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

In the Matter of the Accusation Against: **JOBOB INC., DBA** **LOS BANOS DRUG CO.** **601 J Street** **Los Banos, CA 93635** **Pharmacy Permit No. PHY 48861** **and** **MEL F. HARTSOCH** **201 West L St.,** **Los Banos, CA 93635** **Pharmacist License No. RPH 28786** **Respondents.**	Case No. 6081 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about May 27, 2008, the Board of Pharmacy issued Pharmacy Permit Number PHY 48861 to Jobob, Inc. dba Los Banos Drug Co. (Respondent). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2018, unless renewed.

3. On or about April 28, 1974, the Board of Pharmacy issued Pharmacist License Number RPH 28786 to Mel F. Hartsoch (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on April 30, 2019, unless renewed.

JURISDICTION

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

5. Section 4300 of the Code states:

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

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

(1) Suspending judgment.

(2) Placing him or her upon probation.

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

(4) Revoking his or her license.

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

. . .

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

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

7. Section 4300.1 of the Code states:

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

8. Section 4307 of the Code states:

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, 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 manger, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge 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 any other person with management or control of a licensee as follows:

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

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

STATUTORY PROVISIONS

9. Section 4301 of the Code states:

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

. . .

(c) Gross negligence.

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

. . .

(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.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

(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 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."

12. Code Section 4156 states:

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

13. Code Section 4005 of the Code states:

(a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed; providing for standards of minimum equipment for establishments licensed under this chapter; pertaining to the sale of drugs by or

through any mechanical device; and relating to pharmacy practice experience necessary for licensure as a pharmacist.

(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

14. Title 16 of the California Code of Regulations (CCR), section 1715 states, in part:

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

. . . .

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

15. CCR, section 1735.2 states, in part:

(j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation.

16. CCR, section 1711 states:

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

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

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

. . .

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

discovered. All medication errors discovered shall be subject to a quality assurance review.

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

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

17. CCR, section 1714 states, in pertinent part:

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

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

(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.

18. CCR, section 1717.4 states, in pertinent part:

(h) Any person who transmits, maintains or receives any prescription or prescription refill, orally, in writing or electronically, shall ensure the security, integrity, authenticity, and confidentiality of the prescription and any information contained therein.

19. CCR, section 1707.2 states, in pertinent part:

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

(A) whenever the prescription drug has not previously been dispensed to a patient; or

(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

. . .

20. CCR, section 1707.5 states, in pertinent part:

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. . . .

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

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

. . .

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

21. CCR section 1735, subdivision (a) states in pertinent part:

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

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

(2) Altering the strength of a drug

(3) Combining components or active ingredients

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

22. CCR, section 1735.3 states, in pertinent part:

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

(1) The master formula document.

(2) A compounding log consisting of a single document containing all of the following:

(A) Name and Strength of the compounded drug preparation.

(B) The date the drug preparation was compounded.

(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

(D) The identity of the pharmacist reviewing the final drug preparation.

(E) The quantity of each ingredient used in compounding the drug preparation.

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (*l*) shall apply.

. . .

(G) A pharmacy-assigned unique reference or lot number for the compounded drug preparation.

(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

(I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

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

. . .

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

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23. CCR, section 1761 states:

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

24. Title 21, Code of Federal Regulations, Part 1301.75 states, in pertinent part:

. . . .

(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 non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

25. Health and Safety Code section 11153 states, in pertinent part:

(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

COST RECOVERY

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

DRUG CLASSIFICATIONS

27. Opioids are substances which are most often used medically to relieve pain. Because of opioids' reputation for addiction and fatal overdose, they are highly controlled substances.

28. "Oxycodone" is the generic name for Percolone or Roxicet and is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (a)(1)(M). Oxycodone is an opioid used for pain. The recommended starting dose for patient not currently on opioid therapy is 5-15 mg, every 4-6 hours as needed.

29. "Xanax" is the trade name for alprazolam, a benzodiazepine. Xanax is a Schedule IV controlled substance pursuant to Health and Safety code section 11057(d)(1) and is used to treat anxiety. The recommended starting dose is .25 to .5mg, 3 times daily. A boxed warning, the FDA's strictest warning put on a prescription drugs, states that concomitant use of benzodiazepine and opioids may result in "profound sedation, respiratory depression, coma, and death."

30. "Norco" is the generic name for hydrocodone/acetaminophen, an opioid. Norco is federally scheduled as a CII per Title 21 CFR 1308.12, and a scheduled as CIII per Health and Safety Code section 11056, subdivision (e)(4). It is used for pain with the same warnings and interactions as Oxycodone.

31. "Soma" is the brand name for carisoprodol. Carisoprodol is a Schedule IV controlled substance pursuant to Title 21 CFR 1308.14, subdivision (c)(6) and is used as a muscle relaxant.

32. "Marinol" is the brand name for dronabinol. Dronabinol is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (h) and is used for pain with the same warnings and interactions as Oxycodone.

33. All of the above controlled substances are danger drugs pursuant to code section 4022.

FACTUAL BACKGROUND

34. On and between September 24, 2007 to present, Mel F. Hartsoch ("Respondent Hartsoch") was the pharmacist-in-charge at Jobob Inc., DBA Los Banos Drug Co., ("Respondent Pharmacy") and is also the President and majority owner of Respondent Pharmacy. Respondent Pharmacy is located on the southeast corner of J street and 6th street in in Los Banos, California.

The pharmacy is attached to other businesses on two sides of it, along with a retail area in front of it containing a lunch counter where hot and cold food is served.

35. On or about September 21, 2016, a Board Inspector conducted an inspection at Los Banos Drug Company and determined that Jobob Inc., DBA Los Banos Drug Co., and Mel F. Hartsoch who was the pharmacist-in-charge and is also the President and majority owner of Respondent Pharmacy, had violated the Pharmacy Law. The inspector found questionable practices as to the dispensing of controlled substances, and an internal complaint was opened against Respondents.

36. Prior to the inspection, the Inspector received information that a doctor located in Fresno, California, Terrill Brown, M.D., had surrendered his license due to illegal prescribing of controlled substances. On or abut June 24, 2013, Dr. Terrill Eugene Brown, MD, surrendered his medical license due to prescribing opioids and other controlled substances in a grossly negligent and illegal manner, and without proper patient examinations. Such prescriptions are not considered for legitimate medical purpose, and are not issued in the usual course of professional practice. In or about and between December 1, 2012 and December 16, 2015, Respondent pharmacy was the sixth top dispenser of prescriptions by Dr. Brown, despite red flags for abuse in the prescriptions, which included that Dr. Brown's office was 65 miles away from Respondent Pharmacy, almost all patients paid with cash, the patients were new to Respondent Pharmacy, and controlled substance prescriptions were for the highest dose even when patients had no previous history of taking controlled substances.

FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Self-Assessments on File)

37. Respondent Pharmacy's permit and Respondent Hartsoch's pharmacist license are subject to disciplinary action for unprofessional conduct pursuant to section 4301, subsection (o), for violating pharmacy laws in that on or about September 21, 2016, Respondents did not maintain a completed 2013 or 2015 pharmacy self-assessment on file in the pharmacy in violation of title 16 of the California Code of Regulations (CCR), section 1715, subsections (a) and (d).

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SECOND CAUSE FOR DISCIPLINE

(Failure to Comply with Quality Assurance Program)

38. Respondent Pharmacy's permit and Respondent Hartsoch's pharmacist license are subject to disciplinary action for unprofessional conduct pursuant to section 4301, subsection (o), for violating pharmacy laws in that on or about February 2016, Respondents dispensed the wrong medication to a patient and the prescription was returned by the patient to the pharmacy. Respondents did not document an incident report or review of the error nor were appropriate documentations kept on file regarding this medication error and future error prevention, in violation of CCR, section 1711, subsections (a), (c), (d), (e), and (f) regulating Quality Assurance Programs. Respondents had previously been notified of the deficiencies in their Quality Assurance Program during a 2009 inspection by the Board.

THIRD CAUSE FOR DISCIPLINE

(Failure to Properly Maintain Facilities, Space, Fixtures and Equipment)

39. Respondent Pharmacy's permit and Respondent Hartsoch's pharmacist license are subject to disciplinary action for unprofessional conduct pursuant to section 4301, subsection (o), for violating pharmacy laws in that:

a. On or about September 21, 2016, Respondents did not securely and confidentially store controlled substances. Respondents stored Schedule II controlled substances in cabinets that were unlocked, and allowed customers to enter the pharmacy to utilize the restroom which was in an area where drugs and confidential patient information were visible and accessible, in violation of CCR, section 1714, subsections (b) and (d) and 1717.4 subsection (h), as well as Title 21 of the Code of Federal Regulations, Section 1301.75, subsection (b). Respondents had previously been notified of the deficiencies in confidentiality and security of drugs/information due to the location of the restroom, during a 2009 inspection by the Board.

b. On or about and between September 1, 2012 and September 21, 2016, Respondent did not maintain operational standards and security in the pharmacy in that the pharmacy stored drugs in a refrigerator and freezer with food/drink items, had a sink not suitable for pharmaceutical purposes which was dirty and contained discarded drugs and trash, and prepared,

stored, and/or sealed drugs in an area used for food preparation, in violation of CCR, section 1714, subsections (b) and (c). Respondents had previously been notified of the deficiencies in the sink area during a 2009 inspection by the Board.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Provide Patient Consultation)

40. Respondent Pharmacy's permit and Respondent Hartsoch's pharmacist license are subject to disciplinary action for unprofessional conduct pursuant to section 4301, subsection (o), for violating pharmacy laws in that on or about September 21, 2016, Respondents dispensed medication to a patient who had not previously been dispensed the medication. Respondents failed to provide a medication consultation to the patient, in violation of CCR, section 1707.2, subsections (a) and (b). Respondents had previously been notified of the deficiencies with patient consultations, during a 2009 inspection by the Board.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Comply with Patient-Centered Labeling Requirements)

41. Respondent Pharmacy's permit and Respondent Hartsoch's pharmacist license are subject to disciplinary action for unprofessional conduct pursuant to section 4301, subsection (o), for violating pharmacy laws in that on or about September 21, 2016, Respondents dispensed medications with labels that were not consistent with the format required by CCR section 1707.5, subsection (a), in that the name of the drug and strength were listed on the label after the directions for use.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Provide Adequate Interpretive Services)

42. Respondent Pharmacy's permit and Respondent Hartsoch's pharmacist license are subject to disciplinary action for unprofessional conduct pursuant to section 4301, subsection (o), for violating pharmacy laws in that on or about September 21, 2016, Respondents failed to have an interpretive service policy or have interpretive services available to patients to understand their prescription labels, for any language other than Spanish, in violation of CCR, section 1707.5, subsection (d).

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate Compounding Records)

43. Respondent Pharmacy's permit and Respondent Hartsoch's pharmacist license are subject to disciplinary action for unprofessional conduct pursuant to section 4301, subsection (o), for violating pharmacy laws in that on or about and between 2015 and September 21, 2016, Respondents compounded prescription preparations and did not maintain complete records for each compounded drug product, in violation of CCR, section 1735.3, subsections (a)-(d). Respondents did not maintain complete records of compounded prescription preparations which included:

a. The master formula record

b. The identity of the pharmacy personnel who compounded the drug product

c. The identity of the pharmacist reviewing the final drug product

d. The quantify of each component used in compounding the drug product

e. The manufacturer, expiration date, and lot number of each component

f. The equipment used in compounding the drug product

g. The expiration date of the final compounded drug product.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Properly Supervise Compounding of Drugs)

44. Respondent Hartsoch's pharmacist license is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subsection (o), for violating pharmacy laws in that violated CCR, section 1735.2, subsection (j), in that in and between September 1, 2012 and September 9, 2016, Respondent dispensed improperly prepared, labeled, stored or delivered compounded drugs, as further set forth in paragraphs 37-43, above.

NINTH CAUSE FOR DISCIPLINE

(Failure to Exercise Corresponding Responsibility)

45. Respondent Hartsoch's pharmacist license is subject to disciplinary action for unprofessional conduct in violation of Code section 4306.5, subsections (a)-(c) and 4301, subsection (j), for failing to exercise his corresponding responsibility as required by Health and

Safety Code section 11153, subsection (a) and CCR section 1761, subsections (a)-(b), in that in and between September 1, 2012 and September 9, 2016, Respondent dispensed controlled substances prescriptions with irregularities and red flags for abuse without ensuring the prescriptions were issued for a legitimate medical purpose by a prescriber acting in the usual course of his or her professional practice, thereby failing to exercise their corresponding responsibility to ensure the legitimacy of the prescriptions. The objective factors of irregularity and abuse included but were not limited to:

a. Prescribers from out of the area prescribe;

b. Prescriptions for out of the area patients

c. 141 prescriptions with near uniformity in prescribing trends of controlled substances from a prescriber who surrendered his license due to illegal prescribing;

d. Unusually high cash payment profiles from patients obtaining controlled substances with red flags of abuse

e. Some patients receiving the same or similar cocktail of controlled substances. On occasion, the pharmacy dispensed the same combination of controlled substances written by the same out of area prescriber to different patients on the same day.

f. Prescriptions for controlled substances with dangerous drug interactions

g. Many patients receiving the highest tablet strength of controlled substances with no upward titration from a lower dose

h. Unusually high doses for opioid naïve patients and patients with no recent previous history with the pharmacy.

TENTH CAUSE FOR DISCIPLINE

(Excessive Furnishing of Controlled Substances)

46. Respondent Pharmacy's permit and Respondent Hartsoch's pharmacist license are subject to disciplinary action for unprofessional conduct pursuant to section 4301, subsection (d), in that Respondents excessively furnished controlled substances, in violation of Health and Safety Code section 11153, subsection (a) and CCR section 1761, subsections (a)-(b), as more fully set forth in paragraphs 43, above.

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ELEVENTH CAUSE FOR DISCIPLINE

(Gross Negligence)

47. Respondent Pharmacy's permit and Respondent Hartsoch's pharmacist license are subject to disciplinary action for unprofessional conduct pursuant to section 4301, subsection (c), in that Respondents were grossly negligent in their operations and practice, and grossly deviated from the standard of safe pharmacy practice, which could cause harm to patients or another person by their conduct, and failed to exercise their best professional judgment, education, training and experience in the dispensing of controlled substances as more fully set forth in paragraphs 36-44, above.

OTHER MATTERS

48. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 48861, issued to Jobob, Inc. dba Los Banos Drug Co., it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 39226 is placed on probation or until Pharmacy Permit Number PHY 48861 is reinstated if it is revoked.

49. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 48861 issued to Jobob, Inc. dba Los Banos Drug Co., while Mel F. Hartsoch has been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Mel F. Hartsoch shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if on Pharmacy Permit Number PHY 48861 is placed on probation or until Pharmacy Permit Number PHY 48861 is reinstated if it is revoked.

50. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH Number 28786, issued to Mel F. Hartsoch, Mel F. Hartsoch shall be prohibited from serving as a manager, administrator. owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License No. RPH Number 28786 is placed on probation or until Pharmacist License No. RPH Number 28786 is reinstated if it is revoked.

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PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 48861, issued to Jobob, Inc. dba Los Banos Drug Co.;

2. Revoking or suspending Pharmacy License No. RPH Number 28786, issued to Mel F. Hartsoch;

3. Prohibiting Jobob, Inc. dba Los Banos Drug Co. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if if Pharmacy Permit Number PHY 39226 is placed on probation or until Pharmacy Permit Number PHY 48861 is reinstated if it is revoked;

4. Prohibiting Mel F. Hartsoch from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 48861 is placed on probation or until Pharmacy Permit Number PHY 48861 is reinstated if it is revoked;

5. Prohibiting Mel F. Hartsoch from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License No. RPH Number 28786 is placed on probation or until Pharmacist License No. RPH Number 28786 is reinstated if it is revoked;

6. Ordering Jobob, Inc. dba Los Banos Drug Co. and Mel F. Hartsoch 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,

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

DATED: 2/1/18

Virginia Herold

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

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