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

In the Matter of the Accusation Against: **JOHN NEWTON DABBS III** 2067 W. Vista Way, #195 Vista, CA 92083 Pharmacist License No. RPH 28419 and **GREENFIELD PHARMACY** 2067 W. Vista Avenue Vista, CA 92083 Pharmacy Permit No. PHY 37480 Respondents.	Case No. 4570 and 5155 OAH No. 2013120178 and 2014040196

DECISION AND ORDER

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

This decision shall become effective on June 16, 2014.

It is so ORDERED on June 11, 2014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STAN C. WEISSER
Board President

KAMALA D. HARRIS
Attorney General of California
LINDA K. SCHNEIDER
Supervising Deputy Attorney General
DESIREE KELLOGG
Deputy Attorney General
ADRIAN R. CONTRERAS
Deputy Attorney General
State Bar No. 267200
110 West "A" Street, Suite 1100
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 645-2634
Facsimile: (619) 645-2061
E-mail: Adrian.Contreras@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Accusation Against: **JOHN NEWTON DABBS III** **2067 W. Vista Way #195** **Vista, CA 92083** **Pharmacist License No. RPH 28419,** **and** **GREENFIELD PHARMACY** **2067 W. Vista Avenue** **Vista, CA 92083** **Pharmacy Permit No. PHY 37480** Respondents.	Case Nos. 4570 and 5155 OAH No. 2013120178 and 2014040196 **STIPULATED SURRENDER OF LICENSE AND ORDER**

In the interest of a prompt and speedy settlement of this matter, consistent with the public interest and the responsibility of the Board of Pharmacy of the Department of Consumer Affairs, the parties hereby agree to the following Stipulated Surrender and Disciplinary Order which will be submitted to the Board for approval and adoption as the final disposition of the First Amended Accusation.

///

///

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy. She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Adrian R. Contreras and Desiree Kellogg, Deputy Attorney General.

2. John Newton Dabbs III (Respondent Dabbs) and Greenfield Pharmacy (Respondent Greenfield Pharmacy) are represented in this proceeding by attorney Tony Park, whose address is 6789 Quail Hill Pkwy., #405. Irvine, CA 92603.

3. On or about July 31, 1973, the Board of Pharmacy issued Pharmacist License Number RPH 28419 to John Newton Dabbs III (Respondent Dabbs). The Pharmacist License was expired from January 1, 2012, until it was renewed on January 25, 2012. It was inactive from January 1, 2014, to February 4, 2014. The Pharmacist License was in full force and effect at all other times relevant to the charges brought herein and will expire on December 31, 2015, unless renewed.

4. On or about February 28, 1992, the Board of Pharmacy issued Pharmacy Permit Number PHY 37480 to Greenfield Pharmacy (Respondent Greenfield Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2014, unless renewed. Since 1992, Respondent Dabbs has been Respondent Greenfield's Pharmacist-in-Charge.

JURISDICTION

5. First Amended Accusation No. 4570 and 5155 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondents. The First Amended Accusation and all other statutorily required documents were properly served on Respondents on May 6, 2014. Respondents timely filed a Notice of Defense contesting the First Amended Accusation. A copy of First Amended Accusation No. 4570 and 5155 is attached as Exhibit A and incorporated by reference.

///

///

ADVISEMENT AND WAIVERS

6. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in First Amended Accusation No. 4570 and 5155. Respondents also have carefully read, fully discussed with counsel, and understand the effects of this Stipulated Surrender of License and Order.

7. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

9. Respondents admit the truth of each and every charge and allegation in First Amended Accusation No. 4570 and 5155, agree that cause exists for discipline and hereby surrenders Pharmacist License No. RPH 28419 and Pharmacy Permit Number PHY 37480 for the Board's formal acceptance.

10. Respondents understand that by signing this stipulation they enable the Board to issue an order accepting the surrender of the Pharmacist License and Pharmacy Permit without further process.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw this agreement or seek to rescind the stipulation

prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

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

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

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

ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 28419, issued to Respondent John Newton Dabbs III, and Pharmacy Permit Number PHY 37480, issued to Respondent Greenfield Pharmacy, are surrendered and accepted by the Board of Pharmacy.

1. The surrender of Respondents' Pharmacist License and Pharmacy Permit and the acceptance of the surrendered license and permit by the Board shall constitute the imposition of discipline against Respondents. This stipulation constitutes a record of the discipline and shall become a part of Respondents' license history with the Board of Pharmacy.

2. Respondents shall lose all rights and privileges as a Pharmacist and Pharmacy in California as of the effective date of the Board's Decision and Order.

3. The effective date of the surrender of Pharmacy Permit Number PHY 37480 shall be stayed to either July 1, 2014, or the date of sale of the pharmacy, whatever date occurs first.

4. Respondents shall cause to be delivered to the Board their pocket license and, if one was issued, a wall certificate on or before the effective date of the Decision and Order.

5. If Respondents ever apply for licensure or petition for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondents must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, including, but not limited to, completion of any and all examination or certification requirements applicable to the license category, and all of the charges and allegations contained in First Amended Accusation No. 4570 and 5155 shall be deemed to be true, correct and admitted by Respondents when the Board determines whether to grant or deny the application or petition.

6. Respondents shall pay the agency its costs of investigation and enforcement in the amount of $40,000.00 within 60 days after the effective date of the Decision and Order. Respondents shall be jointly and severally liable for the full payment.

7. If Respondents should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in First Amended Accusation No. 4570 and 5155 shall be deemed to be true, correct, and admitted by Respondents for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

8. Respondents shall not apply, reapply, or petition for any licensure or registration of the Board for three (3) years from the effective date of the Decision and Order.

///

///

///

///

///

///

///

///

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney, Tony Park. I understand the stipulation and the effect it will have on my Pharmacist License and the Pharmacy Permit. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

JOHN NEWTON DABBS III
Respondent, and Authorized Agent of Respondent
Greenfield Pharmacy

I have read and fully discussed with Respondent John Newton Dabbs III the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: May 19, 2014

Tony J. Park

TONY PARK
Attorney for Respondents

ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 5/19/2014

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
LINDA K. SCHNEIDER
Supervising Deputy Attorney General

Adrian R. Contreras

DESIREE KELLOGG
Deputy Attorney General
ADRIAN R. CONTRERAS
Deputy Attorney General
Attorneys for Complainant

SD2013704971
70861237.doc

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney, Tony Park. I understand the stipulation and the effect it will have on my Pharmacist License and the Pharmacy Permit. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 5-14-14

FAX 619-625-2061

JOHN NEWTON DABBS III
Respondent, and Authorized Agent of Respondent
Greenfield Pharmacy

I have read and fully discussed with Respondent John Newton Dabbs III the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: _____

TONY PARK
Attorney for Respondents

ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated:

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
LINDA K. SCHNEIDER
Supervising Deputy Attorney General

DESIREE KELLOGG
Deputy Attorney General
ADRIAN R. CONTRERAS
Deputy Attorney General
Attorneys for Complainant

SD2013704971
70861237.doc

Exhibit A

First Amended Accusation No. 4570 and 5155

KAMALA D. HARRIS
Attorney General of California
JAMES M. LEDAKIS
Supervising Deputy Attorney General
DESIREE KELLOGG
Deputy Attorney General
ADRIAN R. CONTRERAS
Deputy Attorney General
State Bar No. 267200
110 West "A" Street, Suite 1100
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 645-2634
Facsimile: (619) 645-2061
E-mail: Adrian.Contreras@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Accusation Against: **JOHN NEWTON DABBS III** **2067 W. Vista Way #195** **Vista, CA 92083** **Pharmacist License No. RPH 28419,** **and** **GREENFIELD PHARMACY** **2067 W. Vista Avenue** **Vista, CA 92083** **Pharmacy Permit No. PHY 37480** Respondents.	Case Nos. 4570 and 5155 OAH No. 2013120178 and 2014040196 **FIRST AMENDED** **ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about July 31, 1973, the Board of Pharmacy issued Pharmacist License Number RPH 28419 to John Newton Dabbs III (Respondent John Dabbs). The Pharmacist License expired on December 31, 2011. It was delinquent from January 1, 2012 until it was renewed on January 25. 2012. The Pharmacist License expired again on December 31, 2013. It was inactive from January 1, 2014 until it was renewed on February 4, 2014. Except as specified herein, the Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on December 31, 2015, unless renewed. On April 8, 2014, a Decision and Interim Order of Suspension Imposing Restrictions on Respondents' Licenses restricted the Pharmacist License. On April 11, 2014, a Decision on Ex Parte Petition and Interim Suspension Order suspended the Pharmacist License.

3. On or about February 28, 1992, the Board of Pharmacy issued Pharmacy Permit Number PHY 37480 to Greenfield Pharmacy (Respondent Greenfield Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2015, unless renewed. On April 8, 2014, a Decision and Interim Order of Suspension Imposing Restrictions on Respondents' Licenses restricted the Pharmacy Permit. On April 11, 2014, a Decision on Ex Parte Petition and Interim Suspension Order suspended the Pharmacy Permit.

JURISDICTION

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

5. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

6. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

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. Section 494(i) of the Code states:

Failure to comply with an interim order issued pursuant to subdivision (a) or (b) shall constitute a separate cause for disciplinary action against any licentiate, and may be heard at, and as a part of, the noticed hearing provided for in subdivision (f). Allegations of noncompliance with the interim order may be filed at any time prior to the rendering of a decision on the accusation. Violation of the interim order is established upon proof that the licentiate was on notice of the interim order and its terms, and that the order was in effect at the time of the violation. The finding of a violation of an interim order made at the hearing on the accusation shall be reviewed as a part of any review of a final decision of the agency.

9. Section 4051(a) of the Code states:

Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

10. Sections 4081(a) and (b) of the Code states:

(a) All records of manufacture and of sale, acquisition, 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, 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.

(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

11. Section 4104(b) of the Code states:

Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

12. Section 4105(a) of the Code states:

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.

13. Sections 4113(a) and (c) of the Code states:

(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

...

(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. Section 4125(a) of the Code states:

Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

15. Sections 4169(a)(2) and (a)(3) of the Code states:

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

...

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

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

...

///

16. 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:

. . .

(c) Gross negligence.

. . .

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

. . .

(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.

. . .

17. Section 4306.5 of the Code states, in pertinent part:

Unprofessional conduct for a pharmacist may include any of the following:

Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

. . .

///

18. Section 4342(a) of the Code states:

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).

19. Section 111250 of the Health and Safety Code states:

Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

20. Section 111255 of the Health and Safety Code 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.

21. Section 111295 of the Health and Safety Code states:

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

22. Section 111300 of the Health and Safety Code states:

It is unlawful for any person to adulterate any drug or device.

23. Section 111330 of the Health and Safety Code states:

Any drug or device is misbranded if its labeling is false or misleading in any particular.

24. Section 111440 of the Health and Safety Code states:

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

25. Section 11165(d) of the Health and Safety Code states:

. . .

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law 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.

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

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

REGULATORY PROVISIONS

26. California Code of Regulations, title 16, section 1711(a), (c)(1) and (e), states:

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

...

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy....

27. California Code of Regulations, title 16, section 1714(b) and (d), states:

(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 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 the pharmacist.

28. California Code of Regulations, title 16, section 1715.6, states:

The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths.

29. California Code of Regulations, title 16, section 1716 states:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

....

30. California Code of Regulations, title 16, section 1718, states:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332. The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

31. California Code of Regulations, title 16, section 1735, states:

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a drug product from chemicals or bulk drug substances

...

32. California Code of Regulations, title 16, section 1735.2(d), states:

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

(4) Inactive ingredients to be used.

(5) Process and/or procedure used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

....

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

....

33. California Code of Regulations, title 16, section 1735.3(a), (b) and (c), states:

(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

(7) A pharmacy assigned reference or lot number for the compounded drug product.

(8) The expiration date of the final compounded drug product.

(9) The quantity or amount of drug product compounded.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

...

34. California Code of Regulations, title 16, section 1735.5(a) and (c), states:

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

...

(c) The policy and procedure manual shall include the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

35. California Code of Regulations, title 16, section 1735.6(a), states:

Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.

36. California Code of Regulations, title 16, section 1735.7, states:

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities

relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

37. California Code of Regulations, title 16, section 1735.8, states:

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

38. California Code of Regulations, title 16, section 1793.7, states:

(a) Except as otherwise provided in section 1793.8, any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.

(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

. . .

(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these

sections and written policies and procedures.

. . . .

39. Code of Federal Regulations, title 21, section 1304.11(c) states:

> *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

COST RECOVERY

40. Section 125.3 of the Code provides, 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

FACTUAL ALLEGATIONS

41. Respondent John Dabbs has been the Pharmacist-in-Charge of Respondent Greenfield Pharmacy from February 28, 1992 and at all times mentioned herein.

42. Respondent John Dabbs was on duty as a pharmacist and the Pharmacist-in-Charge with a delinquent license from January 3 to January 18, 2012 when he dispensed 510 prescriptions. He was also on duty as a pharmacist and the Pharmacist-in-Charge with an inactive license from January 2, 2014 until February 4, 2014 when he dispensed at least 646 prescriptions.

43. From January 1, 2011 through January 19, 2012, Respondents did not provide prescription data for Schedule II through IV controlled substances to the Department of Justice the Controlled Substance Utilization Review and Evaluation System except for on April 13, 2011. Respondents also did not maintain written policies and procedures addressing licensed employee impairment or theft and diversion of drugs and pharmacy technician job descriptions, as well as written policies and procedures for them.

44. During inspections in 2012, the Board inspectors repeatedly requested records which Respondents failed to provide or provided belatedly, including Respondent Greenfield

Pharmacy's policies for interpretive services, quality assurance, a quality assurance report documenting a dispensing error and a compounding self-assessment form.

45. On February 9, March 6, April 4 and May 8, 2012, Respondents dispensed and furnished budesonide suspension in the amount of 0.25 mg of budesonide (Prescription Number 600004) even though the prescriber had written the prescription for 0.5 mg of budesonide. Respondents did not maintain the quality assurance report documenting these errors or records of the quality assurance program for the prevention of medication errors.

46. From 2011 through March 2014, Respondents did not have records of acquisition and disposition for all dangerous drugs, including 4,200 digitoxin 0.1 mg capsules compounded by Respondents, at least 141 tablets of Oxycontin 80mg, 120 ml of testosterone cypionate 200mg/ml and 3,635 tablets of hydrocodone/APAP 10mg/325mg.

47. During the period of July 15, 2011 through January 30, 2014, Respondents experienced losses in their inventory of controlled substances, namely 120 ml of testosterone cypionate 200 mg/ml and 3,635 tablets of hydrocodone/APAP and did not report those losses to the Board. Respondents also did not conduct an inventory of stocks of controlled substances on hand every two years as the last such inventory was conducted prior to July 15, 2011.

48. On January 14, 2014, Respondent Greenfield Pharmacy was operating without a pharmacist being present on the premises.

49. At all times mentioned herein, Respondent John Dabbs was unaware of Respondent Greenfield Pharmacy's compounding policies and procedures and allowed the pharmacy technician to compound drugs without supervision.

50. During the period of January 15, 2014 through February 27, 2014, there were over one hundred expired components and components without certificates of analysis located on the premises of Respondent Greenfield Pharmacy, including on the shelves.

51. During the period of January 1, 2011 through February 27, 2014, Respondents used expired components to compound 83 drugs, including digitoxin. The digitoxin that Respondents initially bought in January and March 2006, and used to compound 0.1 mg capsules, expired on November 19, 2009. Nonetheless, Respondents compounded digitoxin 0.1 mg capsules with this

expired drug component on at least 13 separate occasions from March 8, 2011 through January 13, 2014, and dispensed 8,835 capsules of that drug product 167 times to unsuspecting patients from November 20, 2009, through February 27, 2014. Respondents continued to compound drug products with expired components even after they were told by the Board to cease this practice.

52. During the period of November 20, 2009 through February 12, 2014, Respondents compounded 69 drug products with components which were set to expire prior to the beyond use date established by the master formulas for the compounded drug products. This practice contravened Respondent Greenfield Pharmacy's written policies and procedures for compounding products. Respondents continued to compound drug products with drug components set to expire before the beyond use dates set for the drugs compounded even after they were informed not to do so by the Board.

53. During the period of March 8, 2011 through January 6, 2014, Respondents compounded ophthalmic drug products without a master formula or did not adhere to the requirements of the master formula, including ensuring the sterility of ophthalmic drug products. Namely, Respondent Greenfield Pharmacy was required to: (1) sterilize the non-sterile components with a filter, (2) test the filter to ensure that it was sterilizing the components properly (i.e., employ the "bubble test") and (3) compound drug products in an International Standards Organization Class 5 environment (an environment with little to no contaminants). However, Respondents did not follow those procedures nor was the pharmacy technician trained in sterilization procedures.

54. During the period of March 13, 2012 through February 12, 2014, in contravention of the requirements of the master formulas, Respondents assigned beyond use dates which were not supported by data showing that the sterilization procedures and testing warranted the more lengthy beyond use dates which were assigned the ophthalmic drug products by them.

55. During the period of March 8, 2011 through January 6, 2014, Respondents did not follow their master formulas in other significant respects. First, when compounding cyclosporine ophthalmic products, they substituted a different compounding component, rapeseed oil, for corn oil stock. Second, they did not use ethyl alcohol 190 proof USP to compound the cyclosporine

ophthalmic products as required by the master formula. Third, they used a component, polysorbate 80, which was not authorized by the master formula to be used in the compounding of cyclosporine ophthalmic products. Fourth, they did not label the end product with a warning to protect it from light and with directions that it must be shaken well, as required by the master formula. Fifth, they did not use or own a sonicator (an instrument designed to reduce the size of the particles and therefore irritation) for compounding cyclosporine ophthalmic products, which was to be used per the master formulas.

56. During the period of March 8, 2011 through January 6, 2014, when making another ophthalmic drug product, DMSO, Respondents substituted a component, benzalkonium chloride 0.1 percent, rather than using a stock solution of benzalkonium chloride 1 percent for DMSO ophthalmic drug products. This increased the risk of the growth of bacteria or fungi in the eye when administered because they used a component of much lesser strength.

57. From March 8, 2011, to February 5, 2014, Respondents compounded 600 drugs where the compounding log lacked the lot or the expiration date of at least one component, compounded 1,500 drugs where the compounding log lacked the identity of the pharmacy personnel who compounded the drug product, and compounded 169 drugs where the identity of the pharmacist reviewing the final compounded drug product was not documented.

58. During the period of January 1, 2011 through February 27, 2014, Respondents did not maintain any records for certain compounded drugs, including prescription number 615529 dispensed on August 29, 2013; prescription number 615783 dispensed on October 22, 2013; prescription number 617727 (also referred to as 61722) dispensed on November 12, 2013; prescription number 618172 dispensed on December 27, 2013; and 4,200 capsules of digitoxin 0.1mg compounded by Respondents from January 1, 2011 to February 27, 2014. Additionally, Respondents compounded 32 ophthalmic drug products and 1,800 capsules of digitoxin 0.1mg without records of the existence of any master formulas.

59. During the period of January 1, 2011 through February 27, 2014, Respondents did not maintain and produce policies and procedures for compounding, records of facilities and equipment used for compounding, training records for compounding staff, a compounding quality

assurance plan, and documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

60. After inspections revealed numerous violations of Pharmacy Law and regulations, on or about April 3, 2014, Complainant filed a petition for an Interim Suspension Order before the Office of Administrative Hearings. On April 8, 2014, an Administrative Law Judge issued an interim suspension order against Respondents. Respondent John Dabbs was present and represented by counsel. Not only did Respondent John Dabbs receive the suspension order that day, but the Administrative Law Judge read him the terms.

61. The April 8, 2014 Decision and Interim Order of Suspension Imposing Restrictions on Respondents' Licenses stated that:

> In order to protect the public, the following limitations are placed on respondents' licenses:
>
> 1. Respondent Greenfield Pharmacy may not engage in compounding any drugs, and is prohibited from selling, dispensing, furnishing, or otherwise providing to the public any compounded drug pending further order of this court.
>
> 2. Respondent John Newton Dabbs may not compound, supervise the compounding, sell, dispense, furnish, or otherwise provide any compounded drug to any member of the public at any facility or pharmacy.

62. On the morning of April 9, 2014, Respondent Greenfield Pharmacy and Respondent Dabbs, violated that suspension order by selling, dispensing, and furnishing compounded drugs. In total, 61 compounded drugs were offered for sale, 16 compounded drugs were sold to patients (3 of these drugs were in the process of being mailed to patients), 6 compounded drugs were dispensed or in the process of being dispensed to patients, and one request for authorization for a refill of a compounded drug was made.

FIRST CAUSE FOR DISCIPLINE

(Practice Pharmacy With an Expired and Inactive License)

63. Respondent John Dabbs is subject to disciplinary action under Code section 4301(o), for violating Business and Professions Code section 4051, in that he compounded, furnished, sold and dispensed dangerous drugs while he was not licensed as a pharmacist from January 2, 2012

through January 25, 2012 and from January 2, 2014 through February 4, 2014, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Operate a Pharmacy without a Pharmacist-in-Charge)

64. Respondent Greenfield Pharmacy is subject to disciplinary action under Code section 4301(o), for violating Business and Professions Code section 4113(a), in that it did not have a Pharmacist-in-Charge duly licensed with the Board in January 2012 and January and February 2014, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Inadequate Record-Keeping and Failure to Transmit Records)

65. Respondents are subject to disciplinary action under Code sections 4301(j) and (o) for violating Pharmacy Law and regulations and federal and state laws regulating controlled substances, as set forth in paragraphs 41 through 62, which are incorporated herein by reference and as described below:

a. **Code sections 4081 and 4105(a)**: Failure to maintain records of manufacture, sale, acquisition, or disposition of dangerous drugs, including a current inventory of 4,200 digitoxin 0.1 mg tablets, at least 141 tablets of Oxycontin 80mg, 120 ml of testosterone cypionate 200mg/ml and 3,635 tablets of hydrocodone/APAP 10mg/325mg.

b. **Code section 4125(a) and California Code of Regulations, title 16, section 1711:** Failure to produce and maintain records of a quality assurance program for the prevention of medication errors and a quality assurance report documenting the errors made when dispensing prescription number 600004.

c. **Health and Safety Code section 11165(d)**: Failure to transmit prescription data for Schedule II through IV controlled substances dispensed and furnished by them to the Department of Justice for inclusion in Controlled Substance Utilization Review and Evaluation System.

d. **California Code of Regulations, title 16, section 1735.5(a)**: Failure to produce and maintain a written policy and procedure manual for compounding.

e. **California Code of Regulations, title 16, section 1735.6(a)**: Failure to produce and maintain written documentation of facilities and equipment for compounding.

f. **California Code of Regulations, title 16, section 1735.7(a)**: Failure to produce and maintain training records for compounding staff.

g. **California Code of Regulations, title 16, section 1735.8(a)**: Failure to produce and maintain a compounding quality assurance plan.

h. **California Code of Regulations, title 16, section 1735.5(c)(4)** : Failure to produce and maintain documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

i. **Code section 4104(b)**: Failure to produce and maintain written policies and procedures addressing licensed employee impairment or theft and diversion of drugs.

j. **California Code of Regulations, title 16, section 1793.7(d)**: Failure to produce and maintain pharmacy technician job descriptions, as well as written policies and procedures for them.

k. **California Code of Regulations, title 16, section 1735.3**: Failure to produce and maintain complete records or any records of compounded drugs, including failing to record the lot number, the expiration date of all components, the pharmacist who verified the compounded drugs and the identity of the pharmacy staff who compounded the drug product. This includes the failure to produce and maintain the compounding records for prescription number 615529 dispensed on August 29, 2013; prescription number 6157883 dispensed on October 22, 2013; prescription number 617727 (also referred to as 61722) dispensed on November 12, 2013; prescription number 618172 dispensed on December 27, 2013; 4,200 capsules of digitoxin 0.1mg compounded by Respondents from January 1, 2011 to February 27, 2014; certificates of analysis for all components; and master formulas for 32 ophthalmic drug products and 1,800 capsules of digitoxin 01mg.

l. **Code of Federal Regulations, title 21, section 1304.11(c)**: Failure to produce and maintain records of biennial inventory for controlled substances.

FOURTH CAUSE FOR DISCIPLINE

(Misrepresentation of Facts)

66. Respondents are subject to discipline under Code section 4301(g), for unprofessional conduct in that Respondent John Dabbs made and signed a document that falsely represented a state of facts, in that he signed a compounding self-assessment dated June 12, 2011, verifying that all required polices, procedures, and documentation for non-sterile compounds were in place when in fact they were not in place, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Subvert an Investigation)

67. Respondents are subject to discipline under section 4301(q) for unprofessional conduct that they subverted an investigation of the Board by failing to produce requested records in a timely manner, produced incomplete records or did not produce the requested records at all, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Variation from Prescription)

68. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1716, in that prescription number 600004 was written by the prescriber for 0.5 mg of budesonide, but that prescription was dispensed and furnished with only 0.25 mg of budesonide on February 9, March 6, April 4, and May 8, 2012, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Supervise Pharmacy Technician)

69. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1793.7, in that Respondent John Dabbs failed to supervise the pharmacy technician when she was compounding drugs, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

EIGHTH CAUSE FOR DISCIPLINE

(Manufacture, Sell, Deliver, Hold or Offer for Sale Adulterated Compounded Drugs)

70. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating Health and Safety Code section 111295 and Code section 4169(a)(2), in that they manufactured, sold, delivered, held or offered for sale, 83 compounded drugs, including digitoxin that were adulterated within the meaning of Health and Safety Code sections 111250 and 111255, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

NINTH CAUSE FOR DISCIPLINE

(Compound Adulterated Drugs)

71. Respondents are subject to disciplinary action under Code section 4301(j), for violating Health and Safety Code section 111300, in that they adulterated 83 compounded drugs, including digitoxin, within the meaning of Health and Safety Code sections 111250 and 111255, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

TENTH CAUSE FOR DISCIPLINE

(Sell Misbranded Compounded Drugs)

72. Respondents are subject to disciplinary action under Code section 4301(j), for violating Health and Safety Code section 111440 and Code section 4169(a)(3), in that they sold 69 misbranded drugs within the meaning of Health and Safety Code section 111330, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

ELEVENTH CAUSE FOR DISCIPLINE

(Compound Drugs Lacking Quality and Strength)

73. Respondents are subject to disciplinary action under Code section 4301(o), for violating Code section 4342(a), in that they compounded drugs lacking quality and strength, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

TWELFTH CAUSE FOR DISCIPLINE

(Gross Negligence)

74. Respondents are subject to disciplinary action under Code section 4301(c), for gross negligence when they compounded ophthalmic drug products which lacked integrity, quality,

potency and labeled strength, including failing to ensure their sterility, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Security of Controlled Substances)

75. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1714(b), in that they did not maintain the security of controlled substances, namely 120ml of testosterone cypionate 200mg/ml and 3,635 tablets of hydrocodone/APAP, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Security of Pharmacy)

76. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1714(d), in that they allowed a pharmacy technician to operate the pharmacy without a pharmacist being present on the premises on January 14, 2014, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

FIFTEENTH CAUSE FOR DISCIPLINE

(Failure to Report Loss of Controlled Substances)

77. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1715.6, in that they failed to report a drug loss of controlled substances, namely 120ml of testosterone cypionate 200mg/ml and 3,635 tablets of hydrocodone/APAP 10 mg/325mg to the Board, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

SIXTEENTH CAUSE FOR DISCIPLINE

(Failure to Adhere to Requirements of Master Formulas)

78. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1732.2(d), in that they failed to adhere to the requirements of the master formulas for compounding ophthalmic drugs and compounded

other drug products without a master formula, including digitoxin, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Failure to Assign Proper Beyond Use Date)

79. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, section 1732.2(h), in that they did not assign a proper beyond use date for the drugs that were compounded with components set to expire in advance of the beyond use date assigned by Respondents, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Failure to Train Compounding Staff)

80. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 21, sections 1735.7(a), (b) and (c), in that they failed to properly train the pharmacy staff who were compounding drugs, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

NINETEENTH CAUSE FOR DISCIPLINE

(Failure to Conduct DEA Biennial Inventory)

81. Respondents are subject to disciplinary action under Code section 4301(o), for violating Code of Federal Regulations, title 21, section 1304.11(c), in that they failed to conduct an inventory of controlled substances within two years from the last such inventory, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

TWENTIETH CAUSE FOR DISCIPLINE

(Failure to Exercise or Implement Best Professional Judgment When Compounding Drugs, Practicing Pharmacy on Invalid Licenses and Maintaining Controlled Substances Records)

82. Respondent John Dabbs is subject to disciplinary action under Code section 4301(o), for violating Business and Professions Code sections 4306.5(a) and (b), in that he failed to exercise or implement his best professional judgment when he compounded and dispensed drugs, practiced pharmacy with an inactive and delinquent license and failed to maintain records for

controlled substances, as set forth in paragraphs 41 through 62 above, which are incorporated herein by reference.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Violation of Interim Suspension Order)

83. Respondents are subject to disciplinary action under Code section 494(i), for violating the April 8, 2014 Interim Suspension Order issued against them, in that they sold, dispensed, and furnished compounded drugs on April 9, 2014 with Respondent John Dabbs' full knowledge of that Interim Suspension Order, as set forth in paragraphs 41 through 62, which are incorporated herein by reference.

DISCIPLINARY CONSIDERATIONS

84. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges:

a. In 2004, the Board issued Citation number CI 2002 24418 to Respondent Greenfield Pharmacy and Citation number CI 2003 26493 to Respondent John Dabbs for violating Business and Professions Code section 4125 and California Code of Regulations, title 16, sections 1711, 1716.2, 1751.3, 1751.7, 1751.8 and 1751(b) in that they failed to maintain policies and procedures, have a quality assurance program in place and failed to maintain the compounding area walls and ceilings with nonporous surfaces. The Board issued fines which Respondents paid.

b. In 2006, the Board issued Citation number CI 2005 31601 to Respondent Greenfield Pharmacy for violating Code section 4342 and California Code of Regulations, title 16, section 1716 in that it dispensed a prescription lacking in quality and label strength. The Board issued a fine, which Respondent paid.

c. In 2006, the Board issued Citation Number CI 2006 32417 to Respondent John Dabbs for violating Code section 4342 in that he compounded a drug which lacked in quality and label strength. The Board issued a fine, which Respondent paid.

d. In 2012, the Board issued Citation Number CI 2011 49332 to Respondent John Dabbs for violating Code sections 4301(h) and (l) in that he was convicted on his plea of guilty of

violating Vehicle Code section 23152(a), driving under the influence of alcohol, a misdemeanor, and he used alcohol in a manner dangerous to himself and the public. The Board issued a fine, which Respondent paid.

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 Pharmacist License Number RPH 28419, issued to John Newton Dabbs III;

2. Revoking or suspending Pharmacy Permit Number PHY 37480, issued to Greenfield Pharmacy;

3. Ordering John Newton Dabbs III and Greenfield Pharmacy to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: 5/1/14

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

SD2013704971
70860326.doc

KAMALA D. HARRIS
Attorney General of California
JAMES M. LEDAKIS
Supervising Deputy Attorney General
ADRIAN R. CONTRERAS
Deputy Attorney General
State Bar No. 267200
110 West "A" Street, Suite 1100
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 645-2634
Facsimile: (619) 645-2061
E-mail: Adrian.Contreras@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Accusation Against: **JOHN NEWTON DABBS III** **2067 W. Vista Way #195** **Vista, CA 92083** **Pharmacist License No. RPH 28419,** **and** **GREENFIELD PHARMACY** **2067 W. Vista Avenue** **Vista, CA 92083** **Pharmacy Permit No. PHY 37480** Respondents.	Case No. 4570 **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.

2. On or about July 31, 1973, the Board of Pharmacy issued Pharmacist License Number RPH 28419 to John Newton Dabbs III (Respondent Dabbs). The Pharmacist License was expired from January 1, 2012, until it was renewed on January 25, 2012. The Pharmacist

License was in full force and effect at all other times relevant to the charges brought herein and will expire on December 31, 2013, unless renewed.

3. On or about February 28, 1992, the Board of Pharmacy issued Pharmacy Permit Number PHY 37480 to Greenfield Pharmacy (Respondent Greenfield). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2014, unless renewed.

JURISDICTION

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

5. Section 4300 of the Code states:

"(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.

". . .

"(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

///

6. 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

7. Section 22 of the Code states:

"(a) 'Board' as used in any provisions of this Code, refers to the board in which the administration of the provision is vested, and unless otherwise expressly provided, shall include 'bureau,' 'commission,' 'committee,' 'department,' 'division,' 'examining committee,' 'program,' and 'agency.'

"(b) Whenever the regulatory program of a board that is subject to review by the Joint Committee on Boards, Commissions, and Consumer Protection, as provided for in Division 1.2 (commencing with Section 473), is taken over by the department, that program shall be designated as a 'bureau.'"

8. Section 4017 of the Code states

"'Authorized officers of the law' means inspectors of the California State Board of Pharmacy, inspectors of the Food and Drug Branch of the State Department of Public Health, and investigators of the department's Division of Investigation or peace officers engaged in official investigations."

9. 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."

10. Section 4032 of the Code states:

"'License' 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."

11. Section 4036 of the Code states:

"'Pharmacist' means a natural person to whom a license has been issued by the board, under Section 4200, except as specifically provided otherwise in this chapter. The holder of an unexpired and active pharmacist license issued by the board is entitled to practice pharmacy as defined by this chapter, within or outside of a licensed pharmacy as authorized by this chapter."

12. Section 4036.5 of the Code states:

"'Pharmacist-in-charge' means a pharmacist proposed by a pharmacy and 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."

13. Section 4037 of the Code states:

"(a) 'Pharmacy' means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded. 'Pharmacy' includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail.

"(b) 'Pharmacy' shall not include any area in a facility licensed by the State Department of Public Health where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of

patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility."

14. Section 4051 of the Code states:

"(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

"(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

"(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

"(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

"(3) Access to the information described in paragraph (2) is secure from unauthorized access and use."

15. Section 4081 of the Code states:

"(a) All records of manufacture and of sale, acquisition, 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, 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.

"(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

"(c) The pharmacist-in-charge or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate."

16. Section 4104 of the Code states:

". . .

"(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy."

". . . ."

17. 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.

"(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

"(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

"(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

"(e)(1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter."

18. Section 4116 of the Code states:

"(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

". . . ."

19. Section 4125 of the Code states:

"(a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

"(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be

construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

". . . ."

20. 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:

". . .

"(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

"(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

"(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.

". . .

"(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the

qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment

"...

"(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.

"...."

21. Section 4307 of the Code states:

"(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

"(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

"(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

"(b) "Manager, administrator, owner, member, officer, director, associate, or partner," as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that capacity in or for a licensee.

"(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law."

22. Section 4330 of the Code states:

"(a) Any person who has obtained a license to conduct a pharmacy, who fails to place in charge of the pharmacy a pharmacist, or any person, who by himself or herself, or by any other person, permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs, in his or her pharmacy, except by a pharmacist, or as otherwise provided in this chapter, is guilty of a misdemeanor.

"(b) Any nonpharmacist owner who commits any act that would subvert or tend to subvert the efforts of the pharmacist-in-charge to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor."

23. Section 4332 of the Code states:

"Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects,

or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor."

24. Section 11165 of the Health and Safety Code states:

". . .

"(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law 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.

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

"(9) Date of origin of the prescription.

"(10) Date of dispensing of the prescription.

". . . ."

///

///

REGULATORY PROVISIONS

25. California Code of Regulations, title 16, (Regulations) section 1711, states:

"(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

"(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

"(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

"(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

"(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

"(B) Communicate to the prescriber the fact that a medication error has occurred.

"(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

"(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

"(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

"(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

"1. the date, location, and participants in the quality assurance review;

"2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);

"3. the findings and determinations generated by the quality assurance review; and,

"4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

"The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

"(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

"(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

"(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section."

26. Regulations, title 16, section 1716, states:

"Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

"Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription."

27. Regulations, title 16, section 1735, states:

"(a) 'Compounding' means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

"(1) Altering the dosage form or delivery system of a drug

"(2) Altering the strength of a drug

"(3) Combining components or active ingredients

"(4) Preparing a drug product from chemicals or bulk drug substances

"(b) 'Compounding' does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.

"(c) 'Compounding' does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

"(d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.)."

28. Regulations, title 16, section 1735.3, states:

"(a) For each compounded drug product, the pharmacy records shall include:

". . .

"(3) The identity of the pharmacy personnel who compounded the drug product.

"(4) The identity of the pharmacist reviewing the final drug product.

". . . ."

29. Regulations, title 16, section 1735.4., states:

". . .

"(b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.

". . . ."

30. Regulations, title 16, section 1735.5, states:

"(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

"(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

"(c) The policy and procedure manual shall include the following

"(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

"(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

"(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

"(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

"(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products."

31. Regulations, title 16, section 1735.6, states:

"(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.

"(b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.

"(c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such

calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy."

32. Regulations, title 16, section 1735.7, states:

"(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

"(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

"(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product."

33. California Code of Regulations, title 16, section 1735.8, states:

"(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

"(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

"(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

"(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength."

34. California Code of Regulations, title 16, section 1793.1, states:

"Only a pharmacist, or an intern pharmacist acting under the supervision of a pharmacist, may:

"...

"(f) Supervise the packaging of drugs and check the packaging procedure and product upon completion.

"(g) Perform all functions which require professional judgment."

35. California Code of Regulations, title 16, section 1793.7, states:

"(a) Except as otherwise provided in section 1793.8, any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.

"(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

"...

"(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.

"...."

COSTS

36. Section 125.3 of the Code provides, 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

FIRST INVESTIGATION

37. On January 18, 2012, Board inspectors conducted a routine inspection at Respondent Greenfield. The owner and pharmacist in charge, Respondent Dabbs, was present. Upon their arrival, the inspectors asked Respondent Dabbs to verify his licensure on the Board's website and it reflected that his license was delinquent with an expiration date of December 31, 2011. Respondent Dabbs told the inspectors that he had been working from January 3 to January 18, 2012. Respondent Dabbs provided a calendar and a copy of daily reports between these time periods. The calendar showed the dates, hours worked, and approximate number of prescriptions Respondent Dabbs had verified. Respondent Dabbs worked on 12 days, for a total of 58.5 hours and verified about 510 prescriptions while his pharmacist license was delinquent as follows:

DATE	HOURS WORKED	NUMBER OF PRESCRIPTIONS VERIFIED
1-3-12	5	54
1-4-12	5	47
1-5-15	5	37
1-6-12	5	30
1-9-12	5	61
1-10-12	5	35
1-11-12	5	42
1-12-12	5	37
1-13-12	5	42
1-16-12	5	35
1-17-12	5	42
1-18-12	3.5	49
Total	58.5	510

38. Respondent Greenfield was then locked until Priti Pathak, a licensed pharmacist, arrived.

39. Respondents failed to provide the Department of Justice the Controlled Substance Utilization Review and Evaluation System (CURES) data in a timely manner. As a result, this data was unavailable for the Board inspectors' review during the January 18, 2012, inspection. Further investigation revealed that Respondents had reported to CURES only once, April 13, 2011, in a twelve-month period (January 1, 2011 – January 19, 2012). CURES data had not been submitted between May 1, 2011, and January 19, 2012.

40. The Board inspectors requested from Respondent Greenfield its policies for interpretive services, quality assurance, and non sterile compounding. However, Respondents did not timely make them available for the Board's review even after the inspectors made two additional requests.

41. Respondent Dabbs signed a compounding self-assessment on June 12, 2011, verifying that all required policies, procedures, and documentation for non sterile compounds were in place at Respondent Greenfield. However, none of the documents were timely given to the Board inspectors upon their request during the inspection.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Practicing With an Expired or Inactive License)

42. Respondent Dabbs is subject to disciplinary action under Code section 4301, subdivisions (j) and (o) in that he acted in the capacity of a pharmacist under Code sections 4036, 4036.5, 4037, 4051, 4116, subdivision (a), and 4330, subdivision (a) with an expired or inactive license. The circumstances are described in paragraphs 37-41, above, and are hereby incorporated as if fully set forth herein.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Inadequate Recordkeeping)

43. Respondents Greenfield and Dabbs are subject to discipline under Code section 4301, subdivisions (j) and (o) for violating laws governing pharmacy, controlled substances, and dangerous drugs. The circumstances are described in paragraphs 37-41, above, and are hereby incorporated as if fully set forth herein. They include violations of the following laws:

a. **Code sections 4081 and 4332**: Failure to maintain records of manufacture, sale, acquisition, or disposition of dangerous drugs.

b. **Code section 4105, subdivision (a)**: Failure to maintain records of acquisition or disposition of dangerous drugs.

c. **Code section 4125 and Regulations section 1711:** Failure to provide records of a quality assurance program on the prevention of medication errors.

d. **Health and Safety Code section 11165, subdivision (d)**: Failure to provide the Department of Justice CURES data in a timely manner for Schedule II through IV controlled substances dispensed.

e. **Regulations section 1735.5, subdivision (a)**: Failure to provide a written policy or procedure manual for compounding.

f. **Regulations section 1735.6, subdivision (a)**: Failure to provide written documentation of facilities and equipment for compounding.

g. **Regulations section 1735.7, subdivision (a)**: Failure to provide training records for compound staff.

h. **Regulations section 1735.8, subdivision (a)**: Failure to provide compounding quality assurance plan.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Misrepresentation of Facts)

44. Respondents Greenfield and Dabbs are subject to discipline under Code section 4301, subdivision (g) for making or signing a document that falsely represents a state of facts in that they signed a compounding self-assessment on June 12, 2011, verifying that all required polices, procedures, and documentation for non sterile compounds were in place when in fact they were not in place. The circumstances are described in paragraphs 37-41 above, and are hereby incorporated as if fully set forth herein.

///

///

///

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Subverting an Investigation)

45. Respondents Greenfield and Dabbs are subject to discipline under section 4301, subdivision (q) for subverting or attempting to subvert a Board investigation. The circumstances are described in paragraphs 37-41 above, and are hereby incorporated as if fully set forth herein.

SECOND INVESTIGATION

46. In August 2012, the Board received a consumer complaint from Nicole Latasa. According to Latasa, Respondents filled a prescription for budesonide for her two-year old daughter with an incorrect dosage or potency. In September 2012, the Board then sent investigators to Respondent's pharmacy and spoke with Respondent Dabbs.

47. Respondent Dabbs verified prescription RX 600004 for Latasa's daughter. The prescription was written for budesonide suspension 0.5 mg/2ml but the prescription was instead processed, filled, and dispensed with budesonide 0.25 mg/2ml suspension. The prescription was refilled on March 6, April 4, and May 8, 2012.

48. During the Board's investigation, Respondents could not produce documents that they were required by law to have reasonably available upon the Board's request for inspection or reproduction. This included the quality assurance report documenting the dispensing error for prescription RX 600004; a technician job description and written policy and procedures.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Variation from Prescription)

49. Respondents Greenfield and Dabbs are subject to discipline under Code section 4301, subdivisions (j) and (o) for violating laws governing pharmacy, controlled substances, and dangerous drugs in that Respondents verified prescription RX 600004 for Latasa. The prescription was written for budesonide suspension 0.5 mg/2ml but the prescription was instead processed, filled, and dispensed with budesonide 0.25 mg/2ml suspension. The prescription was refilled on March 6, April 4, and May 8, 2012. The circumstances are described in paragraphs 46-48 above, and are hereby incorporated as if fully set forth herein

///

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Inadequate Recordkeeping)

50. Respondents Greenfield and Dabbs are subject to discipline under Code section 4301, subdivisions (j) and (o) for violating laws governing pharmacy, controlled substances, and dangerous drugs. The circumstances are described in paragraphs 46-48, above, and are hereby incorporated as if fully set forth herein. They include violations of the following laws:

a. **Code section 4104, subdivision (b)**: Failure to provide for review written policies and procedures addressing licensed employee impairment or theft and diversion.

b. **Regulations section 1711, subdivision (e)**: Failure to provide a quality assurance report documenting the dispensing error for prescription RX 600004.

c. **Regulations section 1793.7, subdivision (d)**: Failure to provide the technician job description and written policy and procedures.

d. **Regulations section 1735.3, subdivision (a); section 1735.4, subdivision (b)**: Failure to provide in the compounding log a pharmacist's initials indicating that the following compounded products had been checked or verified by the pharmacist: Lot # 8971 for 500 gm of 1% testosterone cream; Lot # 8958 for bi-est 2 mg/ prog 200 mg capsules; Lot # 8959 for 100 capsules of trilostane 180 mg; RX 603880 for 30 capsules of quinine sulfate 300 mg; Lot # 8960 for 100 capsules of naltrexone 4.5 mg capsule; Lot # 8961 for 100 capsules of digitoxin 0.1 mg capsule; Lot # 8962 for 100 capsules of trilostane 90 mg; RX 605457 for 30 gm hydroquinone 8% cream; RX 206208 for 200 gm of diclofenac/ketamine/lidocaine 5%/5%/5% cream; RX 605308, 605309, 604129, 602608, 605322, and 601758.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Insufficient Supervision of Pharmacy Technician)

51. Respondents Greenfield and Dabbs are subject to discipline under Code section 4301, subdivisions (j) and (o), in conjunction with Regulations section 1793.1, subdivision (f), and section 1793.7, subdivisions (a)-(b) in that Respondents failed to supervise the functions performed by a pharmacy technician in connection with the dispensing of a prescription. The compounding log documenting the preparation of compounded medications performed by the

pharmacy technician were not verified or documented in writing by Respondents as follows: Lot # 8971 for 500 gm of 1% testosterone cream; Lot # 8958 for bi-est 2 mg/ prog 200 mg capsules; Lot # 8959 for 100 capsules of trilostane 180 mg; RX 603880 for 30 capsules of quinine sulfate 300 mg; Lot # 8960 for 100 capsules of naltrexone 4.5 mg capsule; Lot # 8961 for 100 capsules of digitoxin 0.1 mg capsule; Lot # 8962 for 100 capsules of trilostane 90 mg; RX 605457 for 30 gm hydroquinone 8% cream; RX 206208 for 200 gm of diclofenac/ketamine/lidocaine 5%/5%/5% cream; RX 605308, 605309, 604129, 602608, 605322, and 601758.

MATTERS IN AGGRAVATION

52. To determine the degree of discipline, if any, to be imposed on Respondent Greenfield and Respondent Dabbs, Complainant alleges that in 2004, Respondent Greenfield was issued Citation No. CI 2002 24418 and Respondent Dabbs was issued Citation No. CI 2003 26493. Respondent Greenfield and Respondent Dabbs were charged with a violation of Code section 4125/ Regulations section 1711; Regulations section 1716.2; and Regulations sections 1751.3, 1751.7, 1751.8, and 1751, subdivision (b), for a total amount of $1,500.00 per citation. These citations charged that on or about November 20, 2002, Respondent Greenfield and Respondent Dabbs failed to have written policies and procedures immediately retrievable for the pharmacy's Quality Assurance program to document and assess medication errors; failed to maintain proper records for drug products compounded for future use; and failed to maintain complete and accurate records of compounded drugs, have a quality assurance program in place, have policies and procedures in place for compounding medication, and prepare and maintain the sterile compounding area walls and ceiling with non porous surfaces. These citations are now final.

53. Complainant further alleges that in 2006, Respondent Greenfield was issued Citation No. CI 2005 31601. Respondent Greenfield was charged with a violation of Code section 4342 and title 16, California Code of Regulations, section 1716, for a total amount of $500.00. It charged that in 2006, while under Respondent Dabb's supervision at Respondent Greenfield, a staff pharmacist dispensed a prescription lacking in quality and label strength. The fine was reduced to $400.00. The modified citation was paid in January 2012.

54. Complainant further alleges that in 2006, Respondent Dabbs was issued Citation No. CI 2006 32417. He was charged with a violation of Code section 4342, for a total amount of $500.00. It charged that in 2006, Respondent Dabbs changed the compounding procedures for Tacrolimus, and that the resulting product was lacking in quality and label strength. The fine was reduced to $400.00. The modified citation was paid in January 2012.

55. Complainant further alleges that in 2012, Respondent Dabbs was issued Citation No. CI 2011 49332. He was charged with a violation of Code section 4301, subdivisions (h) and (l), for a total amount of $2,500.00. It charged that in 2011, Respondent Dabbs was convicted on his plea of guilty of violating Vehicle Code section 23152, subdivision (a), driving under the influence, a misdemeanor, and that he used alcohol in a manner dangerous to himself and the public. He paid the citation.

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 Pharmacist License Number RPH 28419, issued to John Newton Dabbs III;

2. Revoking or suspending Pharmacy Permit Number PHY 37480, issued to Greenfield Pharmacy;

3. Ordering John Newton Dabbs III and Greenfield Pharmacy to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: 11/12/13

Adrian R. Contreras

ADRIAN R. CONTRERAS,
DEPUTY ATTORNEY GENERAL
ATTORNEY FOR VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SD2013704971 80754609.doc