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7	BEFORE THE				
8	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS				
9	STATE OF CONSUMER AFFAIRS STATE OF CALIFORNIA				
10		G 31 ***			
11	In the Matter of the Accusation Against: DR. N. VAHEDI PHARMACY INC. DBA FUSION RX COMPOUNDING	Case No. 5899			
12	PHARMACY; NAVID VAHEDI, president	ACCUSATION			
13	12001 Westwood Blvd., Suite A Los Angeles, CA 90025	ACCUSATION .			
14					
15	Pharmacy Permit No. PHY 49937				
16	and				
17	NAVID VAHEDI, (PIC) 12001 Westwood Blvd Ste A.				
18	Los Angeles, CA 90025				
19	Pharmacist License No. RPH 59537				
20	Respondents.				
21					
22	Complainant alleges:				
23	<u>PARTIES</u>				
24	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity				
25	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.				
26	2. On or about June 9, 2009, the Board of Pharmacy issued Pharmacy Permit Number				
27	PHY 49937 to Dr. N. Vahedi Pharmacy Inc. dba Fusion Rx Compounding Pharmacy with Navid				
28	Vahedias the President and Pharmacist in Charge (Respondent Pharmacy). The Pharmacy Permit				
	1 (DR. N. VAHEDI PHARMACY INC. DBA FUSION RX COMPOUNDING PHARMACY;				
	NAVID VAHEDI, PIC) ACCUSATION				

was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2017, unless renewed.

3. On or about May 3, 2007, the Board of Pharmacy issued Original Pharmacist License Number RPH 59537 to Navid Vahedi (Respondent Vahedi). On June 9, 2009, Respondent Vahedi became as PIC for Respondent Pharmacy. The Original 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

- 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 4040 of the Code 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:

. . . .

- (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."
 - 6. Section 4081 of the Code states in pertinent part:
- "(a) All records of manufacture and of sale, acquisition, 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, pharmacy, veterinary food animal drug retailer, 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."

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- 7. Section 4101 of the Code states in pertinent part:
- "(a) A pharmacist may take charge of and act as the pharmacist-in-charge of a pharmacy upon application by the pharmacy and approval by the board. A pharmacist-in-charge who ceases to act as the pharmacist-in-charge of the pharmacy shall notify the board in writing within 30 days of the date of that change in status."
 - 8. Section 4110 of the Code 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."
 - 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:

. . .

- "(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.

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

 10. Section 4342 of the Code states:

- "(a) 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)."
 - 11. Section 11162.1 of the Health and Safety Code states in pertinent part:
- "(a) The prescription forms for controlled substances shall be printed with the following features:
- (1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

. . .

- (b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one."
 - 12. Section 11164 of the Health and Safety Code 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.

. . . .

- (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.
 - 13. Section 11165 of the Health and Safety Code states in pertinent part:

II

- (d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:(1) Full name, address, and, if available, telephone number 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, and the gender, and date of birth of the ultimate user.
- (2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical

license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

- (3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
 - (4) National Drug Code (NDC) number of the controlled substance dispensed.
 - (5) Quantity of the controlled substance dispensed.
- (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.
 - (7) Number of refills ordered.
 - (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
 - (9) Date of origin of the prescription.
 - (10) Date of dispensing of the prescription."
 - 13. Section 11167 of the Health and Safety Code states in pertinent part:

"Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in loss of life or intense suffering, an order for a controlled substance may be dispensed on an oral order, an electronic data transmission order, or a written order not made on a controlled substance form as specified in Section 11162.1, subject to all of the following requirements:(a) The order contains all information required by subdivision (a) of Section 11164.

- (b) Any written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.
- (c) The prescriber provides a written prescription on a controlled substance prescription form that meets the requirements of Section 11162.1, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.
- (d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Department of Justice in writing within 144 hours of the prescriber's failure to do so and shall

make and retain a hard copy, readily retrievable record of the prescription, including the date and method of notification of the Department of Justice.

(e) This section shall become operative on January 1, 2005."

REGULATIONS

14. 16 California Code of Regulations Section 1707.5 states in pertinent part:

. . . .

- "(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 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."
 - 15. 16 California Code of Regulations 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.

COST RECOVERY

16. 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.

FIRST CAUSE FOR DISCIPLINE

(Policies for Interpretive Services)

17. Respondents Pharmacy and Vahedi are subject to disciplinary action under California Code of Regulations section 1707.5 subdivision (d) in that Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy failed to provide Board inspectors with 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 during an inspection by the Pharmacy Board on August 26, 2015 or on a date thereafter.

SECOND CAUSE FOR DISCIPLINE

(Sale of Drugs Lacking Quality and Strength)

18. Respondents Pharmacy and Vahedi are subject to disciplinary action under Business and Professions Code section 4342 subdivision (a) in that Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy, were selling pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength. The circumstances of the violation are that on August 26, 2015, during a Board inspection, Respondent Pharmacy had fourteen (14) jars of expired compounded medications on the stock medication shelves. In addition, several expired medications were found in the drug closet and refrigerator.

THIRD CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

19. Respondents Pharmacy and Vahedi are subject to disciplinary action under California Code of Regulations section 1761 subdivisions (a) and (b) in that on August 26, 2015, during a Board inspection, it was discovered that Vahedi, as PIC, and owner of Respondent Pharmacy, was filling prescriptions for HCG (a controlled substance) from an order form completed by a sales representative. The drug and strength were preprinted on the order form and the physician did not sign the form. In addition, the orders were transferred to a hard copy prescription by an technician and not completed or verified by the pharmacist

FOURTH CAUSE FOR DISCIPLINE

(Unlicensed Activity: License Required)

20. Respondents Pharmacy and Vahedi are subject to disciplinary action under Business and Professions Code section 4110 subdivision (a) in that during an inspection by the Pharmacy Board on August 26, 2015, it was determined that Respondent Vahedi, as PIC, and owner of Respondent Pharmacy was operating an unlicensed pharmacy, called "Fusion IV Specialty Pharmacy," on the same premises as Respondent Pharmacy.

FIFTH CAUSE FOR DISCIPLINE

(Theft and Impairment: Pharmacy Procedures)

21. Respondents Pharmacy and Vahedi are subject to disciplinary action under Business and Professions Code section 4104 subdivision (a) in that Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy were unable to produce a policy for theft or impairment of an employee during an inspection by the Pharmacy Board on August 26, 2015 or at a later date.

SIXTH CAUSE FOR DISCIPLINE

(Prescriptions Requirements)

22. Respondents Pharmacy and Vahedi are subject to disciplinary action under Business and Professions Code section 4040 subdivisions (a)(l)(F) in conjunction with Health and Safety Code section 11164 subdivisions (a)(1)(b) in that on August 26, 2015, the Board conducted an inspection of Respondent Pharmacy where it was discovered that Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy were filling prescriptions for HCG (a controlled substance) from an order form completed by a sales representative. The drug and strength were preprinted on the order form and the physician did not sign the form. In addition, the orders were transferred to a hard copy prescription by a technician and not completed or verified by the pharmacist.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Dishonesty, Fraud and/or Deceit)

23. Respondents Pharmacy and Vahedi are subject to disciplinary action under Business and Professions Code section 4301 (f) for engaging in any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, in that during a Board inspection on August 26, 2015, it

was determined that Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy were operating another pharmacy called "Fusion IV Specialty Pharmacy," from the same location as Respondent Pharmacy. The drugs were dispensed from Respondent Pharmacy with a label for Fusion IV Specialty Pharmacy. The brochure and intake papers for Fusion IV Specialty Pharmacy had a different address (1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025) and claimed to be a pharmacy in full operation. Fusion IV Specialty Pharmacy has not been licensed by the Board.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - False Certifications)

24. Respondents Pharmacy and Vahedi are subject to disciplinary action under Business and Professions Code section 4301 (g) for unprofessional conduct for knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts. Specifically, during a Board inspection on August 26, 2015, it was determined that Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy were operating another pharmacy called "Fusion IV Specialty Pharmacy," from the same location as Respondent Pharmacy. The drugs were dispensed from Respondent Pharmacy used a label for "Fusion IV Specialty Pharmacy." The brochure and intake papers for Fusion IV Specialty Pharmacy had a different address (1990 Westwood Blvd. Ste 135, Los Angeles, CA 90025) and claimed to be a pharmacy in full operation. Fusion IV Specialty Pharmacy has not been licensed by the Board.

NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Failure to Cooperate with Investigation)

25. Respondents Pharmacy and Vahedi are subject to disciplinary action under Business and Professions Code section 4301 subdivision (q) in that between August 26, 2015 and February 29, 2016 Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy failed to respond to the Board's multiple requests for documents including a dispensing report of all products dispensed from January 1, 2013 to January 1, 2016, order forms for HCG, policies and procedures requested at the time of the inspection, and statements from the pharmacist-in-charge.

TENTH CAUSE FOR DISCIPLINE

(Failure to Report Controlled Substances to Cures)

26. Respondents Pharmacy and Vahedi are subject to disciplinary action under Health and Safety Code section 11165(d)(l-10) in that Respondent Pharmacy and Vahedi, as PIC, and owner of Respondent Pharmacy failed to report identified information relating to controlled substances that required under the code for controlled substances to the Department of Justice CURES program from February 22, 2013 to May 2015.

DISCIPLINE CONSIDERATIONS

27. To determine the degree of discipline, if any, to be imposed on Respondents Pharmacy and Vahedi, Complainant alleges as follows:

Fusion Rx Compounding Pharmacy

- a. On or about October 27, 2015, in a prior action, the Board of Pharmacy issued Citation Number CI 2013 59594 based on violations of CCR, Title 16, § 1713 [Participating in an arrangement where prescriptions or prescription medications is left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy] and Bus. & Prof. Code § 4052(a) and CCR, Title 16, § 1735.2 [Compounded medications not for office use and in quantity for advanced male medical in excess of 72 hour supply of compounded medications.] Respondent was ordered to pay \$5,000.00. That Citation is now final and is incorporated by reference as if fully set forth.
- b. On or about September 10, 2015, in a prior action, the Board of Pharmacy issued Citation Number CI 2014 62948 based on violations of Health & Safety Code § 111397 (a) [Compounding with an Unapproved Foreign Drug], Bus. & Prof. Code § 4169(a) and CCR, Title 16, § 1735.3(c) [Prohibited act/obtaining compounding chemicals from unreliable source], 1735(d) [Compounding commercially available drugs/patent infringement] and ordered Respondent to pay \$3,000.00. That Citation is now final and is incorporated by reference as if fully set forth.
- c. On or about September 27, 2012, in a prior action, the Board of Pharmacy issued Citation Number CI 2011 50096 based on violations of Bus. & Prof. Code § 4076(a)(9)

[Prescription label date beyond manufacturing date], Health & Safety Code § 11165(d) [Failure to Report to Cures], and Title 21 CFR § 1304.11 [Failure to take DEA Inventory] and ordered Respondent to pay \$1750.00. That Citation is now final and is incorporated by reference as if fully set forth.

Navid Vahedi

- d. On or about October 27, 2015, in a prior action, the Board of Pharmacy issued Citation Number CI 2015 67653 based on violations of CCR, Title 16, § 1713 [Participating In An Arrangement Where Prescriptions Or Prescription Medications Is Left At, Picked Up From, Accepted By, Or Delivered To Any Place Not Licensed As A Retail Pharmacy] and Bus. & Prof. Code § 4052(a) and CCR, Title 16, § 1735.2 [Compounded medications not for office use and in quantity for advanced male medical in excess of 72 hour supply of compounded medications.] Respondent to pay \$2,000.00. That Citation is now final and is incorporated by reference as if fully set forth.
- e. On or about September 10, 2015, in a prior action, the Board of Pharmacy issued Citation Number CI 2015 66976 based on violations of Health & Safety Code § 111397 (a) [Compounding with an Unapproved Foreign Drug], Bus. & Prof. Code § 4169(a) and CCR, Title 16, § 1735.3(c) [Prohibited Act/Obtaining Compounding Chemicals from Unreliable Source], 1735(d) [Compounding Commercially Available Drugs/Patent Infringement] and ordered Respondent to pay \$3,000.00. That Citation is now final and is incorporated by reference as if fully set forth.
- f. On or about September 27, 2012, in a prior action, the Board of Pharmacy issued Citation Number CI 2012 53992 based on violations of Bus. & Prof. Code § 4076(a)(9) [Prescription label date beyond manufacturing date], Health & Safety Code § 11165(d) [Failure to Report to Cures], and Title 21 CFR § 1304.11 [Failure to take DEA Inventory] and ordered Respondent to pay \$1250.00. That Citation is now final and is incorporated by reference as if fully set forth.

OTHER MATTERS

28. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number

PHY 49937 issued to Fusion Rx Compounding Pharmacy, Navid Vahedi 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 49937 is placed on probation or until Pharmacy Permit Number PHY 49937 is reinstated if it is revoked.

29. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit
Number PHY 49937 issued to Fusion Rx Compounding Pharmacy while Navid Vahedi had been
an officer and owner and had knowledge of or knowingly participated in any conduct for which
the licensee was disciplined, Navid Vahedi 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 49937 is placed on probation or until Pharmacy Permit Number
PHY 49937 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:

- 1. Revoking or suspending Pharmacy Permit Number PHY 49937, issued to Fusion Rx Compounding Pharmacy, with Navid Vahedi as the President, Pharmacist in Charge and owner;
- 2. Revoking or suspending Pharmacist License Number RPH 59537, issued to Navid Vahedi;
- 3. Prohibiting Navid Vahedi from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49937 is placed on probation or until Pharmacy Permit Number PHY 44317 is reinstated if Pharmacy Permit Number 49937 is revoked;
- 4. Ordering Fusion Rx Compounding Pharmacy, and Navid Vahedi jointly and severally, 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;

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1	 Taking such other and further action as deemed necessary and proper. 	
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4		
5	DATED: /130/17 Ungina Herold	
6	VIRGINIA HEROLD Executive Officer	
7	Board of Pharmacy Department of Consumer Affairs State of California	
- 8	State of California Complainant	
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