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

In the Matter of the Accusation Against: **AYN PHARMACY DBA THE PRESCRIPTION CENTER; AFSHIN YOUSEF NASSIR, PRESIDENT; PAYAM NASSIR, VICE PRES.** **9730 Wilshire Blvd., Suite 103 & 114** **Beverly Hills, CA 90212** **Permit No. PHY 41455,** **and** **AFSHIN YOUSEF NASSIR** **9730 Wilshire Blvd # 103** **Beverly Hills, CA 90210** **Pharmacist License No. RPH 46543** Respondents.	Case No. 5056 **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 December 23, 1996, the Board of Pharmacy issued Permit Number PHY 41455 to Ayn Pharmacy dba The Prescription Center; Afshin Yousef Nassir, President; Payam

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Nassir, Vice Pres. (Respondent Pharmacy). The Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2016, unless renewed.

3. On or about August 16, 1993, the Board of Pharmacy issued Pharmacist License Number RPH 46543 to Afshin Yousef Nassir (Respondent Pharmacist). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2015, 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 4300.1 states:

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

STATUTES

6. 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."

7. Section 4301 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:

. . .

"(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

"(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

. . . .

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

. . .

"(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

. . .

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

8. Section 4302 provides:

"The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee."

9. Section 4013 provides, in pertinent part:

"(a) Any facility licensed by the board shall join the board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal.

"(b) Any facility licensed by the board shall update its e-mail address with the board's e-mail notification list within 30 days of a change in the facility's e-mail address.

. . . .

10. Health and Safety Code section 11165, subdivision (d), provides:

"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.

REGULATIONS

11. California Code of Regulations, title 16, section 1707.5, subdivision (a), provides in pertinent part:

"Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following 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 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

(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.

. . . .

12. California Code of Regulations, title 16, section 1714, provides 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.

. . . .

13. California Code of Regulations, title 16, section 1735.2, provides in pertinent part:

. . .

"(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

. . .

(2) Equipment to be used.

. . .

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

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

. . . .

14. California Code of Regulations, title 16, section 1735.3, subdivision (a)(1), provides that pharmacy records shall include the "master formula record" for each compounded drug product.

15. California Code of Regulations, title 16, section 1735.4 provides:

"(a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).

"(b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.

"(c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date."

16. California Code of Regulations, title 16, section 1735.7, provides 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.

. . . .

COST RECOVERY

17. 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

(Unprofessional Conduct)

18. Respondents are subject to disciplinary action under section 4301 in that Respondents engaged in unprofessional conduct. The circumstances are as follows:

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a. Respondents submitted a Community Pharmacy Self-Assessment and a Compounding Self Assessment to the Board, both signed under penalty of perjury by Respondent Pharmacist, wherein Respondents falsely represented that Respondent Pharmacy was in compliance with various state laws. Said misrepresentations include falsely stating that Respondent Pharmacy's prescription labels were in compliance with state law, falsely stating that repackaged drugs were labeled in compliance with state and federal law, falsely stating that records of each compounded drug product included information about the equipment used in compounding the drug, falsely stating labels on compounded drug products complied with state law regulating compounding drugs, falsely stating that Respondent Pharmacy maintained written documentation demonstrating that its compounding staff was properly skilled and trained in the compounding of drugs, and falsely stating that Respondent maintained documentation of all compounding training provided to pharmacy personnel.

b. Respondents have engaged in unprofessional and abusive business practices which exploit and harm the California workers' compensation system. Specifically, for years Respondents have charged exorbitant rates to workers' compensation insurance carriers for costs and fees related to prescription medications. For example, with respect to Prescription No. 07941445, filled for Patient R.E. on or about July 15, 2013, Respondent Pharmacy charged the carrier a total of $6,611.95 for a 15-day supply (i.e., 120 grams) of ketoprofen 20%/lidocaine 5%/cyclobenzaprine 1% cream. The $6,611.05 charge included $1,318.20 for ingredient costs plus a "dispensing fee" of $5,293.73. Pursuant to the Workers' Compensation Pharmacy Fee Schedule, the highest payment price for 120 grams of said cream, including a dispensing fee and compounding fee, was $373.66. Respondents' unprofessional and abusive business tactics also include the sending of demand letters to carriers requiring payment of the exorbitant charges within 30 days, and the filing of workers' compensation liens against the patient recoveries in cases where full payment has not been received from the carrier. For example, in correspondence sent to CNA Claims Plus Brea, dated December 5, 2012, Respondents cited charges totaling $99,179.25 for filling fifteen 120-gram prescriptions of ketoprofen 20%/lidocaine 5%/cyclobenzaprine 1% cream for Patient A.R. over an eight-month period (i.e., $6611.95 per fill/refill). The demand

letter stated that although the charges totaled $99,179.25, Respondents would accept $83,000.00 in satisfaction of the bill as long as payment was received within 30 days. Respondents have routinely engaged in such unprofessional business practices for years.

c. On or about August 16, 2007, Respondent Pharmacy entered into a lease agreement, dated August 9, 2013, with Beverly Hills Triangle, LLC ("Lessor") wherein it agreed to lease certain property located at 9735 Wilshire Boulevard in Beverly Hills, California, pursuant to certain terms and conditions, for a period of four (4) years. The lease agreement was signed on behalf of the lessee by Respondent Pharmacist in his capacity as president of Ayn Pharmacy Corporation and on behalf of the Lessor by E.D. At the time that the lease agreement was executed, E.D. had been diagnosed with terminal cancer and was not expected to survive the duration of the lease agreement. Thereafter, Respondents made certain improvements to the subject property, and in 2008 Respondents produced a purported addendum to the lease agreement which they claimed required the Lessor to pay for said improvements. The claimed addendum to the lease agreement also contained provisions related to purported rent credit concessions, parking issues and lessee options for lease extensions. The claimed addendum to the lease agreement was signed by Respondent Pharmacist on behalf of Ayn Pharmacy Corporation on August 16, 2007, and was also purportedly signed by E.D. on behalf of the Lessor. If valid and enforceable, the addendum to the lease agreement would have cost the Lessor more than $400,000.00 in property improvements and rent credits. The purported addendum to the lease agreement was not genuine, however. Instead, it was a falsified document containing the forged signature of E.D., which Respondents had prepared and produced as part of a scheme to defraud the Lessor. The Lessor and E.D., filed a civil lawsuit against Respondents alleging that the addendum had been forged and that Respondents had hoped to dupe the Lessor into believing it has genuine after E.D. passed away from cancer. In the civil matter entitled *Beverly Hills Triangle, LLC. V. Ayn Pharmacy Corp., et al.* (Super Ct. Los Angeles County, 2010, No. BC399678), the Lessor and E.D. obtained a judgment against Respondents for more than $700,000.00 after a jury found that the signature of E.D. was a forgery. In the criminal matter entitled *The People of the State of California v. Afshin Yousef Nassir* (Super. Ct. Los Angeles

County, 2010, No. SA076100), Respondent Nassir was charged with one felony count of forgery and one count of larceny related to the falsified addendum. On or about October 21, 2014, Respondent Nassir entered a plea of nolo contendere and was convicted of one count of violating Penal Code section 496 (larceny). Pursuant to a plea agreement, the forgery charge was dismissed.

SECOND CAUSE FOR DISCIPLINE

(Act Involving Moral Turpitude/Dishonesty/Fraud/Deceit/Corruption)

19. Respondents are subject to disciplinary action under section 4301, subdivision (f), in that they engaged in an act involving moral turpitude, dishonesty, fraud, deceit and/or corruption. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 18, subparagraphs a through c, inclusive, as though set forth fully herein.

THIRD CAUSE FOR DISCIPLINE

(Substantially-Related Criminal Conviction)

20. Respondents are subject to disciplinary action under section 4301, subdivision (l), in conjunction with section 4302, in that Respondent Nassir was convicted of a crime substantially related to the qualifications, functions, and duties of a licensee. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 18, subparagraph c, inclusive, as though set forth fully herein.

FOURTH CAUSE FOR DISCIPLINE

(Operational Standards Violation)

21. Respondents are subject to disciplinary action under section 4301, subdivision (o), in that they failed to comply with California Code of Regulations, title 16, section 1714. The circumstances are that during an inspection of Respondent pharmacy on or about July 16, 2013, Board inspectors observed the following violations: (1) Respondents' prescription filling station contained numerous unlabeled bottles of prepackaged medications; (2) the medication compounding area contained filled but unlabeled cream dispensers; (3) containers of both tablet/capsule medication and compounded medication failed to identify expiration dates or lot numbers; (4) many medication containers bore unclear labeling; (5) stock medications were

expired; (6) finished compound products had no expiration date; (7) the buckets used to compound and store finish compounded cream were not clean; and (8) the scale used by Respondents was not clean.

FIFTH CAUSE FOR DISCIPLINE

(CURES Reporting Violations)

22. Respondents are subject to disciplinary action under section 4301, subdivision (j), in that they failed to comply with Health and Safety Code section 11165, subdivision (d). The circumstances are that from September 20, 2010, to September 3, 2013, Respondents failed to transmit required data to the California Department of Justice concerning their dispensing of Schedule II, Schedule III and Schedule IV controlled substances.

SIXTH CAUSE FOR DISCIPLINE

(Labeling Violations)

23. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and (o), in that they failed to comply with California Code of Regulations, title 16, section 1707.5, subdivision (a). The circumstances are that during an inspection of Respondent pharmacy on or about July 16, 2013, Board inspectors observed that finished prescription labels used by Respondents failed to set forth drug and patient information in compliance with state law.

SEVENTH CAUSE FOR DISCIPLINE

(Email Notification Violation)

24. Respondents are subject to disciplinary action under section 4301, subdivision (o), in that they failed to comply with section 4013. The circumstances are that Respondents failed to join the Board's email notification list as required by state law.

EIGHTH CAUSE FOR DISCIPLINE

(Violation of Compounding Requirements)

25. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.2, subdivisions (h) and (i). The circumstances are that during an inspection of Respondent

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pharmacy on or about July 16, 2013, Board inspectors observed that numerous prepackaged compounded medications lacked expiration dates in violation of state law.

NINTH CAUSE FOR DISCIPLINE

(Violation of Compounded Drug Labeling Requirements)

26. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.4, subdivision (c). The circumstances are that during an inspection of Respondent pharmacy on or about July 16, 2013, Board inspectors observed that numerous prepackaged compounded medications lacked proper labeling in that they did not provide medication strength, dosage form, quantity, lot number and/or expiration information.

TENTH CAUSE FOR DISCIPLINE

(Violation of Compounded Drug Recordkeeping Requirements)

27. Respondents are subject to disciplinary action under section 4301, subdivisions (j) and (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.3, subdivision (a)(1), in conjunction with section 1735.2, subdivision (d)(2). The circumstances are that during an inspection of Respondent pharmacy on or about July 16, 2013, Board inspectors determined that Respondents' compounding logs failed to identify the equipment used in compounding as required by state law.

ELEVENTH CAUSE FOR DISCIPLINE

(Violation of Compounding Staff Training Requirements)

28. Respondents are subject to disciplinary action under section 4301, subdivision (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.7. The circumstances are that during an inspection of Respondent pharmacy on or about July 16, 2013, Board inspectors determined that Respondents: (1) failed to 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; (2) failed to develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding and/or to maintain documentation of any and all such training.

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 Permit Number PHY 41455, issued to Ayn Pharmacy dba The Prescription Center; Afshin Yousef Nassir, President; Payam Nassir, Vice Pres.;

2. Revoking or suspending Pharmacist License Number RPH 46543, issued to Afshin Yousef Nassir;

3. Ordering The Prescription Center and Afshin Yousef Nassir 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;

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

DATED: 7/21/15

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

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