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8		or tur
9	BEFORE THE BOARD OF PHARMACY	
	DEPARTMENT OF CONSUMER AFFAIRS	
10	STATE OF C	CALIFORNIA
11		G N 6000
12	In the Matter of the Accusation Against:	Case No. 6230
13	JURUPA VALLEY PHARMACY, INC., DBA JURUPA VALLEY PHARMACY	ACCUSATION
14	7990 Limonite Ave., Ste. F Jurupa Valley, CA 92509	ACCUSATION
15	Surupa vancy, CA 72507	
16	Pharmacy License No. PHY 51190	
17	and	
18	EKTA MAYUR PATEL, PHARMACIST 12612 Sierra Creek Dr.	
19	Riverside, CA 92503	
20	Pharmacist License No. RPH 63609	·
21	Respondents.	
22		
23	Complainant alleges:	
24	<u>PARTIES</u>	
25	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity	
26	as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.	
27	2. On or about December 14, 2012, the Board issued Pharmacy License Number PHY	
28	51190 to Jurupa Valley Pharmacy, Inc., dba Jurupa Valley Pharmacy, with Ekta Mayur Patel, as	

(JURUPA VALLEY PHARMACY, INC., DBA JURUPA VALLEY PHARMACY; EKTA MAYUR PATEL, PHARMACIST) ACCUSATION

the Pharmacist-in-Charge (Respondent). The Pharmacy License was in full force and effect at all times relevant to the charges brought herein and will expire on December 1, 2018, unless renewed.

3. On or about January 29, 2010, the Board issued Pharmacist License Number RPH 63609 to Ekta Mayur Patel (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2017, unless renewed.

JURISDICTION

- 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 unless otherwise indicated.
- 5. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].
- 6. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.
 - 7. Section 4300.1 of the Code states:

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

STATUTORY PROVISIONS

8. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

- (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
- (b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

- (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.
- 9. Section 4040 of the Code states:
 - (a) Prescription means an oral, written, or electronic transmission order that is both of the following:
 - (1) Given individually for the person or persons for whom ordered that includes all of the following:
 - (A) The name or names and address of the patient or patients.
 - (B) The name and quantity of the drug or device prescribed and the directions for use.
 - (C) The date of issue.
 - (D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.
 - (E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.
 - (F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to Section 4052.1, 4052.2, or 4052.6.
 - (2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to Section 4052.1, 4052.2, or 4052.6 by a pharmacist licensed in this state.
 - (b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

- (c) Electronic transmission prescription includes both image and data prescriptions. Electronic image transmission prescription means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. Electronic data transmission prescription means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.
- (d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.
- (e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

10. Section 4113(c) of the Code states:

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

11. Section 4301 of the Code 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 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, 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.

12. Section 4307(a) of the Code states that:

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,

15. Health and Safety Code section 11164 states:

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.
- (b)(1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.
- (2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.
- (3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.
- (c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.
- (d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.
 - (e) This section shall become operative on January 1, 2005.

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REGULATORY PROVISIONS

- 16. Section 1304.11(b) of title 21, Code of Federal Regulations states in part:
- (a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.
- (b) Initial inventory date. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.
- (c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

17. Section 1306.04(a) of title 21, Code of Federal Regulations states:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his 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. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

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24. Phenergan/Codeine Syrup, is the brand name for the generic promethazine with codeine, and is a Schedule V controlled substance pursuant to Health and Safety Code section 11058(c)(1), and a dangerous drug pursuant to Business and Professions Code section 4022.

FACTUAL ALLEGATIONS

- 25. Jurupa Valley Pharmacy, Inc., dba Jurupa Valley Pharmacy (Respondent Pharmacy), is an independent retail pharmacy filling approximately 150 prescriptions per day. At all times mentioned herein and since December 14, 2012, Ekta Mayur Patel (Respondent Patel) has been the Pharmacist-in-Charge (PIC) at Respondent Pharmacy.
- 26. On January 10, 2017, a Board of Pharmacy inspector conducted an inspection of Respondent Pharmacy. Respondent Patel was present during the inspection. When the inspector asked to review Respondent Pharmacy's biennial inventory of controlled substances, Respondent Patel could not locate an inventory completed after January 2014.
- 27. After reviewing numerous prescription documents, the inspector discovered that Respondent Pharmacy had filled approximately 91 controlled substance prescriptions written on 38 prescription documents that did not conform to the requirements under the law. Specifically, all 38 of the prescription documents lacked the required "California Security Prescription" watermark and numerous prescription documents lacked an identifying number assigned to the approved security printer or lacked a lot number.
- 28. In addition, the inspector discovered that Respondent Pharmacy dispensed 525 controlled substance prescriptions written by three prescribers (Dr. R.G., Dr. S.K. and PA S.D.) that contained significant irregularities and "red flags" suggesting that the prescriptions were not written for a legitimate medical purpose. The prescribing profiles for all three prescribers contained numerous prescriptions for a limited number of commonly abused controlled substances. For example, 91.5% of Dr. R.G.'s prescriptions were written for controlled substances. In fact, three controlled substances (oxycodone 30 mg, hydrocodone/acetaminophen 10/325 mg, and promethazine/codeine syrup) accounted for 88.8% of Dr. R.G.'s total prescribing.

In another example, 64.1% of Dr. S.K.'s prescriptions were written for the same three controlled
substances (oxycodone 30 mg, hydrocodone/acetaminophen 10/325 mg, and
promethazine/codeine syrup).

- 29. All of Dr. R.G.'s prescriptions reported to the CURES database were purchased in cash. All but one of Dr. S.K. and PA S.D.'s prescriptions reported to the CURES database were purchased in cash.
- 30. The offices of all three prescribers were also located 32 to 67 miles from Respondent Pharmacy. For example, Dr. R.G. had two office locations: one in Orange (32 miles away) and one in Van Nuys (66.8 miles away). Dr. S.K. also had two office locations: one in Van Nuys (67.2 miles away) and one in Anaheim (39.3 miles away).
- 31. Moreover, the brand name for promethazine/codeine syrup (Phenergan with Codeine) was frequently misspelled by the prescribers. For example, all of the prescriptions purportedly written by Dr. R.G. were misspelled as "Phenergan w/ codin." Likewise, all but one of the prescriptions purportedly written by Dr. S.K. were misspelled as "Phenergan w/ codin" and the other one was misspelled as "Phenergan w/ codine."
- 32. The prescriptions from Dr. S.K. and PA S.D. listed diagnoses which did not account for the prescribing of promethazine/codeine syrup. For example, numerous prescriptions were written by Dr. S.K. for lower back pain, sciatic nerve damage, and herniated disc in the lower back. However, promethazine/codeine syrup (a cough suppressant) was prescribed to the patients in the amount of 16 ounces or one pint, even though the patients' listed diagnoses did not include any respiratory conditions or cough.

FIRST CAUSE FOR DISCIPLINE

(Failing to Comply with Controlled Substance Inventory Requirements)

33. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating section 1304.11 of title 21 of the Code of Federal Regulations, in that they failed to complete a biennial inventory of controlled substances since January 2014, as set forth in paragraph 26 above, which is incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Filled Controlled Substances Written on Noncompliant Prescription Forms)

34. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating Health and Safety Code sections 11164 for filling and dispensing controlled substances from forms that did not comply with the requirements of Health and Safety Code section 11162.1, as set forth in paragraph 27 above, which is incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Dispensing Prescriptions Which Contain a Significant Irregularity, Uncertainty, or Ambiguity)

35. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1761, in that Respondents dispensed prescriptions which contained significant irregularities, uncertainties, or ambiguities, as set forth in paragraphs 27 through 32 above, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Failing to Comply with Corresponding Responsibility for Legitimate Controlled Substance Prescriptions)

36. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating Health and Safety Code section 11153(a) and section 1306.04(a) of title 21 of the Code of Federal Regulations, in that they failed to comply with their corresponding responsibility to ensure that controlled substances were dispensed for a legitimate medical purpose when Respondents furnished prescriptions for controlled substances even though "red flags" were present to indicate those prescriptions were not issued for a legitimate medical purpose, as set forth in paragraphs 27 through 32 above, which are incorporated herein by reference.

OTHER MATTERS

37. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 51190 issued to Jurupa Valley Pharmacy, Inc., dba Jurupa Valley Pharmacy, 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 51190 is placed on probation or until Pharmacy Permit Number PHY 51190 is reinstated if it is revoked.

- 38. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 51190 issued to Jurupa Valley Pharmacy, Inc., dba Jurupa Valley Pharmacy, while Ekta Mayur Patel has been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Ekta Mayur Patel 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 51190 is placed on probation or until Pharmacy Permit Number PHY 51190 is reinstated if it is revoked.
- 39. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 63609, issued to Ekta Mayur Patel, Ekta Mayur Patel 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 Number RPH 63609 is placed on probation or until Pharmacist License Number RPH 63609 is reinstated if it is revoked.

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:

- Revoking or suspending Pharmacy License Number PHY 51190, issued to Jurupa Valley Pharmacy, Inc., dba Jurupa Valley Pharmacy;
- 2. Revoking or suspending Pharmacist License Number RPH 63609, issued Ekta Mayur Patel;
- 3. Prohibiting Jurupa Valley Pharmacy, Inc., dba Jurupa Valley Pharmacy from servicing as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51190 is placed on probation or until Pharmacy Permit Number PHY 51190 is reinstated if Pharmacy Permit Number PHY 51190 issued to Jurupa Valley Pharmacy, Inc., dba Jurupa Valley Pharmacy, is revoked;

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- Prohibiting Ekta Mayur Patel from serving as a manager, administrator, owner, 4. member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51190 is placed on probation or until Pharmacy Permit Number PHY 51190 is reinstated if Pharmacy Permit Number PHY 51190 issued to Jurupa Valley Pharmacy, Inc., dba Jurupa Valley Pharmacy, is revoked;
- Prohibiting Ekta Mayur Patel from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 63609 is placed on probation or until Pharmacist License Number RPH 63609 is reinstated if Pharmacist License Number RPH 63609 issued to Ekta Mayur Patel is revoked;
- Ordering Ekta Mayur Patel and Jurupa Valley Pharmacy, Inc., dba Jurupa Valley 3. Pharmacy to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,
 - Taking such other and further action as deemed necessary and proper. 4.

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VIRGINIA HEROLD

Executive Officer Board of Pharmacy

Department of Consumer Affairs

State of California

Complainant