STATUTORY PROVISIONS

17 7. Section 4022 of the Code states

18 "Dangerous drug" or "dangerous device" means any drug or device
unsafe for self use in humans or animals, and includes the following:

19 (a) Any drug that bears the legend: "Caution: federal law prohibits
20 dispensing without prescription," "Rx only," or words of similar import.

21 (b) Any device that bears the statement: "Caution: federal law restricts this
22 device to sale by or on the order of a _____," "Rx only," or words of similar
import, the blank to be filled in with the designation of the practitioner licensed to use
or order use of the device.

23 (c) Any other drug or device that by federal or state law can be lawfully
24 dispensed only on prescription or furnished pursuant to Section 4006.

25 8. Section 4036.5 of the Code states:

26 'Pharmacist-in-charge' means a pharmacist proposed by a pharmacy and
27 approved by the board as the supervisor or manager responsible for ensuring the
pharmacy's compliance with all state and federal laws and regulations pertaining to the
practice of pharmacy.

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9. Section 4059.5 of the Code states:

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

10. Section 4105 of the Code states:

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

11. Section 4113 of the Code states:

....

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

12. Section 4301 of the Code states:

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

....

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

....

(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
business or bankruptcy proceedings and shall follow official instructions given by the
8 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.
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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.

28

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

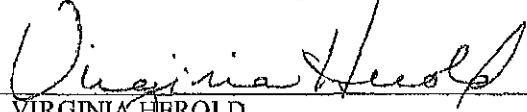
1 of Pharmacy issued Citation Number CI 2011 48883 and ordered Respondent to pay a fine of
2 \$2,000.00. The citation arose out of an arrest and subsequent conviction for driving under the
3 influence of drugs/alcohol, subsequently amended to reckless driving, in 2011. The citation
4 charged a violation 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

24 SD2013705631
25 70768135.doc