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

| | |
|---|---|
| In the Matter of the Accusation Against:<br><br>**AURO PHARMACIES INC.**<br>**DBA CENTRAL DRUGS**<br>**520 W. La Habra Blvd.**<br>**La Habra, CA 90631-5308**<br><br>**Pharmacy Permit No. 49146**<br>**Licensed Sterile Compounding Permit No. LSC 99515**<br><br>**and**<br><br>**NAYAN PATEL**<br>**18939 Bechard Place**<br>**Cerritos, CA 90703**<br><br>**License No. RPH 48867**<br><br>Respondents. | Case No. 5865<br><br>**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 (Board), Department of Consumer Affairs.

2. On or about August 21, 2008, the Board issued Pharmacy Permit Number 49146 to Auro Pharmacies Inc. dba Central Drugs (Central Drugs). Nayan Patel is and has been the

President and 33 percent shareholder of Auro Pharmacies, Inc. since August 21, 2008. Yogesh Patel is and has been the Treasurer/Chief Financial Officer and 33 percent shareholder of Auro Pharmacies, Inc. since August 21, 2008. Ashwin Patel is and has been the 33 percent shareholder of Auro Pharmacies, Inc. since August 21, 2008. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2017, unless renewed. Nayan Patel was the Pharmacist-in-Charge from August 21, 2008 to May 15, 2015. Manisha Patel is and has been the Pharmacist-in-Charge since May 15, 2015.

3. On or about October 7, 2008, the Board issued Licensed Sterile Compounding Permit Number LSC 99515 to Auro Pharmacies Inc. dba Central Drugs (Central Drugs). The Licensed Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2017, unless renewed. Nayan Patel is and has been the President and 33 percent shareholder of Auro Pharmacies, Inc. since October 7, 2008. Yogesh Patel is and has been the Treasurer/Chief Financial Officer and 33 percent shareholder of Auro Pharmacies, Inc. since October 7, 2008. Ashwin Patel is and has been the 33 percent shareholder of Auro Pharmacies, Inc. since October 7, 2008. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2017, unless renewed. Nayan Patel was the Pharmacist-in-Charge from October 7, 2008 to May 15, 2015. Manisha Patel is and has been the Pharmacist-in-Charge since May 15, 2015.

4. On or about August 14, 1996, the Board of Pharmacy issued Pharmacist License Number RPH 48867 to Nayan Patel (Patel). 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**

5. 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.

6. Section 4300 of the Code states in pertinent part:

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

(b) The board shall discipline the holder of any license issued by the board, whose

default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

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

(4) Revoking his or her license.

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

...

(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions.

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

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 AND REGULATORY PROVISIONS

8. Section 4035 of the Code states:

"Person" includes, but is not limited to, firm, association, partnership, corporation, limited liability company, state governmental agency, trust, or political subdivision.

9. 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:

(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.

...

10. Section 4115(e) of the Code states in pertinent part, "(e) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician."

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 by any other state or federal regulatory agency.

...

12. Section 4307 of the Code states:

(a) 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, or partner 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 manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

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

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

(b) "Manager, administrator, owner, member, officer, director, associate, or partner," as used in this section and Section 4308, may refer to a pharmacist or to

any other person who serves in that capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

13. Title 16, California Code of Regulations (CCR), section 1751.7 states in pertinent part:

...

(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

...

**DRUGS**

14. All drugs mentioned in this Accusation are dangerous drugs as defined by Code section 4022.

**FACTS**

15. On or about May 13, 2015, the Board received a complaint that Central Drugs is practicing in the state of Florida as an unregistered sterile compounding outsourcing facility in violation of section 503B of the Federal Food, Drug and Cosmetic Act. (FDCA) The complaint provided a list of injectable solutions made by Central Drugs, IV supplies available at Central Drugs and a document to complete for an account with Central Drugs.

16. On or about July 8, 2015, Board inspectors conducted a routine inspection of Central Drugs. Patel and then Pharmacist C.T. showed the Board inspector the La Habra facility. C.T. was introduced as the supervisor in charge of the sterile compounding pharmacy.

17. During the facility tour, the Board inspector observed five people wearing full protective clothing in the "clean room" of the sterile compounding area. Four of the people were actively compounding sterile products while the fifth was observing. As the Board inspector and

C.T. were about to enter the clean room, four individuals exited. They introduced themselves as pharmacy technicians. The Board inspector asked to inspect the pharmacy technicians' licenses and competencies after the facility tour.

18. After the tour, the Board inspector asked to see the licenses of the four technicians he observed compounding earlier. A California Pharmacy Technician license was provided for all but H.S. A Pharmacy Technician Certification Board identification card was presented for H.S. The Board inspector again requested H.S.'s Board-issued Pharmacy Technician license. Pharmacist-in-Charge (PIC) M.P. stated that H.S. was not a California licensed Pharmacy Technician.

19. H.S. was hired as a Sterile Compounding Laboratory Pharmacy Technician by Central Drugs effective July 16, 2014. A review of Central Drugs' records, including compounding logs and technician's daily duty log in the sterile compounding room, indicated that between November 1, 2014 and July 8, 2015, H.S. compounded at least the following sterile products without being licensed by the Board: magnesium chloride 200 mg/ml lot #150624@3, dexphanthenol 250 mg/ml lot #150624@10, dexpantehnol 250 mg/ml lot #150326@3, ascorbic acid injection 500 mg/ml lot #150219@5, ascorbic acid injection 500 mg/ml lot #150126@8, L-Carnitine 500 mg/ml injectable lot #150505@6, and ascorbic acid 500 mg/ml lot #150219@3. Documents provided by Central Drugs showed that H.S. compounded a total of 2,327,484 ml of product between July 16, 2014 and July 8, 2015.

20. On or about July 15, 2015, the Board inspector received statements from H.S., M.P. and Central Drugs' human resources manager advising that H.S.'s pharmacy technician duties were removed from her on July 8, 2015 and, effective on July 14, 2015, H.S. began to work as a Pharmacy Clerk.

21. On or about September 22, 2015, the Board inspector returned to Central Drugs with T.L., an inspector from the FDA and J.N., an investigator with the California Department of Public Health (CDPH). The Board inspector observed an alcohol bottle hanging on the side of a laminar flow hood in the clean room with H.S.'s name on it. The Board inspector was assured by Patel that H.S. only helped the compliance team by making sure all the paperwork was in order.

22. On or about September 24, 2015, the Board inspector returned to Central Drugs with T.L. and J.N. During this visit, C.T. twice stated that Central Drugs only tested for endotoxin on batch-produced sterile injectable products compounded from non-sterile products and that endotoxin (pyrogen) testing was done 60 percent of the time on these products. Patel interjected and stated that they "are doing more than the law requires." The Board inspector confirmed that Patel was referring to sterile products compounded from non-sterile products and then read the Board's regulations requiring endotoxin testing for every batch of compounded sterile products made from non-sterile products. The Board inspector requested a copy of Central Drugs' policy and procedure with regard to batch-produced sterile products, however no written policy or procedure was provided to the inspector. The Board inspector also requested the batch results of all the randomly selected compounded drugs, including the sterile test results, endotoxin tests and the release date associated with each prescription. PIC M.P. left the room then returned and asked the Board inspector if she could send the batch results on Monday, September 28, 2015; the Board inspector agreed.

23. On September 25, 2015, PIC M.P. contacted the Board inspector and requested an extension to provide the documents requested. The Board inspector granted an extension until October 1, 2015. On October 1, 2015, the Board inspector received compounding log worksheets that indicated that all batch compounded products had been tested for endotoxin, which was contrary to the representations of C.T. and PIC M.P. The endotoxin test information was all handwritten and there were discrepancies noted in the compounding log for magnesium chloride injection 200 mg/ml lot #150205@2 and the "Microbial Log/Pyro Test" sheet. According to the compounding log worksheet, the endotoxin test was conducted on "2/10/2015." However, there were two "Microbial Log/Pyro Test" sheets for magnesium chloride injection 200 mg/ml lot #150205@2: both show a test date of "2/5/2015" and the initials of the preparer on one Test sheet was "TN" and on the other it was "Tim."

24. At least the following compounded sterile products were not tested for endotoxin prior to being released for dispensing:

///

| Date of compounding | Sterile Product | Quantity/ Volume (ml) | Lot Number | Pharmacist/ Technician |
|---|---|---|---|---|
| 2/26/2015 | MSM 100 mg/ml | 7000 | 150226@1 | H. N./H.S. |
| 2/18/2015 | Phosphatidylcholine 50 mg/ml | 2000 | 150218@33 | H.N./H.S. |
| 2/24/2015 | Phosphatidylcholine 2x DOCA 50 mg/ml, 42 mg/ml | 2000 | 150224@4 | H.N./H.S. |
| 2/18/2015 | Prostil 20 mg/ml | 5 ml | 150281@47 | H.N./H.S. |
| 2/23/2015 | Testosterone Cypionate 160/40 | 150 | 150223@18 | H.N./M.A. |
| 2/20/2015 | Calcium Gluconate 11.63MEQ/50 ml | 3500 | 150220@2 | H.N./H.S. |
| 2/20/2015 | Capyrilc Capric Triglycerides+10% Benzyl Alcohol | 50 ml | 150225@5 | H.N./H.S. |
| 2/25/2015 | Chromium 200 mcg/ml | 2000 ml | 150220@31 | H.N./E.C./H.S. |

25. The Board inspector requested and received duplicate labels for prescriptions RX #6423900, RX #6441577, RX #6449573, RX #6459220, RX #6442478, RX #6454501 and RX #6445321. The prescription labels for these prescriptions did not have directions for use as required. All the labels stated: "Bring to physician's office for administration."

**FIRST CAUSE FOR DISCIPLINE**

**As to All Respondents**

**(Unlicensed Activity)**

26. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Code section 4115, subdivision (e), for unprofessional conduct in that between November 1, 2014 and July 8, 2015, Respondents aided and abetted H.S. in practicing as a pharmacy technician without being licensed to do so. H.S. compounded at least the following sterile products without being licensed by the Board: magnesium chloride 200 mg/ml lot #150624@3, dexphanthenol 250 mg/ml lot #150624@10, dexpantehnol 250 mg/ml lot #150326@3, ascorbic acid injection 500 mg/ml lot #150219@5, ascorbic acid injection 500 mg/ml lot #150126@8, L-Carnitine 500 mg/ml injectable lot #150505@6, and ascorbic acid 500 mg/ml lot #150219@3. And, between July 16, 2014 and July 8, 2015, H.S. compounded a totalof

2,327,484 ml of product without being licensed by the Board, as more fully set forth in paragraphs 15 – 25 above and incorporated by this reference as though set forth in full herein.

**SECOND CAUSE FOR DISCIPLINE**

**As to Central Drugs and Patel Only**

**(Sterile Injectable Compounding Quality Assurance and Process Validation)**

27. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), in conjunction with title 16, CCR, 1751.7, subdivision (c), for unprofessional conduct for failing to document end product testing for sterility and pyrogens for batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients. Respondents also failed to quarantine these injectable drug products until the end product testing confirmed sterility and acceptable levels of pyrogens as more fully set forth in paragraphs 15 – 25 above, and incorporated by this reference as though set forth in full herein.

**THIRD CAUSE FOR DISCIPLINE**

**As to Central Drugs and Patel Only**

**(Prescription Content Requirements)**

28. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Code section 4040, subdivision (1)(B), for unprofessional conduct for failing to set forth directions for use in that prescription labels for prescriptions RX #6423900, RX #6441577, RX #6449573, RX #6459220, RX #6442478, RX #6454501 and RX #6445321 failed to contain directions for use as set forth in paragraph 25 above and incorporated herein as though set forth in full.

**OTHER MATTERS**

29. Pursuant to Section 4307, if Pharmacy Permit Number PHY 49146 issued to Auro Pharmacies Inc. dba Central Drugs is suspended, revoked or placed on probation, Respondent Auro Pharmacies Inc. shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

30. Pursuant to Section 4307, if Pharmacy Permit Number PHY 49146 issued to Auro Pharmacies Inc. dba Central Drugs is suspended, revoked or placed on probation, and Respondent

Patel, while acting as the manager, administrator, owner, member, officer, director, associate, or partner, had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 49146 was revoked, suspended, or placed on probation, Respondent Patel shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

31. Pursuant to Section 4307, if Sterile Compounding License Number LSC 99515 issued to Auro Pharmacies Inc. dba Central Drugs is suspended, revoked or placed on probation, and Respondent Patel, while acting as the manager, administrator, owner, member, officer, director, associate, or partner, had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 49146 was revoked, suspended, or placed on probation, Respondent Patel shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

32. Pursuant to Section 4307, if Pharmacist License Number RPH 48867 issued to Nayan Patel is suspended or revoked, Respondent Patel shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee.

**DISCIPLINE CONSIDERATIONS**

33. To determine the degree of discipline, if any, to be imposed on Pharmacy Permit Number PHY 49146 issued to Respondent Auro Pharmacies Inc. dba Central Drugs, Complainant alleges the following:

a. On or about January 29, 2014, in a prior action, the Board of Pharmacy issued Citation Number CI 2012 54846 for violations of title 16, CCR, sections 1793.7(b) and 1735.4(a) and Code sections 4169(a)(4), 4076(a)(9), and ordered Respondent to pay a fine in the amount of $2,500.00. That Citation is now final and is incorporated by reference as if fully set forth.

b. On or about January 19, 2016, in a prior action, the Board of Pharmacy issued Modified Citation Number CI 2008 39038 for violations of title 16, CCR, sections 1761(a), Code sections 4067(a), 4169(a)(1), 4301(o)/4059.5(e), and Health & Safety Code (H&S Code) section 11153 and Code section/4033(a)(1)/H&S Code section 111615. Respondent was ordered to pay a

fine in the amount of $100,000.00. That Citation is now final and is incorporated by reference as if fully set forth.

34. To determine the degree of discipline, if any, to be imposed on Respondent Nayan Patel, Pharmacist Number RPH 48867, Complainant alleges the following:

a. On or about January 29, 2014, in a prior action, the Board of Pharmacy issued Citation Number CI 2013 59617 for violations of title 16, CCR, sections 1793.7(b) and 1735.4(a) and Code sections 4169(a)(4), 4076(a)(9), and ordered Respondent to pay a fine in the amount of $2,500.00. That Citation is now final and is incorporated by reference as if fully set forth.

b. On or about January 19, 2016, in a prior action, the Board of Pharmacy issued Modified Citation Number CI 2010 45127 for violations of title 16, CCR, sections 1761(a), Code sections 4067(a), 4169(a)(1), 4301(o)/4059.5(e), and H&S Code (H&S Code) section 11153 and Code section/4033(a)(1)/H&S Code section 111615. Respondent was ordered to pay a fine in the amount of $75,000.00. That Citation is now final and is incorporated by reference as if fully set forth.

**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 49146, issued to Auro Pharmacies Inc. dba Central Drugs;

2. Revoking or suspending Licensed Sterile Compounding Permit Number LSC 99515, issued to Auro Pharmacies Inc. dba Central Drugs;

3. Prohibiting Auro Pharmacies Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board;

4. Prohibiting Nayan Patel from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board;

5. Ordering Auro Pharmacies Inc. dba Central Drugs and Nayan Patel, jointly and severally to pay the Board the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 3/13/17

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

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