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

In the Matter of the Accusation Against: **PRECISION PHARMACY LLC DBA PRECISION PHARMACY** **4000 Empire Drive, Suite 200** **Bakersfield, CA 93309** **Original Permit No. PHY 47310** **Sterile Compounding License No. LSC 99351** **PATRICIA WALDRIP-HELGREN** **11916 Old Town Rd** **Bakersfield, CA 93312** **Original Pharmacist License No. RPH 42842** Respondents.	Case No. 3769 **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 October 7, 2005, the Board of Pharmacy issued Original Permit Number PHY 47310 to Precision Pharmacy LLC dba Precision Pharmacy (Respondent Precision Pharmacy). The Original Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2013, unless renewed.

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3. On or about May 8, 2006, the Board of Pharmacy issued Sterile Compounding License Number LSC 99351 to Respondent Precision Pharmacy. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2013, unless renewed.

4. On or about August 10, 1989, the Board of Pharmacy issued Original Pharmacist License Number RPH 42842 to Patricia A. Waldrip-Helgren (Respondent Waldrip-Helgren). The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2013, unless renewed.

JURISDICTION

5. 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.

6. Section 118, subdivision (b) of the Code provides that the suspension, expiration, surrender or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

STATUTORY PROVISIONS

7. Section 4022 of the Code defines the term "dangerous drug" as "any drug . . . 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.

. . . .

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

8. Section 4033, subdivision (a)(1) of the Code defines the term "manufacturer" as "every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer."

9. Section 4040, subdivision (a)[1] of the Codes states:

"(a) 'Prescription' means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

"(E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients.

"(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to either Section 4052.1 or 4052.2.

"(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to either subparagraph (d) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 by a pharmacist licensed in this state."

10. Section 4043, subdivision (a) of the Code states the term "wholesaler" as "a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a

[1] Though Business and Professions Code section 4040 has been subsequently amended, the following language reflects the version of section 4040 which was in effect at the time that the facts giving rise to the allegations asserted in this Accusation took place.

nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board."

11. Section 4052 of the Code states, in pertinent part:

"(a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber."

12. Section 4059.5 of the Code states, in pertinent part:

"(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. . . .

. . . .

"(e) A dangerous drug . . . shall not be transferred, sold, or delivered to a person outside this state, . . . unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state . . . to which the dangerous drugs . . . are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state . . . to which the dangerous drugs . . . are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs . . . is authorized by law to receive the dangerous drugs . . . .

"(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered."

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13. Section 4078 of the Code states:

"(a)

(1) No person shall place a false or misleading label on a prescription.

(2) No prescriber shall direct that a prescription be labeled with any information that is false or misleading.

"(b) Notwithstanding subdivision (a), a person may label a prescription, or a prescriber may direct that a prescription be labeled, with information about the drug that is false under either of the following circumstances:

(1) If the labeling is a necessary part of a clinical or investigational drug program approved by the federal Food and Drug Administration or a legitimate investigational drug project involving a drug previously approved by the federal Food and Drug Administration.

(2) If, in the medical judgment of the prescriber, the labeling is appropriate for the proper treatment of the patient.

"(c) The furnisher of a prescription labeled pursuant to subdivision (b) shall make, and retain for three years from the date of making, a record stating the manner in which the information on the prescription label varies from the actual drug in the container and documenting the order of the prescriber to so label the container. The prescriber shall make, and retain for at least three years, a record of his or her order to so label the container.

14. Section 4113, subdivision (c) of the Code states: "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."

15. Section 4115 of the Code states:

"(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist.

"(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty.

"(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

"(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

"(e) No person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

"(f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, and for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would

interfere with the effective performance of the pharmacist' s responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

"(g) Notwithstanding subdivisions (a) and (b), the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. Nothing in this subdivision shall be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (f).

"(h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist."

16. Section 4169 of the Code states:

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

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(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.

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(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.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

"(b) Notwithstanding any other provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

"(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

"(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health."

17. 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.

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"(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. The board may issue the license subject to any terms or conditions not contrary to public policy, including, but not limited to, the following:

(1) Medical or psychiatric evaluation.

(2) Continuing medical or psychiatric treatment.

(3) Restriction of type or circumstances of practice.

(4) Continuing participation in a board-approved rehabilitation program.

(5) Abstention from the use of alcohol or drugs.

(6) Random fluid testing for alcohol or drugs.

(7) Compliance with laws and regulations governing the practice of pharmacy.

"(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions.

"(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."

18. 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:

"(a) Gross immorality.

"(b) Incompetence.

"(c) Gross negligence.

"(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

"(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

"(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

"(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.

"(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering or offering to sell, furnish, give away, or administer any controlled substance to an addict.

"(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.

"(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

"(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.

"(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

"(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

"(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.

"(p) Actions or conduct that would have warranted denial of a license.

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

"(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

"(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. "

19. Section 4076 of the Code states:

"(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of,

subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1., the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11)(A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

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(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

"(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

"(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052,

"(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a

patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000), the Nursing Practice Act (Chapter 6 (commencing with Section 2700), or the Vocational Nursing Act (Chapter 6.5 (commencing with Section 2840), who is acting within his or her scope of practice."

20. Section 11170 of the Health & Safety Code states that "[n]o person shall prescribe, administer, or furnish a controlled substance for himself."

REGULATORY PROVISIONS

21. California Code of Regulations, title 16, section 1714, subdivision (b) states, in pertinent part:

"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."

22. California Code of Regulations, title 16, section 1716.1[2], states:

"As used in Business and Professions Code section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:

"(a) 'Reasonable quantity' means that quantity of an unapproved drug which:

"(1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and

"(2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and

"(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.

"(b) 'Compounded medication' means medications actually compounded by the pharmacy supplying them to a prescriber.

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[2] Though 16 CCR 1716.1 has been repealed, it was in effect at the time that the facts giving rise to the allegations asserted in this Accusation took place.

"(c) 'Prescriber office use' means application or administration in the prescriber's office, or for distribution of not more than a 72 hour supply to the prescriber's patients as estimated by the prescriber."

23. California Code of Regulations, title 16, section 1716.2[3], states:

"(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

(1) The date of preparation.

(2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.

(3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(4) The signature or initials of the pharmacist performing the compounding.

(5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.

(6) The name(s) of the manufacturer(s) of the raw materials.

(7) The quantity in units of finished products or grams of raw materials.

(8) The package size and the number of units prepared."

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[3] Though 16 CCR 1716.2 has been repealed, it was in effect at the time that the facts giving rise to the allegations asserted in this Accusation took place.

24. California Code of Regulations, title 16, section 1717, states:

"(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.

"Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

(3) each patient med pak bears an auxiliary label which reads, store in a cool, dry place.

"(b) In addition to the requirements of Section 4040, Business and Professions Code, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

"(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself.

"All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.

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"Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

"(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.

"(e) A pharmacist may transfer a prescription for Schedule III, IV, or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, section 1306.26.

" Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of section 1716 of this Division. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;

(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;

(3) Original date and last dispensing date;

(4) Number of refills and date originally authorized;

(5) Number of refills remaining but not dispensed;

(6) Number of refills transferred.

"(f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an

automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years."

25. California Code of Regulations, title 16, section 1718.1, states:

"All prescription drugs not bearing a manufacturer's expiration date pursuant to Title 21, Code of Federal Regulations, section 211.137 are deemed to have expired and may not be manufactured, distributed, held for sale, or dispensed by any manufacturer, distributor, pharmacist, pharmacy or other persons authorized to dispense such drugs in California."

26. California Code of Regulations, title 16, section 1751.2, states:

"In addition to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

"(a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.

"(b) Name and concentrations of ingredients contained in the sterile injectable product.

"(c) Instructions for storage and handling.

"(d) All cytotoxic agents shall bear a special label which states 'Chemotherapy - Dispose of Properly.'"

27. California Code of Regulations, title 16, section 1751.3[4], states:

"(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1716.1 shall, in addition to those records required by section 1716.2, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.

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[4] Though 16 CCR 1751.3 has been subsequently amended and renumbered as 16 CCR 1751.1, the following language reflects the version of section 1751.3 which was in effect at the time that the facts giving rise to the allegations asserted in this Accusation took place

"(b) In addition to the records required by subdivision (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:

"(1) The training and competency evaluation of employees in sterile product procedures.

"(2) Refrigerator and freezer temperatures.

"(3) Certification of the sterile compounding environment.

"(4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

"(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.

"(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

"(c) Pharmacies shall maintain records of validation processes as required by section 1751.7(b) for three years."

"(c) Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards."

28. California Code of Regulations, title 16, section 1751.7, states:

"(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

(1) Cleaning and sanitization of the parenteral medication preparation area.

(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

(3) Actions to be taken in the event of a drug recall.

(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

"(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

"(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

"(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures."

29. California Code of Regulations, title 16, section 1770, states:

"For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a

licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare."

REASONABLE COSTS

30. 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.

CONTROLLED SUBSTANCES AND DANGEROUS DRUGS

31. Superiorbute power, whose generic name is Phenylbutazone, is a dangerous drug within the meaning of section 4022.

STATEMENT OF FACTS

32. From on or about October 7, 2005, to February 1, 2009, Bart Tipton was the Pharmacist-in-Charge (PIC) of Respondent Precision Pharmacy.

33. From on or about February 1, 2009 through the present, Respondent Waldrip-Helgren has been the PIC of Respondent Precision Pharmacy.

May 2009 Consumer Complaint[5]

34. On or about May 7, 2009, D.G. of Superior Equine Pharmaceuticals, Inc. submitted a consumer complaint with the Board alleging that in violation of a January 2008 Food and Drug Administration (FDA) "Cease and Desist" letter, Respondent Precision Pharmacy continued to illegally manufacture apple-flavored Phenylbutazone powder from bulk materials and sell the product to veterinarians around the country. D.G. had a patent for apple flavored Superiorbute® powder.

35. The FDA "Cease and Desist" letter was sent to several pharmacies around the country and to the Executive Directors of various boards of pharmacy in several states. It stated, in

[5] The facts alleged in this Accusation are based on four investigative reports. In the interests of clarity, Complainant will provide a footnote referencing the source of the facts alleged in each section. The facts pertaining to the May 2009 consumer complaint can be found in Investigative Report 2009 40885.

pertinent part, that Superior Equine Pharmaceutical, Inc. manufactured the one FDA-approved version of sweetened, apple-flavored Phenylbutazone powder in horse feed for the relief of inflammatory conditions associated with the musculoskeletal system, and that accordingly, any firms that were engaged in the compounding[6] of any of the apple-flavored Phenylbutazone powder products were in violation of the Federal Food, Drug, and Cosmetic Act. It specifically stated that if a firm was engaged in the compounding and/or sale of these illegal phenylbutazone products, it should immediately cease that activity.

September 2009 Inspection[7]

36. On or about September 1, 2009, two (2) Board inspectors conducted an inspection of Respondent Precision Pharmacy. Immediately upon entering, the inspectors noticed several people around several open containers of powders on a large table. Along side of the table were

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[6] The FDA issued a Compliance Policy Guidance (CPG) regarding the compounding of drugs for use in animals that stated, in pertinent part, that the:

> FDA is greatly concerned about veterinarians and pharmacies that are engaged in manufacturing and distributing unapproved new animal drugs in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act (e.g., compounding that is intended to circumvent the drug approval process and provide for the mass marketing of products that have been produced with little or no quality control or manufacturing standards to ensure the purity, potency, and stability of the product). These activities are the focus of this guidance. Pharmacies and veterinarians who engage in activities analogous to manufacturing and distributing drugs for use in animals may be held to the same provisions of the Act as manufacturers.
>
> With regard to compounding from bulk drug substances, two Federal Appeals Court decisions, United States v. Algon Chemical Inc., 879 F.2d 1154 (3d Cir. 1989) and United States v. 9/1 Kg. Containers, 854 F.2d 173 (7th Cir. 1988), affirmed the FDA position that the Act does not permit veterinarians to compound unapproved finished drug products from bulk drug substances, unless the finished drug is not a new animal drug. The principle established by the court applies equally to compounding by pharmacists.

CPG Sec. 608.400 - Compounding of Drugs for Use in Animals (CPG 7125.40), available at: http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074656.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=compounding&utm_content=1.

[7] These facts can be found in Investigative Report 2009 40885.

drums of powders. The inspectors observed the employees compounding apple flavored phenylbutazone powder. The inspectors did not see any gowns, masks, or gloves.

37. The inspectors introduced themselves and met the pharmacist-in-charge (PIC), Respondent Patricia Waldrip-Helgren. The inspectors determined that there was one (1) pharmacist supervising one (1) pharmacist intern, five (5) technicians, and two (2) clerks, which was in violation of the pharmacist:technician ratio of 1:1 for the practice setting. The inspectors observed that compounding was taking place in three (3) different areas in the pharmacy (lobby, pharmacy, and back room).

Illegal Manufacture of Drugs

38. The inspectors observed that there were a large amount of compounded items, made in large enough amounts to have shelves full of product. Records obtained by the inspectors that reflected that Respondent Precision Pharmacy sold the majority of drugs to veterinarians, hospitals, clinics, and rarely to the ultimate consumer, which would be either a horse or a horse owner. In addition, Respondent PIC Waldrip-Helgren told one of the Board inspectors that "a lot of Precision's business is selling directly to veterinarians. Respondent Waldrip-Helgren stated to the Board inspectors that "[Respondent] Precision also fills some prescriptions per specific animal, but that was not the majority of Precision's business." This statement and review of pharmacy records showing the majority of sales to other than a specific patient, strengthens the proof that Precision Pharmacy is manufacturing for office use, rather than selling to ultimate consumer.

39. The inspectors observed that there were large amounts of both commercially available medications, such as Itraconazole 100 mg, DES 3mg, and Griseofulvin 250 mg, as well as large amounts of some medications that are not commercially available, such as Domperidone 10 mg, Estradiol 1mg/Progesterone 100 mg/Testosterone SR 1mg. This demonstrated that Respondent Precision Pharmacy was manufacturing commercially available drugs, which it cannot by law. In addition, it demonstrates that Respondent Precision Pharmacy was compounding large amounts of non-commercially available drugs, which circumvents the FDA process for approving new drugs and is in direct contradiction to the FDA's intent when

permitting pharmacies to compound medication, which is to allow them to create non-commercially available medications to meet specific patient needs.

Illegally Acting as a Wholesaler

40. During the September 2009 inspection, the inspectors observed that though Respondent Precision Pharmacy labeled their Phenylbutazone product as if they were compounding for "office use", in actuality Respondent Precision Pharmacy was not compounding for "office use" because the product was not being applied or administered in the prescriber's office (the patients are horses) and because the product was made in jars and bottles which hold more than a 72 hour supply. Specifically, a printout for all Phenylbutazone 100gm powder sold by Respondent Precision Pharmacy from August 17, 2009, through September 1, 2009, showed that during those two (2) weeks, there were 108 orders filled, and a total of 762 jars dispensed. 33 prescriptions were written for a veterinarian (the veterinarian was listed as the patient), 28 prescriptions were filled for a hospital or clinic, several other prescriptions were filled for equine service or businesses, and only two (2) were written for a specific horse. The 762 containers dispensed each had 100gm of Phenylbutazone powder, thus in a two (2) week period, Respondent Precision Pharmacy dispensed 76,200 grams or 76.2 kg (167 pounds) of Phenylbutazone. The normal dosing of Phenylbutazone in horses is 2-4 grams per 1000 pounds of body weight. Since horses weigh an average of 900-1500 pounds, the dosing is 1.8-6 grams/day. A 72-hour supply of Phenylbutazone for one horse would be 5.4-18 grams/day. Because Precision Pharmacy has 100 gram jars of Phenylbutazone, for each jar Respondent is dispensing a 5.5-18 day supply for one horse which is in excess of a 72 hour supply. Additionally, only one scoop was provided with each jar of Phenylbutazone. Since the dosing of the drug was in scoops, if the prescriber divided what was contained in the large container and placed it in smaller containers, he would not have a scoop to provide with the extra containers of the medication provided. The presence of only one scoop indicates the container was intended for only one patient.

Violations of Prescription Requirements

41. During the September 2009 inspection, one (1) of the inspectors reviewed a sampling of written prescriptions for Phenylbutazone powder and observed that they were not received

telephonically by a pharmacist, did not have a patient name on them and did not have directions for use or strength. The inspector also reviewed a sampling of prescriptions about to be dispensed and observed the following: extra drug coming out near the metal ring which seals the amber bottle, prescription label with no directions or patient name, and sterile compounding labels with no drug names or concentrations of ingredients contained in product.

Discrepancies in Master Formula and Logged Formula Worksheets

42. During the September 2009 inspection, the inspectors found that Respondent Precision Pharmacy's Logged Formula Worksheets did not follow the PCCA (Professional Compounding Centers of America) Master Formulas, despite the fact that Respondent Precision Pharmacy belonged to PCCA. During the inspection, one of the inspectors found vials of the drug Trimethoprim/Sulfadiazine 80/400 Injection Suspension ready to be shipped out to veterinarian, G.W., located in Texas. The vials did not have the lot and expiration stickers that the pharmacy usually puts on the bottom of the vials, but on the dispensing label, there was a lot number of 05152009@12, expiration of 2/27/10, Rx number #134900 and date of 8/31/09, the day before the September 2009 inspection.

43. Respondent Precision Pharmacy's records showed that they made excipient stock solution on September 2, 2008. PCCA master formulas stated that excipient stock solution should expire in thirty days from that date (October 2, 2008), however, Respondent Precision's logged formula worksheets stated that the excipient stock solution expired in 180 days (March 2, 2009). No reason was given as to why the date was extended. The excipient solution was used to compound Sulfadiazine/Trimethoprim on May 15, 2009, after it was already expired (no matter which expiration date was chosen). The PCCA master formula said compounded Sulfadiazine/Trimethoprim expires 90 days after being made (August 15, 2009). Respondent Precision logged formula worksheets said that Sulfadiazine/Trimethoprim expires 180 days after being made (November 11, 2009). The expired excipient that was used to make the Sulfadiazine/Trimethoprim could have posed a serious health hazard, and should not have been dispensed.

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44. When the product was used to dispense Dr. G.W.'s prescription on August 31, 2009, the original lot and expiration sticker which would have shown an expiration of November 11, 2009, was ripped off, and the dispensing prescription label gave the product an expiration date of February 27, 2010, 180 days from the date of the dispensed prescription. Accordingly, expired drugs were being dispensed to unsuspecting consumers.

45. The Logged Formula Worksheets that the investigators secured for the following drugs reflected that each of these drugs had already expired before they were used to make another drug:

a. Edetate disodium expired in May 2009, but was used to make Acetyl-L-Cysteine 20% on August 10, 2009. The new drug was given an expiration date February 6, 2010.

b. Preserved water expired on August 29, 2009, but Respondent Precision Pharmacy pharmacists used it to make Omeprazole 220mg/ml suspension on August 24, 2009. The new drug was given an expiration date of November 22, 2009 by Respondent Precision Pharmacy staff.

c. Preserved water expired on August 29, 2009, but Respondent Precision Pharmacy pharmacists used it to make Rifampin 100mg/ml suspension on August 25, 2009. The new drug was given an expiration date of October 24, 2009, by Respondent Precision Pharmacy staff.

d. Simple syrup expired on October 30, 2009, but Respondent Precision Pharmacy pharmacists used it to make Chloramphenicol 500mg/ml suspension on August 25, 2009. The new drug was given an expiration date of February 21, 2010, by Respondent Precision Pharmacy staff.

e. Simple syrup expired on October 30, 2009, and Fluoxetine had no expiration date, but Respondent Precision Pharmacy pharmacists used both to make Fluoxetine 10mg/ml suspension on August 25, 2009. The new drug was given an expiration date of December 23, 2009, by Respondent Precision Pharmacy staff.

f. Valerian root, passion flower, chamomile powder Apple Vet Paste and Kava Kava root powder expired on September 1, 2009, but Respondent Precision Pharmacy pharmacists used these items to make Valpassikavacam sedative 3/2/0.5gm/1gm/15ml on August 17, 2009. The

new drug was given an expiration date of February 23, 2010, by Respondent Precision Pharmacy staff.

g. Apple vet paste expired on August 26, 2009, but Respondent Precision Pharmacy pharmacists used it to make Griseofulvin 25gm/60ml paste on August 21, 2009. The new drug was given an expiration date of August 26, 2009, or February 17, 2010 (both dates appeared on the sheet).

h. Apple vet paste expired on August 26, 2009, and Glycerin expired on January 1, 2010, but Respondent Precision Pharmacy pharmacists used both to make Rifampin 200mg/ml paste on August 21, 2009. The new drug was given an expiration date of February 17, 2010.

i. Simple syrup expired on October 30, 2009, but Respondent Precision Pharmacy pharmacists used it to make Isoxsuprine 50mg/ml suspension on August 21, 2009. The new drug was given an expiration date of February 17, 2010.

j. Famotidine USP expired on September 1, 2009, but Respondent Precision Pharmacy pharmacists used it to make Famotidine 2mg/ml suspension on August 25, 2009. The new drug was given an expiration date of December 23, 2009.

k. Simple syrup expired on October 30, 2009, but Respondent Precision Pharmacy pharmacists used it to make Pentoxifylline 4gm/30ml suspension on August 21, 2009. The new drug was given an expiration date of November 11, 2009.

l. Distilled water expired on January 1, 2010, but Respondent Precision Pharmacy pharmacists used it to make Zinc sulfate/lead acetate (white lotion) 4.7%/5.7% suspension on August 21, 2009. The new drug was given an expiration date of February 17, 2010.

m. Apple vet paste expired on August 26, 2009, but Respondent Precision Pharmacy pharmacists used it to make Omeprazole 2.2gm/10ml on August 24, 2009. The new drug was given an expiration date of November 22, 2009.

n. Apple vet paste expired on August 26, 2009, but Respondent Precision Pharmacy pharmacists used it to make Omeprazole 2.2gm/10ml on August 24, 2009 [@1]. The new drug was given an expiration date of November 22, 2009.

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o. Apple vet paste expired on August 26, 2009, but Respondent Precision Pharmacy pharmacists used it to make Omeprazole 2.2gm/10ml on August 24, 2009 [@19]. The new drug was given an expiration date of November 22, 2009.

p. Apple vet paste expired on August 26, 2009, but Respondent Precision Pharmacy pharmacists used it to make Clarithromycin/Rifampin 100mg/100mg/ml paste on August 24, 2009. The new drug was given an expiration date of December 22, 2009.

q. Tangerine flavor expired on January 1, 2010 but Respondent Precision Pharmacy pharmacists used it to make Pergolide in oil 2mg/ml on August 24, 2009. The new drug was given an expiration date of February 20, 2010.

r. Apple vet paste expired on August 26, 2009, but Respondent Precision Pharmacy pharmacists used it to make Chloramphenicol apple flavor 25gm/80gm paste on August 24, 2009. The new drug was given an expiration date of February 20, 2010.

s. Glycerol formal expired on August 29, 2009, but Respondent Precision Pharmacy pharmacists used it to make Altrenogest 225mg/ml injectable on August 21, 2009. The new drug was given an expiration date of February 17, 2010.

Additional Violations Discovered During September 2009 Inspection

46. During the September 2009 inspection, the inspectors interviewed Respondent Waldrip-Helgren who admitted that Respondent Precision Pharmacy does not test drugs for pyrogens and that some of the expiration dates for some of the drugs were inaccurate because Respondent Precision Pharmacy staff had not updated the inventory.

47. During the September 2009 inspection, the inspectors also noted that Respondent Precision Pharmacy had failed to include either the lot number or expiration date on the component products, failed to refrigerate drums of large material that were labeled "refrigerate", failed to include lot numbers and expiration dates on all products for future furnishing, maintained drugs with missing manufacturer expiration dates, made, manufactured and/or compounded apple flavored Phenylbutazone powder and maintained drug labels with no route (oral, injection).

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Illegal Shipment of Drugs to North Carolina[8]

48. On or about July 15, 2009, the North Carolina Board of Pharmacy issued a "Cease & Desist Order" to Respondent Precision Pharmacy wherein it indicated that an investigation had specifically determined that Respondent Precision Pharmacy had shipped Pergolide 1mg/ml 100 ml suspension to a veterinarian in North Carolina without holding a valid pharmacy permit in North Carolina. The Order ordered Respondent Precision Pharmacy to immediately cease and desist any further shipping, mailing or dispensing of prescription medications to any person in North Carolina in violation of North Carolina General Statutes section 90-85.3(m), 90-85.21A; 21 North Carolina Administrative Code sections 46.1601 & 1607.

49. In response to a Board inquiry about the North Carolina investigation, Respondent Precision Pharmacy admitted in a letter dated January 20, 2010, that they had shipped drugs to North Carolina. Respondent Precision Pharmacy also produced a list that showed Respondent Precision Pharmacy sales into North Carolina from June 15, 2007, through October 6, 2008.

Illegal Shipment of Drugs to Louisiana[9]

50. On or about September 17, 2009, the Board received a complaint from the Louisiana Board of Pharmacy stating that Respondent Precision Pharmacy had shipped drugs into Louisiana without proper licensing in violation of Louisiana Administrative Code, Title 46:LIII§2301 et seq.

51. In response to a Board inquiry about the Louisiana investigation, Respondent Precision Pharmacy admitted in a letter dated January 20, 2010, that they had shipped drugs to Louisiana. Respondent Precision Pharmacy also produced a list that showed Respondent Precision Pharmacy sent 1583 drug orders to 47 patients in Louisiana.

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[8] These facts can be found in Investigative Report 2009 41041.
[9] These facts can be found in Investigative Report 2009 41533.

FIRST CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Waldrip-Helgren)

(Acting as a Manufacturer Without a License)

52. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 4033, subdivision (a)(1) in that Respondent was acting as a manufacturer without a license in that during inspections of Respondent Precision Pharmacy on or about September 1, 2009, and November 10, 2009, Board inspectors noted large amounts of compounded drugs which were sold to veterinarians nationwide who then sold and/or dispensed them to the ultimate consumer. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

SECOND CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Waldrip-Helgren)

(Acting as a Wholesaler Without a License)

53. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 4043 which provides the definition of "wholesaler." During an inspection of Respondent Precision Pharmacy on September 1, 2009, one of the Board Inspectors determined that the overwhelming majority of Phenylbutazone "prescriptions" (106 prescriptions out of 108) that Respondent Precision Pharmacy filled between August 17, 2009, and September 1, 2009, were not "prescriptions" as defined in Business and Professions Code section 4040 in that they were not given individually for the person or persons for whom they were ordered. Respondent Precision Pharmacy actually filled the orders and then sent them to the prescriber, which is the business of a wholesaler. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

THIRD CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)

(Filling Prescriptions with Missing Prescription Requirements/Components)

54. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 4040, subdivisions (a)(1)(A) and (a)(1)(B) which requires that

prescriptions contain the name or names and addresses of the patient or patients, name and quantity of the drug prescribed and the directions for use, the date of issue, and the name, address and telephone number of the prescriber. Specifically, during an inspection of Respondent Precision Pharmacy on September 1, 2009, Board inspectors secured prescriptions that were missing some of the information required pursuant to section 4040. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

FOURTH CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)

(Filling Prescription With Missing Prescription Label Requirements)

55. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 4076, subdivision (a)(2) and (a)(3) which requires a prescription label to have the directions for use, name of the patient or patients, and strength of drug dispensed. Specifically, during an inspection of Respondent Precision Pharmacy on September 1, 2009, Board inspectors secured prescription labels that were missing some of the information required pursuant to section 4076. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

FIFTH CAUSE FOR DISCIPLINE

(Against Respondents, Precision Pharmacy and Patricia Waldrip-Helgren)

(Failure to Meet Sterile Injectable Product Label Requirements)

56. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 1751.2, subdivision (b) of California Code of Regulations, which requires that the name and concentrations of ingredients contained in the sterile injectable product be included on the label. Specifically, during an inspection of Respondent Precision Pharmacy on September 1, 2009, Board inspectors located labels for sterile injectable products that were not in compliance with 1751.2, subdivision (b) of California Code of Regulations. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

SIXTH CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)

(Failure to Maintain Proper/Accurate Preparation Records)

57. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 1751.3, subdivision (b)(6) of California Code of Regulations, which requires sterile compounding pharmacies to keep preparation records including the master worksheet, the preparation worksheet, and the records of end product evaluation results. Specifically, during an inspection of Respondent Precision Pharmacy on September 1, 2009, Board inspectors located the Logged Formula Worksheets beyond use dates for a certain drug(s) that did not match the Master Formula record beyond use date of 90 days. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

SEVENTH CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)

(Failure to Maintain Proper Expiration Date of Component)

58. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 1716.2, subdivision (a)(3) of California Code of Regulations, which requires that a pharmacy maintain the expiration date of a finished product and that the date shall not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies. Specifically, during an inspection of Respondent Precision Pharmacy on September 1, 2009, Board inspectors located Logged Formula Worksheets for prepared products which did not use the expiration date of the earliest expiration date of the component in the finished products. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

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EIGHTH CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)

(Failure to Include Written Justification of Chosen Expiration Dates)

59. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 1751.7, subdivision (a)(4) of California Code of Regulations, which requires compounders to have written justification of the chosen expiration dates for compounded sterile injectable products. Specifically, Respondent Precision Pharmacy assigned several drugs expiration dates which did not use the expiration date of the earliest component to expire and there is no written justification for the choice in date. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

NINTH CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)

(Failure to Include/Provide Policies & Procedures for Master Formulas and Worksheets)

60. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 1751.02, subdivision (c)(3)(I) of California Code of Regulations, which requires sterile injectable compounders to have written policies and procedures for sterile injectable compounders to have written policies and procedures for sterile batch compounding use of master formulas and worksheets. Specifically, during an inspection of Respondent Precision Pharmacy on September 1, 2009, Board inspectors obtained a sample of Master Formulas and Logged Formula Worksheets which had different beyond use dates from the Master Formulas and Logged Formula Worksheets. There were no explanation or policies and procedures on how to use the Master formulas and Logged Formula Worksheets. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

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TENTH CAUSE FOR DISCIPLINE

(Against Respondents, Precision Pharmacy and Patricia Waldrip-Helgren)

(Failure to Conduct End Product Testing for Sterility on All Batches)

61. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 4342, subdivision (a) as it relates to Business and Professions Code section 4169, subdivisions (a)(3) and (a)(4) which prohibits a person or entity from purchasing, selling, or trading a dangerous drug which the person knew or reasonably should have known were misbranded, and if a drug was purchased, sold, or traded after the beyond use date on the label. Specifically, during an inspection at Precision Pharmacy on September 1, 2009, a Board inspector observed an order for Sulfadiazine Sodium/Trimeth 437/80, prescription #134900 prepared on May 15, 2009, which was given an expiration date of February 27, 2010; however, further research revealed that the drug had actually expired on October 2, 2008. The flagged lot and expiration date labels were not on the vial, suggesting they were removed before dispensing. In addition, several other drugs were found on the shelves of the pharmacy with no expiration date or lot number. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

ELEVENTH CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)

(Sale of Misbranded Drugs)

62. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 1751.7, subdivision (c) of California Code of Regulations, which requires batch produced sterile injectable drugs compounded from one or more non-sterile ingredients to be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable level of pyrogens. Specifically, during an inspection of Respondent Precision Pharmacy on September 1, 2009, a Board inspector noted a large amount of sterile injectable products on the pharmacy shelves and requested proof of pyrogen testing. Respondent Waldrip-Helgren stated that they were not doing pyrogen testing on all items. Later Respondent Waldrip-Helgren admitted that Respondent

Precision Pharmacy was not doing pyrogen testing at all prior to September 1, 2009 Board inspection. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

TWELFTH CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)

(Failure to Keep Lot and Expiration Date on Logged Formula Worksheets)

63. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 1716.2, subdivision (a)(2) of California Code of Regulations, which requires records, including lot numbers and expiration dates, be kept when compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon a prescription. Specifically, during an inspection at Respondent Precision Pharmacy on September 1, 2009, Board inspectors located Logged Formula Worksheets for various medications/drugs with missing lot and/or expiration dates. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

THIRTEENTH CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)

(Knowingly Making a False Document)

64. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 4301, subdivision (g) which defines unprofessional conduct as knowingly making or signing any certificate or other document that falsely represents the existence or non-existence of a state of facts. Specifically, during an inspection at Respondent Precision Pharmacy on September 1, 2009, Board inspectors secured Logged Formula Worksheets for various medications/drugs where the expiration date of the finished product did not correspond with the earliest expiring product. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

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FOURTEENTH CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)

(Keeping Refrigerated Drugs at Room Temperature)

65. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 4169, subdivision (a)(2) which states no person or entity shall purchase, sell or transfer drugs the person knew or reasonably should have known were adulterated. Specifically, during an inspection at Respondent Precision Pharmacy on September 1, 2009, Board inspectors noted that there was one (1) drum of griseofulvin and two (2) drums of omeprazole which stated "REFRIGERATE" but which were kept at room temperature in the pharmacy. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

FIFTEENTH CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)

(Violation of Food, Drug, and Cosmetic Act and FDA Cease and Desist Order)

66. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are not in compliance with an FDA Cease and Desist letter issued for production of apple flavored phenylbutazone powder. Specifically, during an inspection at Respondent Precision Pharmacy on September 1, 2009, Board inspectors observed Respondent Precision Pharmacy staff compounding apple flavored phenylbutazone powder. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

SIXTEENTH CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)

(Maintaining Drugs and Other Items for Manufacture Without Expiration Date)

67. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 1718.1 of the California Code of Regulations which states that all prescription drugs not bearing a manufacturer's expiration date are deemed to have expired and may not be manufactured, distributed, held for sale, or dispensed. Section 211.137 of title 21 of the Code of Federal Regulations states that all drug products must have an expiration date.

Specifically, during an inspection at Respondent Precision Pharmacy on September 1, 2009, Board inspectors observed that the following medications were found inside of Respondent Precision Pharmacy without an expiration date: Phenylbutazone apple flavored paste syringes, Ranitidine 1500mg/scoop-100 scoop jar, Rifampin 300mg/scoop-100 scoop jar, Triple Antibiotic ointment 454 gram jar, Isoxsuprine 600mg/scoop-100 scoop jar, Doxycycline 1gm/scoop-100 scoop jar, Acetylcysteine (N) 2gm/scoop-100 scoop jar, Potassium Bromide 500mg capsule-bottle of 100 capsules. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Against Respondents, Precision Pharmacy and Patricia Waldrip-Helgren)

(Placing False or Misleading Labels on Prescription)

68. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 4078, subdivision (a)(1) which states that no person shall place a false or misleading label on a prescription. Specifically, during an inspection at Respondent Precision Pharmacy on September 1, 2009, a Board inspector located a label for apple flavored bute powder with no route of administration. It did not give directions on whether it was to be mixed in with food or water or taken "as is." The label stated "1gm/scoop, 100gm jar." However, the "scoop size" was not defined, and if the scoop were to be misplaced, the patient may potentially get a different dose of the drug. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Against Respondents, Precision Pharmacy and Patricia Waldrip-Helgren)

(Failure to Maintain Proper Pharmacist-Technician Ratio)

69. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 4115, subdivision (f)(1) as it relates to California Code of Regulations section 1793.7, subdivision (b), which states that the ratio of pharmacist to technicians shall not be greater than 1:1 in a retail pharmacy. Specifically, during the inspection at Respondent Precision Pharmacy on September 1, 2009, there was one (1) pharmacist with one

(1) intern, five (5) technicians, and two (2) clerks. Another pharmacist came in an hour after the inspector had been at the pharmacy. In addition, during the inspection at Respondent Precision Pharmacy on November 10, 2009, there were two (2) pharmacists with one (1) intern, seven (7) technicians, and one (1) clerk. The inspector found more technicians than allowed for by the ratio, and not all could be supervised by the pharmacist due to the layout of the pharmacy. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

NINETEENTH CAUSE FOR DISCIPLINE

(Against Respondents, Precision Pharmacy and Patricia Waldrip-Helgren)

(Orally Transmitted Prescriptions Taken by Pharmacy Technicians)

70. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 1717, subdivision (c) which states an oral prescription may only be taken and transcribed by a pharmacist. Specifically, during inspections at Respondent Precision Pharmacy on September 1, 2009, and November 10, 2009, a Board inspector was told by the technicians that they took the prescription orders and wrote them on the blanks, and that the pharmacists rarely wrote the prescriptions. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

TWENTIETH CAUSE FOR DISCIPLINE

(Against Respondents, Precision Pharmacy and Patricia Waldrip-Helgren)

(Dispensing Controlled Substance Prescriptions Written by Prescribers for Themselves)

71. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 11170 of the Health and Safety Code which states that a prescriber may not prescribe a controlled substance for himself. Specifically, Respondent Precision Pharmacy provided a printout showing that it dispensed 14 controlled substance prescriptions which had been self-prescribed. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

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TWENTY-FIRST CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and PIC Patricia Waldrip-Helgren)

(Failure to Comply with Other States' Laws When Transferring Drugs to Other States)

72. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 4059.5, in that Respondent Precision Pharmacy transferred medications to other states in violation of the other states' laws. The circumstances are as follows:

a. From on or about June 15, 2007, through October 6, 2008, Respondent Precision Pharmacy sent medications to North Carolina without a license in North Carolina, in violation of North Carolina General Statutes sections 90-85.3(m) and 90-85.21A, and 21 North Carolina Administrative Code sections 46.1601 and 1607. Complainant also refers to and incorporates all the allegations contained in paragraphs 48 and 49, above, as though set forth fully.

b. On dates unknown prior to on or about September 14, 2009, Respondent Precision Pharmacy sent approximately 1,583 prescriptions to Louisiana without a license in Louisiana, in violation of title 46 of the Louisiana Administrative Code, section LIII 2301 et cetera. Complainant also refers to and incorporates all the allegations contained in paragraphs 50 and 51, above, as though set forth fully.

DISCIPLINE CONSIDERATIONS

73. To determine the degree of discipline, if any, to be imposed on Respondent Precision Pharmacy, Complainant alleges that on or about July 28, 2009, in a prior action, the Board issued Citation Number C1 2007 36942 and ordered Respondent to pay a total of $3,000.00 in fines. The fines were imposed for violation of Code section 4059.5(2) (i.e., subdivision (f)(2)), which requires that only the PIC or the pharmacist designated by the PIC have access to the pharmacy's dangerous drugs' secure storage facility; and for violation of section 1714, subdivision (b) of title 16 of the California Code of Regulations, which requires that pharmacies maintain their dangerous drugs in a safe and secure manner. That Citation is now final and is incorporated by reference as if fully set forth.

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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 Original Permit Number PHY 47310, issued to Precision Pharmacy LLC dba Precision Pharmacy;

2. Revoking or suspending Sterile Compounding License Number LSC 99351, issued to Precision Pharmacy LLC dba Precision Pharmacy;

3. Revoking or suspending Original Pharmacist License Number RPH 42842, issued to Patricia A. Waldrip-Helgren;

4. Ordering Precision Pharmacy to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Code section 125.3; and

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

DATED: 3/30/13

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

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