KAMALA D. HARRIS
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General
LESLIE A. BURGERMYER
Deputy Attorney General
State Bar No. 117576
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 324-5337
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: **ANDERSON BROS. TOWN & COUNTRY PHARMACY, INC.** **Stephen Vincent Anderson, President** **John Harold Anderson, Secretary** **2900 Fulton Avenue** **Sacramento, California 95821** **Pharmacy Permit Number No. PHY 49115** **And** **STEPHEN VINCENT ANDERSON,** **Pharmacist-In-Charge** **2900 Fulton Avenue** **Sacramento, California 95821** **Pharmacist License Number No. RPH 42685** Respondents.	Case No. 5489 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about September 11, 2008, the Board issued Pharmacy Permit Number PHY 49115 to Anderson Bros. Town & Country Pharmacy, Inc. ("Respondent Pharmacy"). The

Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2016, unless renewed.

3. On or about August 8, 1989, the Board issued Pharmacist License Number RPH 42685 to Stephen Vincent Anderson ("Respondent Anderson"). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2017, unless renewed. At all times alleged herein, Respondent Anderson was the Pharmacist-in-Charge of Anderson Bros. Town & Country Pharmacy, Inc. within the meaning of Business and Professions Code section 4113.

4. As used herein, "Respondents" shall collectively refer to Respondent Pharmacy and Respondent Anderson.

JURISDICTION

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

6. Section 4300 of the Code 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. Section 4300.1 of the Code 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.

STATUTORY PROVISIONS

8. Code section 4301 states, in pertinent part:

(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.

9. Code section 4342 states, in pertinent part:

(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

10. Section 4022 of the Code 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 4023.5 states:

For the purpose of this chapter, "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

12. Code section 4081 states, in pertinent part:

(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

13. Code section 4113 states, in pertinent part:

(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.

14. Code section 4114 states, in pertinent part:

(a) An intern pharmacist may perform all functions of a pharmacist at the discretion of and under the direct supervision and control of a pharmacist whose license is in good standing with the board.

15. Health and Safety Code section 111255 states:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

16. Health and Safety Code section 111295 states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

REGULATORY PROVISIONS

17. California Code of Regulations, title 16, section 1714 states, in pertinent part:

(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

. . .

(d) 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

18. Section 125.3 of the Code states, in pertinent part, that the 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.

BACKGROUND

19. On or about February 4, 2015, a Board inspector conducted a routine inspection of Respondent Pharmacy. Respondent Anderson is, and was, the Pharmacist-In-Charge at Respondent Pharmacy since on or about September 11, 2008.

20. During the February 4, 2015, routine inspection, the Board inspector observed two pharmacy interns, M.H. and K.P, performing pharmacist duties of final inspection verification while working alone in a room separate from on-duty Pharmacist C.J., and without the pharmacist's direct supervision and control.

21. During the February 4, 2015, routine inspection, the Board inspector found a room in the pharmacy where he observed shelves contained hundreds of vials, bottles, boxes, and punch cards of dangerous and controlled drugs. Most of them were labeled with Respondent Pharmacy's name, including patients' names, and categorized as follows:

a. "Return to stock prescriptions." The inspector observed this category to include filled and labeled vials and punch cards filled recently which had not been delivered to or picked up by patients, had not left the pharmacy, and were labeled as within the manufacturers' or pharmacy's labeled expiration date;

b. "Returned prescriptions." The inspector observed this category to include prescriptions that had been delivered or picked up by patients and returned to the pharmacy. The drugs included a combination of vials and punch cards, with Respondent Pharmacy's label, patients' names, labeled within the manufacturers' or pharmacy's expiration date or outside the expiration date. Sealed punch card cells contained none to many different drugs, and some had an empty cell with foil and paper shreds partially covering the cell;

c. "Outdated drugs." The inspector observed this category to include drugs that were beyond the manufacturers' or Respondent Pharmacy's labeled expiration date and included returned prescriptions (vials and punch cards) and handwritten notations as being expired;

d. "Unlabeled drugs." The inspector observed this category to include bottles and vials containing outdated drugs.

22. The drugs mentioned in paragraph 20, and its subparts, above, were stored in a manner that Respondent Anderson conceded to the inspector that he, Anderson, could not totally distinguish whether the drugs were safe to use. Due to the intermingling of the drugs, it could not be determined if they had not been altered, adulterated, or lacked quality.

23. Respondents failed to maintain an inventory record of the drugs allegedly returned to the pharmacy from patients. The Board inspector instructed Respondents to prepare and submit an inventory of the drugs and to destroy them. Attached hereto, marked Addendum A, and incorporated herein is a true and correct copy of the inventory of drugs, referenced above, that was prepared by Respondents and submitted to the Board on or about February 11, 2015.

FIRST CAUSE FOR DISCIPLINE

(Failure to Supervise Pharmacist Interns)

24. Respondent Pharmacy is subject to disciplinary action under Code sections 4300 and 4301, subdivisions (j) and (o), in conjunction with Code section 4114, in that on or about February 4, 2015, it failed to provide direct supervision and control of Interns M.H and K.P. as alleged in paragraphs 19 and 20, above, incorporated herein by reference.

25. Respondent Anderson, Pharmacist-in-Charge of Respondent Pharmacy, is subject to disciplinary action under Code sections 4300 and 4301, subdivisions (j) and (o), in conjunction with Code section 4113, in that on or about February 4, 2015, he failed to provide direct supervision and control of Interns M.H and K.P. as alleged in paragraphs 19 and 20, above, incorporated herein by reference.

///

///

///

SECOND CAUSE FOR DISCIPLINE

(Altered, Adulterated, Lack of Quality Drugs)

26. Respondent Pharmacy and Respondent Anderson, Pharmacist-in-Charge, are subject to disciplinary action under Code sections 4300 and 4301, subdivisions (j) and (o), in conjunction with Code sections 4081, subdivision (a), and 4342, subdivision (a), and Health and Safety Code sections 111255 and 111295, and California Code of Regulations, title 16, section 1714, subdivision (b), in that on or about February 4, 2015, they permitted drugs[1] that were altered, adulterated, and lacking quality to be included in the pharmacy's saleable drug stock, and which were indistinguishable from safe to use drugs that had not been altered, adulterated, or lacked quality as alleged in paragraphs 19, 21, and all of its subparts, 22, and 23, above, and Addendum A, hereto, all of which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Failed to Maintain Inventory)

27. Respondent Pharmacy is subject to disciplinary action under Code sections 4300 and 4301, subdivisions (j) and (o), in conjunction with California Code of Regulations, title 16, section 1714, subdivision (b), in that Respondent failed to maintain its facilities, space, fixtures, and equipment so that drugs in its stock were safely and properly prepared, maintained, secured and distributed, resulting in Respondent's failure to maintain an inventory of the drugs allegedly returned by patients, paragraphs 19, 21, and all of its subparts, 22, and 23, above, and Addendum A, hereto, all of which are incorporated herein by reference.

28. Respondent Anderson is subject to disciplinary action sections 4300 and 4300.1, subdivisions (j) and (o), in conjunction with California Code of Regulations, title 16, section 1714, subdivision (d), in that Respondent, the Pharmacist-in-Charge, failed to secure the prescription department of Respondent Pharmacy, failed to provide for the effective control against theft or diversion of dangerous drugs, and failed to provide for records of dangerous drugs, resulting in Respondent's failure to maintain an inventory of the drugs allegedly returned

[1] The drugs allegedly had been returned to Respondent Pharmacy by patients.

by patients, as set forth in paragraphs 19, 21, and all of its subparts, 22, and 23, above, and Addendum A, hereto, all of which are incorporated herein by reference.

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 49115 issued to Anderson Bros. Town & Country Pharmacy, Inc.;

2. Revoking or suspending Pharmacist License Number RPH 42685 issued to Stephen Vincent Anderson, Pharmacist-In-Charge for Anderson Bros. Town & Country Pharmacy Inc.;

3. Ordering Anderson Bros. Town & Country Pharmacy, Inc. and Stephen Vincent Anderson 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

SA2015103839 / 11950289.doc