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8	BEFORE THE	
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA	
10	STATE OF C	CALIFORN!A
11	In the Matter of the Accusation Against:	Case No. 5113
12	JEFFERSON PLAZA PHARMACY 3137 Jefferson Avenue	
13	Redwood City, CA 94061	ACCUSATION
14	Pharmacy Permit No. PHY 11062	
15	JOHNNY PINGHON CHAN 260 Sierra Drive	
16	Hillsborough, CA 94010	
17	Pharmacist License No. RPH 32261	
18	MARICON PAYTE ESMABE 3561 Farmhill Blvd., #10	
19	Redwood City, CA 94061	
20	Pharmacy Technician Registration No. TCH 124483	
21	Respondents.	
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24	Complainant alleges:	
25	PARTIES	
26	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity	
27	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.	
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- 2. On or about October 1, 1981, the Board of Pharmacy issued Pharmacy Permit Number PHY 11062 to Medical Plaza Pharmacies, doing business as Jefferson Plaza Pharmacy ("Respondent Jefferson Plaza Pharmacy"). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on October 1, 2014, unless renewed.
- 3. On or about August 8, 1978, the Board of Pharmacy issued Pharmacist License Number RPH 32261 to Johnny Pinghon Chan ("Respondent Chan"). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on May 31, 2016, unless renewed.
- 4. On or about August 23, 2013, the Board of Pharmacy issued Original Pharmacy
 Technician Registration Number TCH 124483 to Maricon Payte Esmabe ("Respondent Esmabe").
 The Pharmacy Technician Registration will expire on May 31, 2016, unless renewed.

JURISDICTION

- 5. This Accusation is brought before the Board of Pharmacy ("Board"), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.
- 6. Section 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, subdivision (a), of the Code provides that every license issued by the Board may be suspended or revoked.
 - 8. Section 4300.1 of the Code states:

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

STATUTORY AND REGULATORY 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 procured by fraud or misrepresentation or issued by mistake.

Unprofessional conduct shall include, but is not limited to, any of the following:

. .

- "(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.
- "(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

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

- "(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or any other state or federal regulatory agency."
- 10. Code section 4113, subdivision (c), states, "[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."

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11. Section 4306.5 of the Code 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."
 - 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. Code section 4115, subdivision (e)(1), states:

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

14. Code section 4051, subdivision (a), states:

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

 15. Code section 4328 provides, "[e]xcept as otherwise provided in this chapter, any person who permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs in his or her pharmacy, except by a pharmacist, is guilty of a misdemeanor."

16. Health and Safety Code section 11153, subdivision (a) states:

"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."

- 17. California Code of Regulations, title 16, section 1714, states, in pertinent part:
- "(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.
- "(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."
 - 18. California Code of Regulations, title 16, section 1735.5, states, in pertinent part:
- "(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the

formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

- "(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented."
 - 19. California Code of Regulations, title 16, section 1735.7, states, in pertinent part:
- "(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.
- "(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel."
 - 20. California Code of Regulations, title 16, section 1735.8, subdivision (a), states:
- "Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products."
 - 21. California Code of Regulations, title 16, section 1793 states:
- "'Pharmacy technician' means an individual who, under the direct supervision and control of a pharmacist, performs packaging, manipulative, repetitive, or other nondiscretionary tasks related to the processing of a prescription in a pharmacy, but who does not perform duties restricted to a pharmacist under section 1793.1."
- 22. California Code of Regulations, title 16, section 1793.2 addresses the duties of a pharmacy technician and states:
 - "'Nondiscretionary tasks' as used in Business and Professions Code section 4115, include:
 - "(a) removing the drug or drugs from stock;
 - "(b) counting, pouring, or mixing pharmaceuticals;
 - "(c) placing the product into a container;
 - "(d) affixing the label or labels to the container;
 - "(e) packaging and repackaging."

FACTUAL ALLEGATIONS

- 28. From March 1, 1986, through the present, Respondent Chan has been the Pharmacist-in-Charge ("PIC") of Respondent Jefferson Plaza Pharmacy.
- 29. On or about January 30, 2012, the Board received a complaint from Dr. N.A. stating that Respondent Jefferson Plaza Pharmacy dispensed five different narcotics in a ten day period to a patient he was treating for opioid dependence. On July 12, 2013, a Board inspector went to Respondent Jefferson Plaza Pharmacy and conducted an inspection. Respondent Chan, the PIC, was present and assisted with the inspection. Patient profiles, prescription records, and other documents were obtained and reviewed during and after the inspection.
- 30. During the inspection on July 12, 2013, Respondent Jefferson Plaza Pharmacy and Respondent Chan were unable to provide a written policy and procedure manual for compounding. They were also unable to provide written documentation sufficient to demonstrate that the pharmacy personnel had the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding. Additionally, Respondents were unable to provide any training records for compounding staff or any written quality assurance plans for compounded prescriptions.
- 31. The inspection revealed that pharmacy clerk and Respondent Esmabe compounded prescriptions at the pharmacy from January 19, 2013, through July 9, 2013. Respondent Esmabe had applied for a pharmacy technician's license, but had not yet been granted one. Respondent Esmabe's intern pharmacist license had expired on January 31, 2012.
- 32. During the inspection conducted on July 12, 2013, the inspector observed that Respondent Jefferson Plaza Pharmacy and Respondent Chan maintained numerous outdated drugs in the pharmacy's current inventory of the compounding bulk ingredients and in the general inventory of the pharmacy. The inspector also observed that the pharmacy was extremely disorganized, dirty, and cluttered, especially in the compounding area of the pharmacy.
- 33. An overall review of the dispensing practice of Respondent Jefferson Plaza Pharmacy revealed that between July 12, 2010, and July 12, 2013, Respondent Jefferson Plaza Pharmacy and Respondent Chan dispensed 25,261 prescriptions for controlled substances, 4,178 of which

were for Dr. B.W., who prescribed excessive quantities of "drug cocktails" of controlled substances, and provided early re-fills for patients as revealed by the Controlled Substance Utilization Review and Evaluation System ("CURES") data for some of his patients.

- 34. The CURES program started in 1998, and required mandatory pharmacy reporting of dispensed Schedule II controlled substances. The CURES program was amended in January 2005, to require mandatory pharmacy reporting of Schedule II, III, and IV controlled substances. The data is collected statewide and can be used by healthcare professionals such as pharmacists and prescribers to evaluate and determine whether their patients are utilizing their prescriptions for controlled substances correctly. The data may be used to aid in the determination of whether a patient has been to multiple prescribers and multiple pharmacies to fill controlled substance prescriptions through the CURES Prescription Drug Monitoring Program ("PDMP"). The CURES program currently requires mandatory weekly pharmacy reporting of Schedule II, III, and IV controlled substances.
- 35. During the July 12, 2013, inspection, Respondent Chan stated that Dr. B.W. was a local doctor who typically prescribed high doses of controlled substances. Respondent Chan did not question the quantities because Dr. B.W. was a local "pain specialist." After initially calling Dr. B.W. a few times to verify prescriptions, Respondent Chan no longer called Dr. B.W. regarding the prescriptions he wrote. Respondent Chan was unfamiliar with the PDMP, and was unable to articulate a clear understanding of the meaning of corresponding responsibility.
- 36. Further investigation of the records obtained during the inspection revealed questionable dispensing by Respondent Jefferson Plaza Pharmacy. Between the period of July 12, 2010, and July 12, 2013, Respondent Jefferson Plaza Pharmacy and Respondent Chan dispensed controlled substance prescriptions for prescribers and patients who were outside of the pharmacy's normal service area. Respondents did not verify whether the prescriptions were issued for a legitimate medical purpose. Respondents failed to use industry tools, such as the PDMP, to verify early or duplicate dispensing for patients who were "doctor shopping" or "pharmacy shopping," or both, as demonstrated by the activities of at least ten different patients. Respondents failed to recognize "red flags," which should have given them the inkling of a

potential problem with the prescriptions, and invoked a duty of inquiry. These "red flags" included filling prescriptions for patients outside the pharmacy service area and prescribers outside of the pharmacy service area, the payment method of cash was far greater than third party insurance, and early dispensing of controlled substances for various patients as determined by CURES data.

37. Between July 12, 2010, and July 12, 2013, Respondent Jefferson Plaza Pharmacy and Respondent Chan dispensed 25,261 prescriptions for various controlled substances. Respondent Jefferson Plaza Pharmacy and Respondent Chan dispensed 204,195 doses of Hydrocodone/APAP 10/325 milligrams, and 528,718 tablets of Oxycodone 30 milligrams, far exceeding the volumes of the same drugs dispensed by other pharmacies in the area with longer operating hours.

FIRST CAUSE FOR DISCIPLINE

(Drugs Lacking Quality or Strength)
(Bus. & Prof Code, §§ 4301, subd. (o), 4342, subd, (a))

38. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their licenses to disciplinary action in that Respondents possessed pharmaceutical preparations and drugs that did not conform to the standards and tests for quality and strength, as provided in the latest edition of the United States Pharmacopeia or the National formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law. (Bus. & Prof. Code, §§ 4301, subd. (o), 4342, subd. (a).) The circumstances are set forth in paragraphs 28 through 35, above.

SECOND CAUSE FOR DISCIPLINE

(Operational Standards and Security)

(Bus. & Prof. Code, § 4301, subd. (o), Cal. Code Regs., tit. 15, § 1714, subds. (b), (c))

39. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their licenses to disciplinary action in that they failed to maintain Jefferson Plaza Pharmacy's facility, space, fixtures, and equipment so that drugs could be safely and properly prepared, maintained, secured and distributed. (Bus. & Prof. Code, § 4301, subd. (o), Cal. Code of Regs., tit. 16, § 1714, subd. (b).) Respondent Jefferson Plaza Pharmacy and Respondent Chan also failed to maintain Jefferson Plaza Pharmacy's fixtures and equipment in a clean and orderly condition.

(Bus. & Prof. Code, § 4301, subd. (o), Cal. Code of Regs., tit. 16, § 1714, subd. (c).) The circumstances are set forth in paragraphs 28 through 37, above.

THIRD CAUSE FOR DISCIPLINE

(No Written Compounding Procedure and Manual)

(Bus. & Prof. Code, § 4301, subd. (o), Cal. Code Regs., tit. 16, § 1735.5, subds. (a),(b))

40. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their licenses to disciplinary action in that they failed to maintain a written policy and procedure manual for compounding and failed to maintain clearly defined compounding policy and procedures to reflect the compounding activities of the pharmacy. (Bus. & Prof. Code, § 4301, subd. (o), Cal. Code Regs., tit. 16, § 1735.5, subds. (a), (b).) The circumstances are set forth in paragraphs 28 through 37, above.

FOURTH CAUSE FOR DISCIPLINE

(Training Records and Competency Evaluation Process)
(Bus. & Prof. Code, § 4301, subd. (o), Cal. Code Regs., tit. 16, § 1735.7, subd. (a), (b))

41. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their licenses to disciplinary action in that they failed to maintain written documentation sufficient to demonstrate that their pharmacy personnel had the skills and training to perform compounding activities and they failed to develop and maintain an on-going competency evaluation process. (Bus. & Prof. Code, § 4301, subd. (o), Cal. Code Regs., tit. 16, § 1735.7, subd. (a), (b).) The circumstances are set forth in paragraphs 28 through 37, above.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Provide Compounding Quality Assurance)
(Bus. & Prof. Code, § 4301. subd. (o), Cal. Code of Regs., tit. 16, § 1735.8, subd. (a))

42. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their licenses to disciplinary action in that they failed to maintain a written policy and procedure designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products. (Bus. & Prof. Code, § 4301, subd. (o), Cal. Code of Regs., tit. 16, § 1735.8, subd. (a).) The circumstances are set forth in paragraphs 28 through 37, above.

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SIXTH CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4115, subd. (e), 4051, subd. (a)) (Engaging in Acts of Pharmacy Technician or Pharmacist Without a License)

43. Respondent Esmabe has subjected her pharmacy technician registration to disciplinary action in that she engaged in compounding activities without a pharmacy technician registration or pharmacist license. (Bus. & Prof. Code, §§ 4301, subd. (o), 4115, subd. (e), 4051, subd. (a).) The circumstances are set forth in paragraphs 28 through 37, above.

SEVENTH CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, §§ 4301, subd. (o), 4115, subd. (e), 4051, subd. (a), 4328) (Engaging in Acts of Pharmacy Technician Without a License)

44. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their licenses to disciplinary action in that they allowed Respondent Esmabe to compound prescriptions without a pharmacist license or pharmacy technician registration. (Bus. & Prof. Code, §§ 4301, subd. (o), 4115, subd. (e), 4051, subd. (a), 4328.) The circumstances are set forth in paragraphs 28 through 37, above.

EIGHTH CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, § 4301, subd. (i))

(Failure To Exercise Corresponding Responsibility In Dispensing Controlled Substances)

45. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their licenses to disciplinary action in that they failed to comply with their corresponding responsibility to ensure that controlled substances are dispensed for a legitimate medical purpose when they furnished prescriptions for controlled substances despite the presence of numerous "red flags." (Bus. & Prof. Code, § 4307, subd. (j), Health and Saf. Code, § 11153, subd. (a).) The circumstances are set forth in paragraphs 28 through 37, above.

NINTH CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, § 4301, subd. (d)) (Excessive Furnishing of Controlled Substances)

46. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their licenses to disciplinary action in that from July 11, 2010, through July 11, 2013, Respondents furnished clearly excessive amounts of controlled substances in violation of Health and Safety Code section 11153, subdivision (a). (Bus. & Prof. Code, § 4301, subd. (d).) Specifically, from

July 11, 2010, through July 11, 2013, Respondents dispensed 25,261 prescriptions for various controlled substances. Respondents dispensed 204,195 doses of Hydrocodone/APAP 10/325 milligrams, and 528,718 tablets of Oxycodone 30 milligrams. These amounts far exceeded the volumes of the same drugs dispensed by other pharmacies in the area with longer operating hours. The circumstances are set forth in paragraphs 28 through 37, above.

TENTH CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, § 4306.5, subd. (a)) (Misuse of Education by Pharmacist)

47. Respondent Chan has subjected his Pharmacist License to disciplinary action in that from July 11, 2010, through July 11, 2013, he failed to use his education, training, and experience as a pharmacist when he filled prescriptions for large quantities of narcotics for patients who used multiple prescribers and obtained early refills at Respondent Jefferson Plaza Pharmacy, as set forth above in paragraphs 28 through 37. (Bus. & Prof. Code, § 4301, subd. (c), Bus. & Prof. Code, § 4306.5, subd. (a).)

ELEVENTH CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, § 4306.5, subd. (b))

(Failure to Exercise or Implement Best Professional Judgment or Corresponding Responsibility)

48. Respondent Chan has subjected his Pharmacist License to disciplinary action in that he failed to exercise or implement his 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. (Bus. & Prof. Code, § 4306.5, subd. (b).) Specifically, from July 11, 2010, through July 11, 2013, Respondent Chan filled prescriptions for large quantities of narcotics for patients who used multiple prescribers, paid cash, and obtained early refills at Respondent Jefferson Plaza Pharmacy without taking measures to confirm the prescriptions and that the large quantities of narcotics were prescribed for a legitimate medical purpose. The circumstances are set forth in paragraphs 28 through 37, above.

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TWELFTH CAUSE FOR DISCIPLINE

(Bus. & Prof. Code, § 4301) (Unprofessional Conduct)

Respondents have subjected their licenses to disciplinary action in that they engaged in unprofessional conduct as set forth in paragraphs 28 through 37, above. (Bus. & Prof. Code, §

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:

- Revoking or suspending Pharmacy Permit Number PHY 11062, issued to Jefferson
- Revoking or suspending Pharmacist License Number RPH 32261, issued to Johnny
- Revoking or suspending Original Pharmacy Technician Registration Number TCH 124483, issued to Maricon Payte Esmabe;
- Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section
 - Taking such other and further action as deemed necessary and proper.

Executive Øfficer Board of Pharmacy

Department of Consumer Affairs

State of California Complainant

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