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

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

In the Matter of the Accusation Against: **GRANDPA'S COMPOUNDING PHARMACY** **WILLIAM R. WILLS, OWNER** **DARRELL CAVALARI,** **aka DARRELL WILLIAM CAVALARI,** **PHARMACIST-IN-CHARGE** **7563 Green Valley Road** **Placerville, CA 95667** **Pharmacy Permit No. PHY 45878** **and** **WILLIAM R. WILLS** **AKA WILLIAM RAY WILLS** **7563 Green Valley Road** **Placerville, CA 95667** **Pharmacist License NO. RPH 27496** **and** **DARRELL WILLIAM CAVALARI** **5933 Adana Circle** **Carmichael, CA 95608** **Pharmacist License No. RPH 30372** **and**	Case No. 5787 **F I R S T A M E N D E D** **A C C U S A T I O N**

DANIEL R. WILLS
7563 Green Valley Road
Placerville, CA

Pharmacy Technician License No. TCH 36985

Respondents.

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 ("Board"), Department of Consumer Affairs.

2. On or about May 30, 2002, the Board issued Pharmacy Permit Number PHY 45878 to William R. Wills, also known as (aka) William Ray Wills ("Respondent W. Wills"), owner of Grandpa's Compounding Pharmacy (Respondent Grandpa's) and pharmacist-in-charge. On or about July 15, 2013, Darrell Cavalari aka Darrell William Cavalari ("Respondent Cavalari"), became the pharmacist-in-charge. The pharmacy permit was in full force and effect at all times relevant to the charges brought herein. On or about May 3, 2017, the Board received a discontinuance of business notification from Respondent Grandpa's, thereby ceasing to practice as a pharmacy. On or about May 18, 2017, the Board filed a petition for interim suspension order to which Respondent Grandpa's stipulated, and an interim suspension order was issued against Respondent Grandpa's on June 5, 2017.

3. On or about August 25, 1971, the Board issued Pharmacist License Number RPH 27496 to Respondent W. Wills. The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2017, unless renewed. On or about May 18, 2017, the Board filed a petition for interim suspension order to which Respondent W. Wills stipulated, and an interim suspension order was issued against Respondent W. Wills on June 5, 2017.

4. On or about August 2, 1976, the Board issued Pharmacist License Number RPH 30372 to Respondent Cavalari. The pharmacist license was in full force and effect at all times

relevant to the charges brought herein and will expire on May 31, 2019, unless renewed. On or about May 18, 2017, the Board filed a petition for interim suspension order for which a hearing was held on June 5, 2017. An interim suspension order was issued against Respondent Cavalari on June 9, 2017. Subsequently, the Board was notified that Respondent Cavalari died on or about June 8, 2017.

5. On or about March 26, 2001, the Board issued Pharmacy Technician License Number TCH 36985 to Daniel R. Wills (Respondent D. Wills). The pharmacy technician license was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2019, unless renewed. On or about May 18, 2017, the Board filed a petition for interim suspension order to which Respondent D. Wills stipulated, and an interim suspension order was issued against Respondent D. Wills on June 5, 2017.

JURISDICTION/STATUTORY AND REGULATORY PROVISIONS

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

7. Code section 4300 states, in pertinent part:

(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper . . .

8. Code section 4300.1 states:

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

proceeding against, the licensee or to render a decision suspending or revoking the license.

9. Code section 4301 states, in pertinent part:

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

(b) Incompetence.

(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.

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency . . . .

10. Code section 4306.5 states, in pertinent part:

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

(a) 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.

(c) 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.

11. Code section 4025 states:

"Drug" means any of the following:

(a) Articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement of any of them.

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals.

(c) Articles (other than food) intended to affect the structure or any function of the body of human beings or other animals.

(d) Articles intended for use as a component of any article specified in subdivision (a), (b), or (c).

///

12. Code section 4040 states in pertinent part:

(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:

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

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

13. Code section 4059, subdivision (e), states:

A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, 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 or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

14. Code section 4072 states in pertinent part:

(a) Notwithstanding any other provision of law, a pharmacist, registered nurse, licensed vocational nurse, licensed psychiatric technician, or other healing arts licentiate, if so authorized by administrative regulation, who is employed by or serves as a consultant for a licensed skilled nursing, intermediate care, or other health care facility, may orally or electronically transmit to the furnisher a prescription lawfully ordered by a person authorized to prescribe drugs or devices pursuant to Sections 4040 and 4070. The furnisher shall take appropriate steps to determine that the person who transmits the prescription is authorized to do so and shall record the name of the person who transmits the order. This section shall not apply to orders for Schedule II controlled substances.

15. Code section 4081 states in pertinent part:

(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, 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, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-

in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.

16. Code section 4110 states in pertinent part:

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

17. Code section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

18. Code section 4307 states in pertinent part:

(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, partner, or any other person with management or control of any partnership, corporation, trust, 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, partner, or any other person with management or control 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, partner, or in any other position with management or control of a licensee as follows:

(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, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

19. Code section 4330 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 pharmacy 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.

20. Code section 4332 states that "[A]ny 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."

21. Code section 4342, subdivision (a), 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).

HEALTH AND SAFETY CODE SECTIONS

22. Health and Safety Code section 11159.2 states in pertinent part:

(a) Notwithstanding any other provision of law, a prescription for a controlled substance for use by a patient who has a terminal illness may be written on a prescription form that does not meet the requirements of Section 11162.1 if the prescription meets the following requirements:

(1) Contain the information specified in subdivision (a) of Section 11164.

(2) Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

23. Health and Safety Code section 11164 states in pertinent part:

Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name 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; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist

shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

24. Health and Safety Code section 111335 provides that any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290.)

25. Health and Safety Code section 110290 states:

> In determining whether the labeling or advertisement of a food, drug, device, or cosmetic is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account. The extent that the labeling or advertising fails to reveal facts concerning the food, drug, device, or cosmetic or consequences of customary use of the food, drug, device, or cosmetic shall also be considered.

26. Health and Safety Code section 111330 states that "[a]ny drug or device is misbranded if its labeling is false or misleading in any particular."

27. Health and Safety Code section 111400 provides that any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

28. Health and Safety Code section 111440 provides that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

29. Health and Safety Code section 111450 provides that it is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

30. Health and Safety Code section 111550 provides, in pertinent part:

> No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:
>
> (a) It is one of the following:
>
> (1) A new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355).
>
> (b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended . . .

FEDERAL STATUTES AND REGULATIONS

31. Section 201, subdivision (p), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. section 321, subdivision (p)), states, in pertinent part:

> The term "new drug" means--
>
> (1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof . . .
>
> (2) Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

32. Title 21, United States Code, section 352, states in pertinent part:

> A Drug or device shall be deemed to be misbranded—
>
> (f) Directions for use and warnings on label
>
> Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

33. Section 505, subdivision (a), of the Act (21 U.S.C. section 355, subdivision (a)), states, in pertinent part, that ". . . [n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."

34. Title 21, Code of Federal Regulations, section 201.5 states:

> "Adequate directions for use" means directions under which the layman can use a drug safely and for the purposes for which it is intended. (Section 201.128 defines "intended use.") Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of:
>
> (a) Statements of all conditions, purposes, or uses for which such drug is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug is commonly used; except that such statements shall not refer to conditions, uses, or

purposes for which the drug can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(b) Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions.

(c) Frequency of administration or application.

(d) Duration of administration or application.

(e) Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factors).

(f) Route or method of administration or application.

(g) Preparation for use, i.e., shaking, dilution, adjustment of temperature, or, other manipulation or process.

35. Title 21, Code of Federal Regulations, section 1301.75 states in pertinent part:

(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

CALIFORNIA CODE OF REGULATIONS

36. Title 16, California Code of Regulations (Regulation), section 1709 states:

(a) Each permit to operate a pharmacy shall show the name and address of the pharmacy, the form of ownership (individual, partnership or corporation) and the pharmacist-in-charge. Each pharmacy shall, in its initial application on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the Board within 30 days.

(b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original permit was issued, shall require written notification to the board within 30 days.

(c) The following shall constitute a transfer of permit and require application for a change of ownership: any transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license.

37. Regulation section 1714 states in permanent part:

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

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

38. Regulation 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.

39. Regulation section 1735.2, states in pertinent part:

> (c) A "reasonable quantity" as used in Business and Professions Code section 4052(a)(1) means that amount of compounded drug product that:
>
> (1) is sufficient for administration or application to patients 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 . . .

40. Regulation section 1735.5 states in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain written policies and procedures 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. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

(c) The policies and procedures shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.

(3) 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) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

41. Regulation section 1735.6 states in pertinent part:

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

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy.

Documentation of each such calibration shall be recorded in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

42. Regulation section 1735.7 states:

(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.

(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 preparation.

43. Regulation 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 preparations.

(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 analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

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

(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

NORTH CAROLINA GENERAL STATUTES

44. North Carolina General Statutes, section 90-85.21A, subdivision (a), states:

> Any pharmacy operating outside the State which ships, mails, or delivers in any manner a dispensed legend drug into this State shall annually register with the Board on a form provided by the Board. In order to satisfy the registration requirements of this subsection, a pharmacy shall certify that the pharmacy employs a pharmacist who is responsible for dispensing, shipping, mailing, or delivering dispensed legend drugs into this State or in a state approved by the Board and has met requirements for licensure equivalent to the requirements for licensure in this State. In order for the pharmacy's certification of the pharmacists to be valid, a pharmacist shall agree in writing, on a form approved by the Board, to be subject to the jurisdiction of the Board . . .

COST RECOVERY

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

DRUG CLASSIFICATIONS

46. Cocaine is a Schedule II controlled substance pursuant to Health and Safety Code section 11055 subdivision (b)(6), and a dangerous drug under Code section 4022.

///

47. Codeine is a Schedule II controlled substance pursuant to Health and Safety Code section 11055 subdivision (b)(1)(G), and a dangerous drug under Code section 4022.

48. Domperidone is an anti-dopaminergic drug that acts as an antiemetic and a prokinetic agent. It is a dangerous drug under Code section 4022. Domperidone is not currently a legally marketed human drug and is not approved for sale in the United States. The U.S. Food and Drug Administration ("FDA") has determined that any products containing domperidone are unapproved new drugs and misbranded. Consequently, any product containing domperidone violates the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301, et seq.; "the Act"). Domperidone is available for use in the treatment of certain gastrointestinal disorders, but only if an Investigational New Drug Application ("IND") is submitted to and approved by the FDA.

49. Hydrocodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055 subdivision (b)(1)(I), and a dangerous drug under Code section 4022.

50. Hydromorphone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055 subdivision (b)(1)(J), and a dangerous drug under Code section 4022.

51. Ketamine is a Schedule III controlled substance pursuant to Health and Safety Code section 11056 subdivision (g), and a dangerous drug under Code section 4022.

52. Methadone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055 subdivision (c)(14), and a dangerous drug under Code section 4022.

53. Morphine is a Schedule II controlled substance pursuant to Health and Safety Code section 11055 subdivision (b)(1)(L), and a dangerous drug under Code section 4022.

54. Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055 subdivision (b)(1)(M), and a dangerous drug under Code section 4022.

55. Sildenafil is a dangerous drug under Code section 4022 and is indicated for use in the treatment of erectile dysfunction. "Viagra" is the brand name for sildenafil.

56. Tadalafil is a dangerous drug under Code section 4022 and is indicated for use in the treatment of erectile dysfunction. "Cialis" is the brand name for tadalafil.

///

///

57. Testosterone is a Schedule III controlled substance under Health and Safety Code section 11056, subdivision (f)(30), and a dangerous drug under Code section 4022. It is indicated for use as a hormone replacement.

BACKGROUND

58. On or about June 7, 2004, the FDA issued a Talk Paper entitled, "FDA Warns against Women Using Unapproved Drug, Domperidone, to Increase Milk Production", warning breastfeeding women not to use the product because of safety concerns. The FDA stated that although domperidone was approved in several countries outside the U.S. to treat certain gastric disorders, it is not approved in any country, including the U.S., for enhancing breast milk production in lactating women and is also not approved in the U.S. for any indication.[1]

59. On or about March 12, 2012, the FDA issued Import Alert 61-07, stating that domperidone was being imported as a bulk API (active pharmaceutical ingredient) for pharmacy compounding and that importation of the drug presented a public health risk and violated the Act.

60. On and between June 7, 2004 and April 14, 2015, the FDA issued warning letters to 17 pharmacies, each of which compounded products containing domperidone. The FDA advised the pharmacies that (1) all products containing domperidone are new drugs as defined by section 201, subdivision (p), of the Act (21 U.S.C. section 321, subdivision (p)), in that they are not recognized by qualified experts as safe and effective for their labeled use; (2) no approved application pursuant to section 505 of the Act is in effect with respect to these products and as such, their introduction, or delivery for introduction into interstate commerce, is in violation of section 505, subdivision (a), of the Act (21 U.S.C. section 355, subdivision (a)); (3) because the domperidone products that the pharmacy manufactures and distributes without valid prescriptions for individually-identified patients are not the subject of approved applications, they are unapproved new drugs in violation of section 505 of the Act; and/or (4) the domperidone products

[1] The FDA stated that there were several published reports and case studies of cardiac arrhythmias, cardiac arrest, and sudden death in patients receiving an IV form of domperidone, which had been withdrawn from marketing in a number of countries. Further, in several countries where the oral form of domperidone continued to be marketed, labels for the product contained specific warnings against use of domperidone by breastfeeding women.

are also misbranded under section 502, subdivision (f)(1), of the Act (21 U.S.C. section 352, subdivision (f)(1)) because they do not bear adequate directions for use.

61. On or about April 14, 2015, the Board issued a Subscriber Alert[2], stating that domperidone is not approved by the FDA for any use in humans in the U.S. The Board also stated that the FDA currently permits patients 12 years of age and older with various gastrointestinal conditions that are refractory to standard therapy to be treated with domperidone through an Expanded Access Program, that physicians who are interested in obtaining expanded access for domperidone must submit an IND, and that currently, no pharmacies are authorized to compound domperidone under the Expanded Access program.

INSPECTION OF SEPTEMBER 2, 2015

62. On or about September 2, 2015, Inspector H. of the Board and Investigator P. and Consumer Safety Officer L. of the FDA conducted a joint inspection of Grandpa's Compounding Pharmacy. The FDA had received a consumer complaint, alleging that the pharmacy furnished domperidone prescriptions and that the consumer had an adverse reaction to the drug.

63. Respondent Cavalari and pharmacist W. told Inspector H., Investigator P. and Officer L. that they stopped dispensing domperidone after receiving the Board's Subscriber Alert. Pharmacist W. stated that he did not receive the Alert until April 22, 2015, when a colleague emailed him a copy. The same day that he received the alert, Pharmacist W. removed all domperidone from the active inventory and placed it in a box to be sent to their drug return/destruction wholesaler. Pharmacist W. retrieved the box from a back room. There were 8 containers of domperidone in 3 stages of compounding in the box; 2 prescription vials of compounded drug stock, 5 prescription vials of finished product, and a 100 gram bulk bottle of API obtained from Kalchem International, Inc. ("Kalchem"). The label on the bulk bottle indicated that the drug had been acquired by the pharmacy on February 2, 2015; the lot number was BDOM/1302037. The warning, "NOT FOR HUMAN USE", was displayed on the label.

64. Respondent Cavalari told Inspector H., Investigator P. and Officer L. that the pharmacy had acquired domperidone from PCCA (Professional Compounding Centers of

[2] All pharmacists are required to subscribe to the Board's Subscriber Alert email blasts.

America), and then from Kalchem. Inspector H., Investigator P. and Officer L. obtained a copy of the Kalchem Certificate of Analysis for domperidone, Lot # BDOM/1302037. Respondent Cavalari stated that they used master formulas from PCCA to prepare diluted domperidone powder in various concentrations, which were then used to fill capsules (finished product). Using PCCA's compounding software, Respondent Cavalari printed a report listing all of the compounding logs showing the pharmacy's use of Kalchem Lot # BDOM/1302037 in making drug preparations. The logs showed that from May 16, 2014 to April 16, 2015, the pharmacy used this lot number of domperidone to make 61 compounded drug stock preparations. Respondent Cavalari also printed a report listing every prescription the pharmacy had dispensed using Kalchem Lot # BDOM/1302037. Inspector H., Investigator P. and Officer L. found that from May 21, 2014 to September 2, 2015, the pharmacy used this lot number of domperidone to furnish 140 new and refill prescriptions in various strengths and quantities to 51 patients, including patient B. B. from North Carolina. The pharmacy furnished 300 domperidone 10 mg capsules to B. B. via prescription number 302571 on June 4, 2014, and June 26, 2014.

65. Respondent Cavalari printed a "Log of Scripts" report listing every domperidone prescription the pharmacy had dispensed from January 1, 2013 to September 2, 2015. The pharmacy had dispensed a total of 312 domperidone prescriptions in various strengths and quantities during this time period. Inspector H. determined based on the Log of Scripts report that from July 15, 2013 to September 2, 2015, 237 domperidone prescriptions were dispensed to patients while Respondent Cavalari was the pharmacist-in-charge.

66. Inspector H., Investigator P. and Officer L. reviewed documentation pertaining to the pharmacy's domperidone acquisitions, including two invoices from Kalchem. The two invoices showed that the pharmacy had also acquired 100 grams of sildenafil citrate API. Respondent Cavalari stated that the sildenafil API was used to compound 100 mg sildenafil troches[3] for Dr. D., who dispensed them from his office. Respondent Cavalari printed a Log of Scripts report showing that between September 26, 2013 and September 1, 2015, the pharmacy filled 26

[3] Troches are small lozenges that dissolve between the check and gum over a period of about 30 minutes.

prescriptions of 3 different compounded medications for Dr. D., sildenafil citrate lemon 100 mg troche, sildenafil citrate/testosterone lemon 100/25 mg, and tadalafil orange 20 mg troche.

67. On or about October 19, 2015, Inspector H. sent Respondent Cavalari a letter requesting copies of 25 of the 26 prescriptions and 24 compounding logs for the compounded drug preparations furnished to Dr. D.

68. On or about November 2, 2015, Inspector H. returned to the pharmacy and obtained copies of the prescriptions and compounding logs. Inspector H. asked Respondent Cavalari if the pharmacy was licensed by any other state, and he said that they were not.

FIRST CAUSE FOR DISCIPLINE

(Failure to Exercise or Implement

Best Professional Judgment or Corresponding Responsibility)

69. Respondent Cavalari is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5, subdivision (b), for failing to exercise or implement his best professional judgment or corresponding responsibility, as follows: On and between July 15, 2013 and September 2, 2015, Respondent, as pharmacist-in-charge of Grandpa's Compounding Pharmacy, compounded and dispensed 237 domperidone prescriptions in various strengths and quantities to patients, as set forth in paragraphs 63 through 65, above, when, in fact, there was no IND Application approved by the FDA.

SECOND CAUSE FOR DISCIPLINE

(Failing to Consult Appropriate Records)

70. Respondent Cavalari is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5, subdivision (c), for failing to consult appropriate records pertaining to compounding and dispensing domperidone even though there was no IND Application approved by the FDA, as set forth in paragraphs 63 through 65, above.

///

///

///

THIRD CAUSE FOR DISCIPLINE

(Sold Misbranded Drugs)

71. Respondents Grandpa's and Cavalari are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (j), for violating statutes regulating controlled substances and dangerous drugs, in that Respondents sold misbranded drugs, as defined by Health and Safety Code sections 110290 and 111330, and Title 21, United States Code, section 352, subdivision (f), in violation of Health and Safety Code section 111440, as set forth in paragraphs 63 through 65, above.

FOURTH CAUSE FOR DISCIPLINE

(Delivered or Proffered for Delivery Misbranded Drugs)

72. Respondents Grandpa's and Cavalari are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301 subdivision (j), for violating statutes regulating controlled substances and dangerous drugs, in that Respondents delivered or proffered for delivery misbranded drugs, as defined by Health and Safety Code sections 110290, 111330, and 111400, in violation of Health and Safety Code section 111450, as set forth in paragraphs 63 through 65, above.

FIFTH CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and

Federal and State Laws Governing Pharmacy)

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

a. On and between July 15, 2013 and September 2, 2015, Respondents introduced or delivered for introduction into interstate commerce the drug, domperidone, by compounding and dispensing 237 domperidone prescriptions in various strengths and quantities to patients, as set

///

forth in paragraphs 63 through 65, above, when, in fact, there was no IND application for domperidone approved by the FDA, in violation of 21 U.S.C. section 355, subdivision (a).

b. On and between July 15, 2013 and September 2, 2015, Respondents sold, delivered, or gave away the drug domperidone by dispensing the drug to patients, as set forth in paragraphs 63 through 65, above, when, in fact, there was no IND for domperidone approved by the FDA, in violation of Health and Safety Code section 111550.

SIXTH CAUSE FOR DISCIPLINE

(Furnishing an Unreasonable Quantity of a Compounded Drug to a Prescriber)

74. Respondents Grandpa's and Cavalari are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondents violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.), and federal and state laws governing pharmacy, as follows: On and between September 26, 2013 and September 1, 2015, Respondents furnished 26 prescriptions of compounded medications to Dr. D. for dispensing to patients in quantities which were more than a 72-hour supply, as set forth below, in violation of Title 16, California Code of Regulations, section 1735.2. The prescriptions were compounded by Respondent Cavalari and pharmacist S.W.

RX#	Date Dispensed	QTY	Drug	Compounded by
C298535	09/26/2013	100	sildenafil citrate/testosterone lemon	S.W.
C299059	10/28/2013	100	sildenafil citrate/testosterone lemon	Cavalari
C299326	11/13/2013	100	sildenafil citrate/testosterone lemon	S.W.
299776	12/13/2013	100	sildenafil citrate lemon 100 mg troche	S.W.
299797	12/16/2013	30	sildenafil citrate lemon 100 mg troche	Cavalari
C300424	01/24/2014	150	sildenafil citrate/testosterone lemon	Cavalari
301182	03/13/2014	150	sildenafil citrate lemon 100 mg troche	S.W.
301768	04/16/2014	150	sildenafil citrate lemon 100 mg troche	Cavalari
302390	05/22/2014	150	sildenafil citrate lemon 100 mg troche	S.W.
303219	07/15/2014	150	sildenafil citrate lemon 100 mg troche	S.W.
304115	09/15/2014	100	sildenafil citrate lemon 100 mg troche	Cavalari
304444	10/06/2014	100	sildenafil citrate lemon 100 mg troche	Cavalari
305039	11/10/2014	100	sildenafil citrate lemon 100 mg troche	Cavalari
305318	12/01/2014	100	sildenafil citrate lemon 100 mg troche	Cavalari
305932	01/13/2015	100	sildenafil citrate lemon 100 mg troche	S.W.
306180	01/27/2015	150	tadalafil orange 20 mg troche	S.W.
306405	02/10/2015	100	sildenafil citrate lemon 100 mg troche	S.W.
306881	03/10/2015	150	sildenafil citrate lemon 100 mg troche	S.W.
306989	03/18/2015	150	tadalafil orange 20 mg troche	S.W.

RX#	Date Dispensed	QTY	Drug	Compounded by
C307571	04/23/2015	100	sildenafil citrate/testosterone lemon	Cavalari
308004	05/20/2015	100	tadalafil orange 20 mg troche	Cavalari
308226	06/04/2015	100	sildenafil citrate lemon 100 mg troche	S.W.
308227	06/04/2015	100	tadalafil orange 20 mg troche	S.W.
308950	07/17/2015	150	tadalafil orange 20 mg troche	Cavalari
309439	08/18/2015	100	sildenafil citrate lemon 100 mg troche	S.W.
309675	09/01/2015	100	tadalafil orange 20 mg troche	S.W.

SEVENTH CAUSE FOR DISCIPLINE

(Unlicensed Non-Resident Pharmacy)

75. Respondents Grandpa's and Cavalari are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondents violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.), and federal and state laws governing pharmacy, as follows: On or about June 4, 2014 and June 26, 2014, Respondents furnished 300 domperidone 10 mg capsules to patient B. B. located in North Carolina, as set forth in paragraph 56 above, when, in fact, Grandpa's Compounding Pharmacy failed to have a non-resident pharmacy registration on file with the North Carolina Board of Pharmacy as required by North Carolina General Statutes, section 90-85.21A, subdivision (a), in violation of Code section 4059, subdivision (e).

INSPECTION OF MARCH 9, 2017

76. On or about November 29, 2016, the Board received a copy of a DEA-106 form from Respondent Grandpa's notifying the Board of a theft of controlled substances that occurred from the pharmacy on or about November 6, 2016. This form is used to report the theft or loss of controlled substances to the Drug Enforcement Administration (DEA), and is required to be sent to the Board. On or about January 23, 2017, Inspector P. with the Board was notified by a law enforcement officer that Respondent Grandpa's had experienced a break-in and theft of controlled substances, and that the law enforcement officer believed that the perpetrator may have been an employee of Respondent Grandpa's. The Board opened an investigation on this theft and Inspectors P. and H. conducted an inspection related to this theft on March 9, 2017.

77. During the inspection, the Inspectors were informed that Respondent D. Wills was managing the pharmacy and acting as the owner.

78. Inspector P. was informed by Respondent Cavalari and an employee of the pharmacy that prior to the November 6, 2016, theft, the stolen controlled substances were stored all together in a chest of drawers similar to a clothes dresser. Approximately three (3) weeks after the theft, the pharmacy had another break-in and theft of dangerous drugs, which were dispersed throughout the pharmacy's stock. After this second break-in, Respondents began storing controlled substances in a small floor safe that was bolted to the floor. During the day, the pharmacy technicians would take the controlled substances out of the floor safe and place them on the counter above the safe for ease of access, returning the controlled substances to the safe upon close of business.

79. Inspector P. asked Respondent Cavalari and the employee working at the pharmacy what dangerous drugs had been stolen during the second theft and was informed that Respondents were unsure what dangerous drugs had been stolen or how much, but since that theft in November 2016, Respondents had identified three (3) dangerous drugs that they expected to have on hand that were missing and therefore had apparently been stolen in this second theft. Respondents failed to conduct any inventory or audit to determine what dangerous drugs had been stolen or the amounts that had been stolen.

80. Respondents stated that their negative pressure room was completed on or about February 15, 2017. Respondents compounded hazardous drugs from January 1, 2017, to February 15, 2017, despite the fact that their hazardous compounding room was not in compliance.

81. During the inspection, Inspector P. notified Respondent Cavalari that he needed to complete compounding personnel training and provide Inspector P. with the verification of training.

82. At the conclusion of the inspection, Inspector P. requested that Respondent Cavalari complete and produce the compounding P&Ps[4] within seventy-two (72) hours based on open business hours. This would make the new P&Ps due by Tuesday March 14, 2017.

---

[4] P&Ps stands for "Policies and Procedures." Respondents refer to their P&Ps as "SOPs" or "Standard Operating Procedures." "P&Ps" and "SOPs" are used interchangeably herein.

INSPECTION OF MARCH 14, 2017

83. On March 13, 2017, Respondent Cavalari called Inspector P. and told her that the SOPs were ready and that staff had reviewed them. Inspector P. asked Respondent Cavalari to fax the SOPs to her, but Respondent Cavalari said it was too many pages. Therefore, Inspector P. asked Inspector H. to stop by the pharmacy and pick up the completed SOPs.

84. On March 14, 2017, Inspector H. went to the pharmacy to pick up the completed SOPs. They were not completed, and staff had not reviewed them. Respondent Cavalari said he planned to have staff review the new SOPs the following Monday, March 20, 2017.

85. Inspector H. noted that the window in the pharmacy was open, allowing outside contaminants into the pharmacy. The window is located immediately adjacent to a powder hood.

86. Respondent Cavalari told Inspector H. that he did not know how he would comply with Regulations 1735.8 and 1735.5 subdivision (a)(5), which require a written quality assurance plan and P&Ps for validating integrity, potency, quality, and labeled strength of compounded drug preparations. On or about June 30, 2015, Respondent Cavalari completed a compounding self-assessment stating under penalty of perjury that he and Respondent Grandpa's were in compliance with these regulations.

AFTER THE INSPECTIONS

87. On March 20, 2017, Inspector P. received a fax from Respondent Cavalari in which he stated that all staff except one technician had reviewed the SOPs on March 14, 2017. However, Respondent Cavalari also provided signatures from the staff showing that all staff reviewed the SOPs on or after March 15, 2017.

88. On March 28, 2017, Respondent Cavalari provided training logs to Inspector P. via email. These training logs had additional entries that had not been present at the March 9, 2017, inspection; however, the alleged training dates were prior to the March 9, 2017, inspection. Specifically, technician J.W. had an additional training date added of August 18, 2016, pharmacist S.W. had approximately 50 changes to his training including dates changed, and additional slots were now filled in with back-dated training. Further, pharmacist S.W., Respondent Cavalari, and Respondent D. Wills had done training that they each signed off for

themselves (i.e. Respondent Cavalari signed off on his own training), which is invalid.

89. Inspector P. audited the drugs Respondents reported stolen in the first burglary, reported to have occurred November 6, 2016. Inspector P. used the following information to conduct the audits.

a. Biennial Inventory[5]: On or about June 11, 2015, Respondent Cavalari performed a biennial inventory. A biennial inventory is required by the DEA within two years of the previous inventory and shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.

b. Perpetual Inventory: Respondents' perpetual inventory is a handwritten, paper inventory that provides the prescription number, patient's name, prescription amount, additional amount when an order from the wholesaler comes in, the balance remaining, and the technician initials for each time the controlled substance is accessed. There is no place for a pharmacist to notate review or monitoring of the perpetual inventory.

c. Dispensing Report: Respondents' dispensing report is a log of scripts showing prescription numbers, the quantity and drug dispensed, and the pharmacist's initials who dispensed the prescription.

90. Respondent Cavalari told Inspector P. that the amount of controlled substances from the November 6, 2016, theft listed on the DEA 106 form was determined by the amount of controlled substance listed in the last entry prior to the theft set forth on the perpetual inventory. Inspector P. reviewed the perpetual inventory and found that there were significant unexplained discrepancies. For example, a technician would do an inventory line, meaning that the technician just weighed the controlled substance without adding or subtracting any amount. The inventory amount would differ from the amount on the previous line that was remaining after the last prescription was dispensed. However, there is no indication of the reason for this discrepancy, nor does it appear that any attempt was ever made to identify, document, or prevent these discrepancies. There is no indication that any pharmacist ever reviewed the perpetual inventory. Other discrepancies included math errors such as failing to subtract an amount that was

[5] 21 CFR 1304.11

dispensed, and discrepancies such as the technician subtracting 12 mg when in fact only 1.2 mg was dispensed. While certain math errors may have been inadvertent, other discrepancies indicate a pattern and practice of falsifying inventory numbers, and a failure to review the inventory by any pharmacist.

91. Due to the issues in the perpetual inventory, Inspector P. prepared two audits, as set forth in the table below. In the column titled "1st Audit Loss or Overage," Inspector P. used the perpetual inventory as prepared by Respondents and found that there were discrepancies indicating that a significant amount of controlled substances had been lost or stolen without being accounted for. In addition, there are overages which indicate that Respondents sold or dispensed more controlled substances than they purchased. Overages are an indication of billing fraud. In the column titled "2nd Audit Loss or Overage" Inspector P. took the amount dispensed as listed on the perpetual inventory and calculated the actual amount of controlled substance Respondents should have had once the math errors were eliminated. Inspector P. then assumed that the amount of controlled substance Respondents should have had was the amount that was stolen by the burglar on November 6, 2016. This second audit showed significant discrepancies as well, but the discrepancies were different. This indicates that there are more errors, falsified inventory counts, or falsified prescriptions that cannot be ascertained from Respondents' records.

Drug:[6]	**1st Audit Loss or Overage**	**2nd Audit Loss or Overage**
Cocaine	333 mg Overage	90 mg Loss
Codeine Phosphate	314 mg Overage	938 mg Overage
Hydrocodone Bitartrate	10,331 mg Overage	1,222 mg Overage
Hydromorphone HCI	160 mg Loss	149 mg Loss
Ketamine	22,585 mg Overage	25,475 mg Overage
Methadone HCI	20 mg Loss	0
Morphine SO4	5 mg Loss	5 mg Loss
Oxycodone HCI	51 mg Overage	9,855 mg Overage

[6] All stolen drugs were in powder form.

EIGHTH CAUSE FOR DISCIPLINE

(Moral Turpitude, Dishonesty, Fraud, or Deceit)

92. Respondents, and each of them, are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (f), in that Respondents committed acts of moral turpitude, dishonesty, fraud, or deceit as follows:

a. Respondents failed to accurately account for, and maintain records of the purchases and sales of hydrocodone, ketamine, oxycodone, codeine, cocaine, and hydromorphone, and documented false inventory amounts as set forth in paragraphs 89 through 91, above.

b. Respondents provided altered training documents for their employee as set forth in paragraphs 81 and 88, above.

c. Respondents allowed Respondent D. Wills to write and sign checks to pay for dangerous drugs, and sign contracts as an owner or officer of the pharmacy when in fact Respondent D. Wills was not listed on the pharmacy permit.

d. On March 13, 2017, Respondent Cavalari told Inspector P. that new and revised SOPs had been drafted and all staff had reviewed them as set forth in paragraphs 82 through 84, above. In fact, the new and revised SOPs had not been completed, and the staff had not reviewed them.

e. On March 14, 2017, Respondent Cavalari stated that he did not know how to comply with Regulations sections 1735.5 subdivision (a)(5) and 1735.8, despite the fact that he had signed a self-assessment on June 30, 2015, stating under penalty of perjury that the pharmacy was in compliance as set forth in paragraph 86, above.

NINTH CAUSE FOR DISCIPLINE

(Fail to Maintain Security of Pharmacy)

93. Respondents, and each of them, are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), by failing to follow Title 21 Code of Federal Regulations Section 1301.75 subdivision (b), and Regulation 1714, subdivision (d), in that Respondents failed to maintain the security of the pharmacy, failed to institute measures to

prevent future theft after the break in on November 6, 2016, and maintained all of the controlled substances together in a non-locking cabinet or storage place. Respondents made no attempt to determine the number or amount of dangerous drugs that were stolen in the second burglary. Significant losses or overages of controlled substances were identified as set forth in paragraphs 89 through 91, above.

TENTH CAUSE FOR DISCIPLINE

(Unaccountable Losses of Controlled Substances and Dangerous Drugs)

94. Respondents, and each of them, are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), by violating Sections 4081 and 4332, as defined in part by Regulation 1718, as follows:

a. Approximately three (3) weeks after a reported burglary on November 6, 2016, Respondent Grandpa's was burglarized again. Respondents failed to conduct an inventory to discover which dangerous drugs were stolen during the second burglary or determine the amounts of the drugs that were stolen.

b. After the November 6, 2016, burglary, an audit conducted by Inspector P. identified additional losses and overages of controlled substances which Respondents did not account for as set forth in paragraphs 89 through 91, above.

ELEVENTH CAUSE FOR DISCIPLINE

(Violation of Health and Safety Code Section 11159.2)

95. Respondents Grandpa's and Cavalari are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), for violating Health and Safety Code section 11159.2, by dispensing a Schedule II controlled substance, hydromorphone, to hospice patients, without first complying with Health and Safety Code section 11164, subdivision (a), by obtaining the hard copy prescription from the prescriber, patient, or caregiver.

TWELFTH CAUSE FOR DISCIPLINE

(Invalid Verbal Prescription)

96. Respondents Grandpa's and Cavalari are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), for violating Section 4040

subdivisions (a)(B) and (d), in that on or about March 7, 2017, Respondent Cavalari received a verbal prescription and transcribed the prescription with the unapproved and unknown abbreviations and directions "HMA" or "HM4."

THIRTEENTH CAUSE FOR DISCIPLINE

(Violation of Ownership Interest in Pharmacy)

97. Respondents, and each of them, are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), for violating section 4110, subdivision (a), and Regulation section 1709, in that Respondents Grandpa's, Cavalari, and W. Wills allowed Respondent D. Wills to obtain and sign contracts with wholesalers of pharmaceuticals V.W. and B.B.P., and further, allowed Respondent D. Wills to sign checks on Respondents Grandpa's and W. Wills' bank account.

FOURTEENTH CAUSE FOR DISCIPLINE

(Violation of Prohibition of Association of Individual)

98. Respondents, and each of them, are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), for violating section 4307, subdivisions (a) and (b), in that Respondents Grandpa's, Cavalari, and W. Wills allowed Respondent D. Wills to work in the capacity of manager of the pharmacy. Respondent Grandpa's previously had Licensed Sterile Compounding (LSC) permit number 99109, which was surrendered and accepted by the Board. Respondent D. Wills was acting as the manager of Grandpa's at the time and knowingly participated in the conduct for which LSC permit number 99109 was revoked. He is therefore prohibited from acting as a manager, administrator, owner, member, officer, director, associate, partner, or exercising any ownership or control over any licensee of the Board.

FIFTEENTH CAUSE FOR DISCIPLINE

(Violation of Regulations Governing Hazardous Compounding)

99. Respondents, and each of them, are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), for violating the following regulations. The circumstances are as follows:

///

a. Regulation 1735.5, subdivision (a), in that Respondents failed to have and provide most P&Ps (or SOPs) required for compounding. Specifically, there were no P&Ps for procurement, methodologies, temperature monitoring, recall procedures, notification of P&Ps to staff, storing, calibrating, cleaning, and disinfecting equipment and training thereof, ensuring the appropriate functioning of refrigeration devices, testing of qualitative and quantitative analysis of compounded drug preparations and garbing. Further, Respondents failed to ensure that compounding personnel followed Respondent Grandpa's SOPs as set forth below:

i. SOP 1.4(5) states compounding personnel would review, date, and sign the review of SOPs.

ii. SOP 1.4(9) states the pharmacist in charge would make updates and review the entire manual annually.

iii. SOP 14.745 states compounding personnel would clean with isopropyl alcohol.

iv. SOP 14.201 requires training to be completed prior to conducting hazardous compounding.

v. SOP 14.900, 14.903, and 14.905 requires training in the event of a spill, eye contamination, and emergencies.

vi. SOP 14.801 requires the pressure gauge to be maintained between 0.01 and 0.03 inches of water column as required by regulation.

vii. SOP 14.010 required training for proper garbing when handling and compounding hazardous drugs.

viii. SOP 14.201 required training in order to conduct hazardous compounding.

b. Regulation 1735.5, subdivision (c)(1), in that Respondents failed to have a SOP in place setting forth the procedures for notifying staff assigned to compounding duties of any changes in policies or procedures. Respondent Cavalari failed to provide the policies and procedures applicable to conducting compounding to the compounding personnel.

c. Regulation 1735.5, subdivision (c)(4), in that Respondents' SOPs did not identify training and competency of staff on cleaning procedures. A household-type bottle was

identified as containing isopropyl alcohol for cleaning of the hazardous compounding area and hood. The bottle was extremely dirty and had previously been used as a hydrogen peroxide/surfactant cleaner.

d. Regulation 1735.5, subdivision (c)(5), and Regulation 1735.8, in that Respondents' SOP did not provide a written quality assurance plan or documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations.

e. Regulation 1735.5, subdivisions (c)(9) and (10), in that Respondents failed to provide a SOP for monitoring the room, refrigerator, and freezer temperatures. Respondent Grandpa's staff was able to provide partial monitoring logs in February 2017, but not for any time before or after February 2017.

f. Regulation 1735.6, subdivisions (a) and (c), in that Respondents failed to certify the hazardous compounding hood and four (4) powder hoods prior to use. The hazardous compounding hood was installed on or about February 15, 2017, and was not certified prior to compounding. The powder hoods were last inspected on or about February 12, 2016.

g. Regulation 1735.6, subdivision (e)(1), in that from January 1, 2017, to March 9, 2017, Respondents failed to do, measure, or document the air changes per hour in the hazardous compounding area.

h. Regulation 1735.6, subdivision (e)(2), in that Respondents failed to maintain a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces. On March 9, 2017, the gauge for negative pressure read 0.25 inches of water column.

i. Regulation 1735.6, subdivision (f), in that from January 1, 2017, to March 9, 2017, Respondents performed hazardous compounding in a room that was not certified and did not comply with regulations, and failed to request a waiver from the Board.

j. Regulation 1735.6, subdivision (e)(4), in that Respondents created and had a hazardous compounding area that was not smooth, seamless, impervious, and non-shedding. Specifically, tubing attached to vents was uneven and could not be easily cleaned.

k. Regulation 1735.7, in that Respondents failed to maintain documentation demonstrating that compounding personnel had the skills and training required to properly and accurately perform their assigned responsibilities and are trained in all aspects of policies and procedures. Respondent Cavalari as PIC had no demonstrable training on file and the other pharmacist on staff's training was incomplete.

SIXTEENTH CAUSE FOR DISCIPLINE

(Interference with Pharmacist-in-Charge)

100. Respondents W. Wills and D. Wills are subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), in that on or about February 15, 2017, Respondent D. Wills was acting in the capacity of the owner, partner, or manager of Respondent Grandpa's when he was not allowed to do so, and Respondent D. Wills interfered with the professional judgment of the pharmacist-in-charge, Respondent Cavalari. The circumstances are that Respondent Cavalari had scheduled the hazardous compounding hood and four (4) powder hoods to be certified. When the technician arrived to certify the hoods, Respondent D. Wills, as authorized by Respondent W. Wills, refused to allow the technician to perform the certification.

SEVENTEENTH CAUSE FOR DISCIPLINE

(False Statement of Fact)

101. Respondent D. Wills is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (g), in that Respondent D. Wills knowingly signed documents falsely representing that he was an owner, partner, manager, or otherwise had ownership interest or control over the pharmacy when in fact he was not an owner, partner, manager, or had any other ownership interest or control over the pharmacy.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Incompetence)

102. Respondents, and each of them, are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (b), in that Respondents committed acts of

///

incompetence. The circumstances are set forth in paragraphs 62 through 101, above, and as follows:

a. Respondent Grandpa's predominant business was non-sterile compounding. However, the pharmacist-in-charge and the staff did not have knowledge of current compounding regulations or training requirements. Further, Respondent Grandpa's staff placed hazardous drug waste in biomedical waste containers, operated equipment to compound hazardous and nonhazardous drugs without the equipment being certified, failed to do or document cleaning, failed to monitor or document drug storage area temperatures, failed to have policies and procedures for handling hazardous drugs, and failed to review policies and procedures with staff.

b. At the March 14, 2017, inspection, Inspector H. observed that a window was open in the pharmacy directly adjacent to a powder hood that is used for compounding purposes as set forth in paragraph 85, above. This could allow contaminants including pollen and dust into the pharmacy and onto compounding surfaces.

MATTERS IN AGGRAVATION

103. To determine the degree of discipline to be assessed against Respondent Grandpa's, if any, Complainant alleges as follows: On or about July 28, 2014, pursuant to the Stipulated Settlement and Disciplinary Order adopted by the Board in the disciplinary action entitled "In the Matter of the Accusation Against Grandpa's Compounding Pharmacy", Case No. 4929, Sterile Compounding License No. LSC 99109, issued to Grandpa's Compounding Pharmacy, was surrendered and accepted by the Board.

PRAYER

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

1. Revoking or suspending Pharmacy Permit No. PHY 45878, issued to William R. Wills, owner of Grandpa's Compounding Pharmacy;

2. Revoking or suspending Pharmacist License No. RPH 27496, issued to William R. Wills, also known as William Ray Wills;

3. Revoking or suspending Pharmacist License No. RPH 30372, issued to Darrell Cavalari, also known as Darrell William Cavalari;

4. Revoking or suspending Pharmacy Technician License NO. TCH 36985, issued to Daniel R. Wills;

5. Ordering William R. Wills, both independently and as owner of Grandpa's Compounding Pharmacy, Darrell Cavalari, also known as Darrell William Cavalari, and Daniel R. Wills 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

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

DATED: 7/3/17

Virginia Herold

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

SA2016101447

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

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

In the Matter of the Accusation Against: **GRANDPA'S COMPOUNDING PHARMACY** **WILLIAM R. WILLS, OWNER** **DARRELL CAVALARI,** **aka DARRELL WILLIAM CAVALARI,** **PHARMACIST-IN-CHARGE** **7563 Green Valley Road** **Placerville, CA 95667** **Pharmacy Permit No. PHY 45878** **and** **DARRELL WILLIAM CAVALARI** **5933 Adana Circle** **Carmichael, CA 95608** **Pharmacist License No. RPH 30372** Respondents.	Case No. 5787 **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 ("Board"), Department of Consumer Affairs.

2. On or about May 30, 2002, the Board issued Pharmacy Permit Number PHY 45878 to William R. Wills ("Respondent Wills"), owner of Grandpa's Compounding Pharmacy and

pharmacist-in-charge. On or about July 15, 2013, Darrell Cavalari, also known as Darrell William Cavalari ("Respondent Cavalari"), became the pharmacist-in-charge. The pharmacy permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2017, unless renewed.

3. On or about August 2, 1976, the Board issued Pharmacist License Number RPH 30372 to Respondent Cavalari. The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2017, unless renewed.

JURISDICTION/STATUTORY AND REGULATORY PROVISIONS

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

5. Code section 4300 states, in pertinent part:

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

6. Code section 4300.1 states:

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

///

///

7. Code section 4301 states, in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
>
> (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
>
> (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency . . . .

8. Code section 4306.5 states, in pertinent part:

> Unprofessional conduct for a pharmacist may include any of the following:
>
> (a) 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.
>
> (c) 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.

9. Code section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

10. Code section 4025 states:

> "Drug" means any of the following:
>
> (a) Articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement of any of them.
>
> (b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals.
>
> (c) Articles (other than food) intended to affect the structure or any function of the body of human beings or other animals.
>
> (d) Articles intended for use as a component of any article specified in subdivision (a), (b), or (c).

11. Code section 4059, subdivision (e), states:

> A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, 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 or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

12. Code section 4342, subdivision (a), 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).

13. Health and Safety Code section 111335 provides that any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290.)

14. Health and Safety Code section 110290 states:

> In determining whether the labeling or advertisement of a food, drug, device, or cosmetic is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account. The extent that the labeling or advertising fails to reveal facts concerning the food, drug, device, or cosmetic or consequences of customary use of the food, drug, device, or cosmetic shall also be considered.

15. Health and Safety Code section 111330 states that "[a]ny drug or device is misbranded if its labeling is false or misleading in any particular."

16. Health and Safety Code section 111400 provides that any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

17. Health and Safety Code section 111440 provides that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

///

///

18. Health and Safety Code section 111450 provides that it is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

19. Health and Safety Code section 111550 provides, in pertinent part:

> No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:
>
> (a) It is one of the following:
>
> (1) A new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355).
>
> (b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended . . .

20. Section 201, subdivision (p), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. section 321, subdivision (p)), states, in pertinent part:

> The term "new drug" means--
>
> (1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof . . .
>
> (2) Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

21. Title 21, United States Code, section 352, states in pertinent part:

A Drug or device shall be deemed to be misbranded—

(f) Directions for use and warnings on label

> Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro

diagnostic devices intended solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

22. Section 505, subdivision (a), of the Act (21 U.S.C. section 355, subdivision (a)), states, in pertinent part, that ". . . [n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."

23. North Carolina General Statutes, section 90-85.21A, subdivision (a), states:

> Any pharmacy operating outside the State which ships, mails, or delivers in any manner a dispensed legend drug into this State shall annually register with the Board on a form provided by the Board. In order to satisfy the registration requirements of this subsection, a pharmacy shall certify that the pharmacy employs a pharmacist who is responsible for dispensing, shipping, mailing, or delivering dispensed legend drugs into this State or in a state approved by the Board and has met requirements for licensure equivalent to the requirements for licensure in this State. In order for the pharmacy's certification of the pharmacists to be valid, a pharmacist shall agree in writing, on a form approved by the Board, to be subject to the jurisdiction of the Board . . .

24. Title 21, Code of Federal Regulations, section 201.5 states:

> "Adequate directions for use" means directions under which the layman can use a drug safely and for the purposes for which it is intended. (Section 201.128 defines "intended use.") Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of:
>
> (a) Statements of all conditions, purposes, or uses for which such drug is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.
>
> (b) Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions.
>
> (c) Frequency of administration or application.
>
> (d) Duration of administration or application.
>
> (e) Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factors).
>
> (f) Route or method of administration or application.

///

(g) Preparation for use, i.e., shaking, dilution, adjustment of temperature, or, other manipulation or process.

25. Title 16, California Code of Regulations, section 1735.2, states, in pertinent part:

(c) A "reasonable quantity" as used in Business and Professions Code section 4052(a)(1) means that amount of compounded drug product that:

(1) is sufficient for administration or application to patients 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 . . .

COST RECOVERY

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

DRUG CLASSIFICATIONS

27. Domperidone is an anti-dopaminergic drug that acts as an antiemetic and a prokinetic agent. It is a dangerous drug under Code section 4022. Domperidone is not currently a legally marketed human drug and is not approved for sale in the United States. The U.S. Food and Drug Administration ("FDA") has determined that any products containing domperidone are unapproved new drugs and misbranded. Consequently, any product containing domperidone violates the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301, et seq.; "the Act"). Domperidone is available for use in the treatment of certain gastrointestinal disorders, but only if an Investigational New Drug Application ("IND") is submitted to and approved by the FDA.

28. Sildenafil is a dangerous drug under Code section 4022 and is indicated for use in the treatment of erectile dysfunction. "Viagra" is the brand name for sildenafil.

29. Tadalafil is a dangerous drug under Code section 4022 and is indicated for use in the treatment of erectile dysfunction. "Cialis" is the brand name for tadalafil.

30. Testosterone is a Schedule III controlled substance under Health and Safety Code section 11056, subdivision (f)(30), and a dangerous drug under Code section 4022. It is indicated for use as a hormone replacement drug.

///

BACKGROUND

31. On or about June 7, 2004, the FDA issued a Talk Paper entitled, "FDA Warns against Women Using Unapproved Drug, Domperidone, to Increase Milk Production", warning breastfeeding women not to use the product because of safety concerns. The FDA stated that although domperidone was approved in several countries outside the U.S. to treat certain gastric disorders, it is not approved in any country, including the U.S., for enhancing breast milk production in lactating women and is also not approved in the U.S. for any indication.[1]

32. On or about March 12, 2012, the FDA issued Import Alert 61-07, stating that domperidone was being imported as a bulk API (active pharmaceutical ingredient) for pharmacy compounding and that importation of the drug presented a public health risk and violated the Act.

33. On and between June 7, 2004 and April 14, 2015, the FDA issued warning letters to 17 pharmacies, each of which compounded products containing domperidone. The FDA advised the pharmacies that (1) all products containing domperidone are new drugs as defined by section 201, subdivision (p), of the Act (21 U.S.C. section 321, subdivision (p)), in that they are not recognized by qualified experts as safe and effective for their labeled use; (2) no approved application pursuant to section 505 of the Act is in effect with respect to these products and as such, their introduction, or delivery for introduction into interstate commerce, is in violation of section 505, subdivision (a), of the Act (21 U.S.C. section 355, subdivision (a)); (3) because the domperidone products that the pharmacy manufactures and distributes without valid prescriptions for individually-identified patients are not the subject of approved applications, they are unapproved new drugs in violation of section 505 of the Act; and/or (4) the domperidone products are also misbranded under section 502, subdivision (f)(1), of the Act (21 U.S.C. section 352, subdivision (f)(1)) because they do not bear adequate directions for use.

///

[1] The FDA stated that there were several published reports and case studies of cardiac arrhythmias, cardiac arrest, and sudden death in patients receiving an IV form of domperidone, which had been withdrawn from marketing in a number of countries. Further, in several countries where the oral form of domperidone continued to be marketed, labels for the product contained specific warnings against use of domperidone by breastfeeding women.

34. On or about April 14, 2015, the Board issued a Subscriber Alert[2], stating that domperidone is not approved by the FDA for any use in humans in the U.S. The Board also stated that the FDA currently permits patients 12 years of age and older with various gastrointestinal conditions that are refractory to standard therapy to be treated with domperidone through an Expanded Access Program, that physicians who are interested in obtaining expanded access for domperidone must submit an IND, and that currently, no pharmacies are authorized to compound domperidone under the Expanded Access program.

INSPECTION OF SEPTEMBER 2, 2015

35. On or about September 2, 2015, Inspector H. of the Board and Investigator P. and Consumer Safety Officer L. of the FDA conducted a joint inspection of Grandpa's Compounding Pharmacy. The FDA had received a consumer complaint, alleging that the pharmacy furnished domperidone prescriptions and that the consumer had an adverse reaction to the drug.

36. Respondent Cavalari ("Cavalari") and pharmacist W. told Inspector H., Investigator P. and Officer L. that they stopped dispensing domperidone after receiving the Board's Subscriber Alert. Pharmacist W. stated that he did not receive the Alert until April 22, 2015, when a colleague emailed him a copy. The same day that he received the alert, Pharmacist W. removed all domperidone from the active inventory and placed it in a box to be sent to their drug return/destruction wholesaler. Pharmacist W. retrieved the box from a back room. There were 8 containers of domperidone in 3 stages of compounding in the box; 2 prescription vials of compounded drug stock, 5 prescription vials of finished product, and a 100 gram bulk bottle of API obtained from Kalchem International, Inc. ("Kalchem"). The label on the bulk bottle indicated that the drug had been acquired by the pharmacy on February 2, 2015; the lot number was BDOM/1302037. The warning, "NOT FOR HUMAN USE", was displayed on the label.

37. Cavalari told Inspector H., Investigator P. and Officer L. that the pharmacy had acquired domperidone from PCCA (Professional Compounding Centers of America), and then from Kalchem. Inspector H., Investigator P. and Officer L. obtained a copy of the Kalchem

[2] All pharmacists are required to subscribe to the Board's Subscriber Alert email blasts.

Certificate of Analysis for domperidone, Lot # BDOM/1302037. Cavalari stated that they used master formulas from PCCA to prepare diluted domperidone powder in various concentrations, which were then used to fill capsules (finished product). Using PCCA's compounding software, Cavalari printed a report listing all of the compounding logs showing the pharmacy's use of Kalchem Lot # BDOM/1302037 in making drug preparations. The logs showed that from May 16, 2014 to April 16, 2015, the pharmacy used this lot number of domperidone to make 61 compounded drug stock preparations. Cavalari also printed a report listing every prescription the pharmacy had dispensed using Kalchem Lot # BDOM/1302037. Inspector H., Investigator P. and Officer L. found that from May 21, 2014 to September 2, 2015, the pharmacy used this lot number of domperidone to furnish 140 new and refill prescriptions in various strengths and quantities to 51 patients, including patient B. B. from North Carolina. The pharmacy furnished 300 domperidone 10 mg capsules to B. B. via prescription number 302571 on June 4, 2014, and June 26, 2014.

38. Cavalari printed a "Log of Scripts" report listing every domperidone prescription the pharmacy had dispensed from January 1, 2013 to September 2, 2015. The pharmacy had dispensed a total of 312 domperidone prescriptions in various strengths and quantities during this time period. Inspector H. determined based on the Log of Scripts report that from July 15, 2013 to September 2, 2015, 237 domperidone prescriptions were dispensed to patients while Cavalari was the pharmacist-in-charge.

39. Inspector H., Investigator P. and Officer L. reviewed documentation pertaining to the pharmacy's domperidone acquisitions, including two invoices from Kalchem. The two invoices showed that the pharmacy had also acquired 100 grams of sildenafil citrate API. Cavalari stated that the sildenafil API was used to compound 100 mg sildenafil troches[3] for Dr. D., who dispensed them from his office. Cavalari printed a Log of Scripts report showing that between September 26, 2013 and September 1, 2015, the pharmacy filled 26 prescriptions of 3 different

///

[3] Troches are small lozenges that dissolve between the check and gum over a period of about 30 minutes.

compounded medications for Dr. D., sildenafil citrate lemon 100 mg troche, sildenafil citrate/testosterone lemon 100/25 mg, and tadalafil orange 20 mg troche.

40. On or about October 19, 2015, Inspector H. sent Cavalari a letter requesting copies of 25 of the 26 prescriptions and 24 compounding logs for the compounded drug preparations furnished to Dr. D.

41. On or about November 2, 2015, Inspector H. returned to the pharmacy and obtained copies of the prescriptions and compounding logs. Inspector H. asked Cavalari if the pharmacy was licensed by any other state, and he said that they were not.

FIRST CAUSE FOR DISCIPLINE

(Failure to Exercise or Implement

Best Professional Judgment or Corresponding Responsibility)

42. Respondent Cavalari is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5, subdivision (b), for failing to exercise or implement his best professional judgment or corresponding responsibility, as follows: On and between July 15, 2013 and September 2, 2015, Respondent, as pharmacist-in-charge of Grandpa's Compounding Pharmacy, compounded and dispensed 237 domperidone prescriptions in various strengths and quantities to patients, as set forth in paragraphs 36 through 38 above, when, in fact, there was no IND Application approved by the FDA.

SECOND CAUSE FOR DISCIPLINE

(Failing to Consult Appropriate Records)

43. Respondent Cavalari is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5, subdivision (c), for failing to consult appropriate records pertaining to compounding and dispensing domperidone even though there was no IND Application approved by the FDA, as set forth in paragraphs 36 through 38 above.

///

///

///

THIRD CAUSE FOR DISCIPLINE

(Sold Misbranded Drugs)

44. Respondents Wills and Cavalari are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (j), for violating statutes regulating controlled substances and dangerous drugs, in that Respondents sold misbranded drugs, as defined by Health and Safety Code sections 110290 and 111330, and Title 21, United States Code, section 352, subdivision (f), in violation of Health and Safety Code section 111440, as set forth in paragraphs 36 through 38, above.

FOURTH CAUSE FOR DISCIPLINE

(Delivered or Proffered for Delivery Misbranded Drugs)

45. Respondents Wills and Cavalari are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301 subdivision (j), for violating statutes regulating controlled substances and dangerous drugs, in that Respondents delivered or proffered for delivery misbranded drugs, as defined by Health and Safety Code sections 110290, 111330, and 111400, in violation of Health and Safety Code section 111450, as set forth in paragraphs 36 through 38, above.

FIFTH CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and

Federal and State Laws Governing Pharmacy)

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

a. On and between July 15, 2013 and September 2, 2015, Respondents introduced or delivered for introduction into interstate commerce the drug, domperidone, by compounding and dispensing 237 domperidone prescriptions in various strengths and quantities to patients, as set

forth in paragraphs 36 through 38, when, in fact, there was no IND application for domperidone approved by the FDA, in violation of 21 U.S.C. section 355, subdivision (a).

b. On and between July 15, 2013 and September 2, 2015, Respondents sold, delivered, or gave away the drug domperidone by dispensing the drug to patients, as set forth in paragraphs 36 through 38 above, when, in fact, there was no IND for domperidone approved by the FDA, in violation of Health and Safety Code section 111550.

SIXTH CAUSE FOR DISCIPLINE

(Furnishing an Unreasonable Quantity of a Compounded Drug to a Prescriber)

47. Respondents Wills and Cavalari are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondents violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.), and federal and state laws governing pharmacy, as follows: On and between September 26, 2013 and September 1, 2015, Respondents furnished 26 prescriptions of compounded medications to Dr. D. for dispensing to patients in quantities which were more than a 72-hour supply, as set forth below, in violation of Title 16, California Code of Regulations, section 1735.2. The prescriptions were compounded by Respondent Cavalari and pharmacist S.W.

RX#	Date Dispensed	QTY	Drug	Compounded by
C298535	09/26/2013	100	sildenafil citrate/testosterone lemon	S.W.
C299059	10/28/2013	100	sildenafil citrate/testosterone lemon	Cavalari
C299326	11/13/2013	100	sildenafil citrate/testosterone lemon	S.W.
299776	12/13/2013	100	sildenafil citrate lemon 100 mg troche	S.W.
299797	12/16/2013	30	sildenafil citrate lemon 100 mg troche	Cavalari
C300424	01/24/2014	150	sildenafil citrate/testosterone lemon	Cavalari
301182	03/13/2014	150	sildenafil citrate lemon 100 mg troche	S.W.
301768	04/16/2014	150	sildenafil citrate lemon 100 mg troche	Cavalari
302390	05/22/2014	150	sildenafil citrate lemon 100 mg troche	S.W.
303219	07/15/2014	150	sildenafil citrate lemon 100 mg troche	S.W.
304115	09/15/2014	100	sildenafil citrate lemon 100 mg troche	Cavalari
304444	10/06/2014	100	sildenafil citrate lemon 100 mg troche	Cavalari
305039	11/10/2014	100	sildenafil citrate lemon 100 mg troche	Cavalari
305318	12/01/2014	100	sildenafil citrate lemon 100 mg troche	Cavalari
305932	01/13/2015	100	sildenafil citrate lemon 100 mg troche	S.W.
306180	01/27/2015	150	tadalafil orange 20 mg troche	S.W.
306405	02/10/2015	100	sildenafil citrate lemon 100 mg troche	S.W.

RX#	Date Dispensed	QTY	Drug	Compounded by
306881	03/10/2015	150	sildenafil citrate lemon 100 mg troche	S.W.
306989	03/18/2015	150	tadalafil orange 20 mg troche	S.W.
C307571	04/23/2015	100	sildenafil citrate/testosterone lemon	Cavalari
308004	05/20/2015	100	tadalafil orange 20 mg troche	Cavalari
308226	06/04/2015	100	sildenafil citrate lemon 100 mg troche	S.W.
308227	06/04/2015	100	tadalafil orange 20 mg troche	S.W.
308950	07/17/2015	150	tadalafil orange 20 mg troche	Cavalari
309439	08/18/2015	100	sildenafil citrate lemon 100 mg troche	S.W.
309675	09/01/2015	100	tadalafil orange 20 mg troche	S.W.

SEVENTH CAUSE FOR DISCIPLINE

(Unlicensed Non-Resident Pharmacy)

48. Respondents Wills and Cavalari are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondents violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.), and federal and state laws governing pharmacy, as follows: On or about June 4, 2014 and June 26, 2014, Respondents furnished 300 domperidone 10 mg capsules to patient B. B. located in North Carolina, as set forth in paragraph 37 above, when, in fact, Grandpa's Compounding Pharmacy failed to have a non-resident pharmacy registration on file with the North Carolina Board of Pharmacy as required by North Carolina General Statutes, section 90-85.21A, subdivision (a), in violation of Code section 4059, subdivision (e).

MATTERS IN AGGRAVATION

49. To determine the degree of discipline to be assessed against Respondent Wills, if any, Complainant alleges as follows: On or about July 28, 2014, pursuant to the Stipulated Settlement and Disciplinary Order adopted by the Board in the disciplinary action entitled "In the Matter of the Accusation Against Grandpa's Compounding Pharmacy", Case No. 4929, Sterile Compounding License No. LSC 99109, issued to Grandpa's Compounding Pharmacy, was surrendered and accepted by the Board.

///

///

///

PRAYER

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

1. Revoking or suspending Pharmacy Permit No. PHY 45878, issued to William R. Wills, owner of Grandpa's Compounding Pharmacy;

2. Revoking or suspending Pharmacist License No. RPH 30372, issued to Darrell Cavalari, also known as Darrell William Cavalari;

3. Ordering William R. Wills, owner of Grandpa's Compounding Pharmacy, and Darrell Cavalari, also known as Darrell William Cavalari, 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: 12/9/16

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

SA2016101447