KAMALA D. HARRIS
Attorney General of California
JANICE K. LACHMAN
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
State Bar No. 258229
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 324-5403
Facsimile: (916) 327-8643
Attorneys for Complainant

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

In the Matter of the Accusation Against: **PCC VENTURES LLC,** **dba PHARMACY CARE CONCEPTS** **STEPHEN L. STANGE, PIC** **HAROLD G. DELAMARTER, MEMBER** **GREGORY JOHN VISLOCKY, MEMBER** **RICK B. DELAMARTER, MD, MEMBER** **SCOTT BRADLEY HANCOCK, MEMBER** **TRACY WILLIAM ZARLING, MEMBER** **PAUL ERNEST HAFFNER, MEMBER** **7720 Lorraine Avenue, Suite 102/103** **Stockton, CA 95210** **Original Pharmacy Permit No. PHY 51484** **and** **STEPHEN L. STANGE** **4230 Heron Lakes Drive** **Stockton, CA 95219** **Pharmacist License No. RPH 28242** Respondents.	Case No. 5294 **A C C U S A T I O N**

Complainant alleges:

PARTIES/LICENSE INFORMATION

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

2. On or about March 14, 2001, the Board issued Original Pharmacy Permit Number PHY 45169 to Pharmacy Care Concepts, Inc., with Stephen L. Stange ("Respondent Stange") as pharmacist-in-charge ("PIC") and president/treasurer. The pharmacy permit was canceled on July 2, 2013, due to a change in ownership of the pharmacy, as set forth in paragraph 3 below.

3. On or about July 1, 2013, the Board issued Original Pharmacy Permit Number PHY 51484 to PCC Ventures LLC ("Respondent PCC" or "PCC"), doing business as Pharmacy Care Concepts, with Respondent Stange as PIC and Harold G. Delamarter, Gregory John Vislocky, Rick B. Delamarter, MD, Scott Bradley Hancock, Tracy William Zarling, and Paul Ernest Haffner as members. The pharmacy permit was in full force and effect at all times relevant to the charges brought herein and will expire on July 1, 2016, unless renewed.

4. On or about April 24, 1973, the Board issued Pharmacist License Number RPH 28242 Respondent Stange. The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2017, unless renewed.

JURISDICTION

5. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

STATUTORY AND REGULATORY PROVISIONS

6. Code section 4300 states, in pertinent part:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper . . .

///

7. Code section 4300.1 states:

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

8. Code section 4301 states, in pertinent part:

> 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:
>
> . . . .
>
> (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 . . . .

9. Code section 4032 states that "[l]icense means and includes any license, permit, registration, certificate, or exemption issued by the board and includes the process of applying for and renewing the same."

10. Code section 4022 states:

> "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:
>
> (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
>
> (b) Any device that bears the statement: "Caution: federal law restricts this 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.
>
> (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

11. Code section 4063 states, in pertinent part, that "[n]o prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given orally or at the time of giving the original prescription . . ."

///

12. Code section 4105, subdivision (a), states that "[a]ll 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."

13. 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.

14. California Code of Regulations, title 16, section ("Regulation") 1714, subdivision (d), states:

> Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

COST RECOVERY

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

CONTROLLED SUBSTANCES/DANGEROUS DRUGS

16. "Norco", "Lortab", and "Vicodin ES" are compounds consisting of varying quantities of acetaminophen and hydrocodone bitartrate, also known as dihydrocodeinone, and are Schedule III controlled substances as designated by Health and Safety Code section 11056, subdivision (e)(4). Norco, Lortab, and Vicodin ES are used to relieve moderate to severe pain.

17. "Percocet" is a compound consisting of oxycodone and acetaminophen, and is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (b)(1)(M). Percocet is used to relieve moderate to severe pain.

18. "Methadose", a brand of methadone hydrochloride, is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (c)(14). Methadose is used to treat opioid addiction as well as relieve severe pain.

///

19. "Concerta", a brand of methylphenidate, is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (d)(6). Concerta is used to treat attention deficit hyperactivity disorder (ADHD).

20. "Fentanyl" is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (c)(8). Fentanyl is used as part of anesthesia to help prevent pain after surgery or other medical procedure.

21. "Adderall XR" is a compound consisting of mixed salts of dextroamphetamine and/or amphetamine, and is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (d)(1). Adderall XR is indicated for the treatment of ADHD.

22. The above controlled substances are dangerous drugs within the meaning of Code section 4022 in that they require a prescription under federal law.

BACKGROUND

23. On or about November 6, 2013, the Board received a report from PIC Stange, notifying them that an unlicensed staff member, M. M., may have obtained 960 tablets of Norco 10/325 mg from the pharmacy without a valid prescription. PIC Stange stated that on or about June 10, 2013, a legal prescription was obtained from a physician's assistant for M. M.'s husband, J. M., for 240 tablets of Norco 10/325 mg, *with zero refills.* On August 2, 2013, M. M. presented a photocopy of the prescription to the billing technician, who processed it, and the prescription was then filled by pharmacy technician C. L. M. M. took the prescription before it was reviewed by a pharmacist.

24. PIC Stange also stated that on August 29, 2013, September 14, 2013, and October 2, 2013, M. M. presented C. L. with prescription labels "from the initial dispensing date (August 2, 2013)." C. L. filled the prescriptions (240 tablets of Norco 10/325 mg in each instance) after M. M. "promised" that she had a valid refill for each label. It appeared that M. M. took each of the prescriptions before final review by a pharmacist.

25. PIC Stange listed various corrective actions the pharmacy had taken since the incident, including filing a police report with the Stockton Police Department and suspending

///

M. M. from her employment on October 12, 2013 (M. M. subsequently resigned on October 14, 2013).

26. On or about November 14, 2013, the Board sent a letter to PIC Stange, requesting certain information and documents pertaining to the reported theft/loss of controlled substances.

27. On or about December 19, 2013, the Board received various documents from PIC Stange, including a Drug Enforcement Agency (DEA) Form 106 dated October 16, 2013. PCC reported a loss of controlled substances valued at $2,000, including 14,706 tablets of hydrocodone/acetaminophen 10/325; the type of theft/loss was listed as "Employee Pilferage". PIC Stange also provided the Board with a statement, indicating that the business was sold to PCC on June 27, 2013, and that he and the new owner, pharmacist Scott Hancock ("Hancock"), conducted an inventory or audit of Schedule 2 medications and hydrocodone-related products, which "reflected a much larger problem than previously discovered." PIC Stange submitted a copy of the audit; it was conducted for the time period from June 28, 2013 to November 26, 2013. PIC Stange indicated in an additional statement that the audit was based on an inventory from June 27, 2013 to November 26, 2013, purchase records from various wholesalers, including Valley Wholesale and HD Smith (Smart Source), prescription utilization reports, and reverse distributor reports.

28. On or about January 17, 2014, PIC Stange submitted additional documents to the Board, including a letter dated January 10, 2014. PIC Stange stated that since the reported loss of controlled substances following the sale of PCC was significant, he and Hancock conducted another audit for a time period prior to the sale, specifically, from January 18, 2013 (the date the last biennial inventory was completed at PPC prior to the sale) to June 27, 2013 (the date of sale). This audit revealed significant losses as well, as set forth below. PIC Stange also provided DEA Form 106 dated January 14, 2014, showing that the losses applied to Pharmacy Care Concepts,

///

///

///

///

Inc. PIC Stange stated in an additional statement to the Board that the audit was based on inventory records from January 18, 2013 to June 26, 2013, purchase records from wholesalers Valley Wholesale and HD Smith, prescription utilization reports, and reverse distributor reports.

Drug and Strength	Quantity Reported Loss (Units) for Audit Period from 01/18/2013 – 11/26/2013
hydrocodone/acetaminophen 10/325 mg	20,601
hydrocodone/acetaminophen 10/500 mg	489
hydrocodone/acetaminophen 7.5/325 mg	2,230
hydrocodone/acetaminophen 7.5/500 mg	705
hydrocodone/acetaminophen 7.5/750 mg	3,604
hydrocodone/acetaminophen 5/325 mg	850
hydrocodone/acetaminophen 5/500 mg	1,192
Fentanyl 12 mcg patch	17
Mixed amphetamine salts ER 20 mg	90

29. On or about March 4, 2014, Board Inspector C. H. conducted an inspection and investigation at the pharmacy.

30. C. H. asked PIC Stange if they ever found the original prescription. PIC Stange told C. H. that they only had a copy. C. H. asked PIC Stange why the prescription was filled when only a copy of the original prescription was presented. PIC Stange stated that he thought M. M. may have exploited the normal workflow for long-term care facilities.

31. PIC Stange explained that for some controlled substance prescriptions, the board and care facility had the original order from the patient or the patient's family. The care facility normally faxed a copy of the original prescription to PCC so the order could be prepared for the patient and delivered the same day. The fax copy of the prescription was sent through the workflow in order to get it filled, and the medication was then placed in a bin for delivery the same day. Once the medication was delivered, the original prescription was picked up and brought to the pharmacy that day. The pharmacist would sign the original prescription as well as the faxed copy, indicating final review of the prescription. The clerk or technician would keep a second copy of the prescription at their workstation as a reminder to follow up with the pharmacist and driver to ensure the original prescription was brought to the pharmacy. The only copy the pharmacy had of the prescription was the one found next to clerk S. The copy had not

///

been signed by a pharmacist. PIC Stange told C. H. he verified with the physician's assistant that the prescription was valid and that there were no refills authorized.

32. C. H. obtained various documents from the pharmacy, including a copy of the original prescription and copies of pharmacy labels confirming that the prescription was processed as RX# 1326725 on August 2, 2013, with no refills. C. H. also obtained a controlled substances inventory log, purchase records from June 28, 2013 to November 26, 2013, from Smart Source, Cardinal, and Valley Wholesale, and drug usage reports from June 28, 2013 to November 26, 2013, for each controlled substance included in the audit.

33. On or about May 30, 2014, C. H. sent HD Smith and Valley Wholesaler requests for copies of records of purchases, sales, returns, and credits for certain products sold to or purchased from PCC for the time period from June 28, 2013 through November 26, 2013.

34. On or about June 2, 2014, C. H. received copies of purchase records from HD Smith. C. H. found that the purchase record data corresponded to the data from PCC's audit.

35. On or about June 5, 2014, C. H. received copies of purchase records from Valley Wholesaler. C. H. reviewed the purchase data twice for accuracy and compared it to the purchase data reported in PCC's audit. C. H. found no discrepancies.

36. On or about June 20, 2014, C. H. used the documents she received from PCC, including the inventory records, purchase records, and dispensing records, to verify their audit results for all drugs which showed a significant loss, as well as oxycodone IR (all strengths), methadone 5 mg, methylphenidate 36 mg, and oxycodone/acetaminophen 5/325 mg and 10/325. C. H. found no discrepancies. C. H. then used the purchase records she received from HD Smith and Valley Wholesaler to independently verify selected PCC audit entries for the

///

///

///

///

///

///

hydrocodone/acetaminophen products with a significant loss. C. H. found no discrepancies. The audit conducted by PCC revealed the following losses as verified by C. H.:

Drug and Strength	Reported Loss (Units) for Audit Period from 06/28/2013 – 11/26/2013	% of Acquisition
hydrocodone/acetaminophen 10/325 mg	14,706	34.2
hydrocodone/acetaminophen 10/500 mg	204	40.8
hydrocodone/acetaminophen 7.5/325 mg	911	13.6
hydrocodone/acetaminophen 7.5/500 mg	614.5	61.4
hydrocodone/acetaminophen 7.5/750 mg	751	150
oxycodone/acetaminophen 10/325 mg	141	3.8
methadone 5 mg	100	8.3
methylphenidate 36 mg	30	33

CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and State Laws and Regulations Governing Pharmacy)

37. Respondents PCC and Stange are subject to disciplinary action pursuant to Code section 4301, subdivision (o), for unprofessional conduct, in that Respondents violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.) and state laws and regulations governing pharmacy, as follows:

a. On or about August 29, 2013, September 14, 2013, and October 2, 2013, Respondents PCC and Stange authorized or permitted pharmacy technician C. L. to dispense refills of RX# 1326725, for 240 tablets of the controlled substance hydrocodone/acetaminophen 10/325 mg, for patient J. M. when, in fact, the physician's assistant who issued the original prescription had not authorized any refills, in violation of Code section 4063.

b. Respondents PCC and Stange failed to maintain on their premises and/or have available for inspection by Board inspector C. H. the original prescription for RX# 1326725 issued for patient J. M., as set forth in paragraphs 30 and 31 above, in violation of Code section 4105.

c. On and between June 28, 2013 and November 26, 2013, Respondents PCC and Stange failed to maintain or ensure the security of the prescription department and/or include

provisions for effective control against theft or diversion of dangerous drugs and devices, resulting in a significant loss of controlled substances, as set forth in paragraph 36 above, in violation of Regulation 1714, subdivision (d).

d. On and between January 18, 2013 and June 27, 2013, Respondent Stange failed to maintain or ensure the security of the prescription department and/or include provisions for effective control against theft or diversion of dangerous drugs and devices, resulting in a significant loss of controlled substances, as set forth in paragraph 28 above, in violation of Regulation 1714, subdivision (d).

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 51484, issued to PCC Ventures LLC, doing business as Pharmacy Care Concepts;

2. Revoking or suspending Pharmacist License Number RPH 28242, issued to Stephen L. Stange;

3. Ordering PCC Ventures LLC, doing business as Pharmacy Care Concepts, and Stephen L. Stange 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;

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

DATED: 9/12/15

Virginia Herold

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

SA2014117593