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

In the Matter of the Petitions for Early Termination of Probation by:

NAYAN PATEL, Pharm.D.

Pharmacist License No. RPH 48867

and

AURO PHARMACIES, INC., dba CENTRAL DRUGS

Pharmacy Permit No. PHY 49146

Case No. 5865

OAH No. 2021050598

DECISION

This matter was heard by video conference before a quorum of the Board of Pharmacy (Board) in Sacramento, California, on May 27, 2021. Jonathan Lew, Administrative Law Judge, Office of Administrative Hearings (OAH), presided at the hearing.

Kristina Jarvis, Deputy Attorney General, appeared pursuant to Government Code section 11522.

Petitioners Nayan Patel, Pharm.D., and Auro Pharmacies, Inc., doing business as Central Drugs, were represented by Ivan Petrzelka, Pharm.D., Attorney at Law.

Evidence was received, the record was closed, and the matter was submitted for decision on May 27, 2021.

FACTUAL FINDINGS

Background and Procedural History

1. On August 14, 1996, the Board issued petitioner Pharmacist License No. RPH 48867 (license). Petitioner's license will expire on November 30, 2021, unless renewed or revoked. On August 21, 2008, the Board issued Pharmacy Permit No. PHY 49146 (permit), to Auro Pharmacies, Inc., doing business as Central Drugs. The permit will expire on August 1, 2021, unless renewed or revoked.

2. On March 13, 2017, complainant Virginia K. Herold, a former Executive Officer for the Board, issued an Accusation against petitioners. Petitioner was president and 33 percent co-owner of Central Drugs, as well as its pharmacist-in-charge. Complainant alleged that between 2014 and 2015, petitioner violated Business and Professions Code sections 4115 and 4301, and regulations governing the practice of pharmacy, by failing to document end product testing for sterility and pyrogens for eight sets of batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients, and failed to quarantine these products until the end product testing confirmed sterility and acceptable levels of pyrogens. Petitioners also

aided and abetted the practice of an unlicensed pharmacy technician performing work in the pharmacy.

3. On August 3, 2018, the Board issued its Decision and Order by which terms petitioners' licenses and permits were revoked, stayed and placed on probation for five years, subject to various terms and conditions, including to obey all laws, submit quarterly reports, not supervise interns, not serve as a pharmacist-in-charge or consultant, reimburse the Board $16,145.67 for investigation and enforcement costs, complete continuing education, and complete a Board-approved ethics course. The Board's Decision and Order was effective on September 2, 2018.

Petitions for Early Termination of Probation

4. On October 6, 2020, petitioner signed and thereafter filed with the Board a Petition for Early Termination of Probation (Petition), for both pharmacist and pharmacy licenses. Petitioner has not previously applied for termination of his probation. Petitioner submitted in support of his Petition documentation of compliance and operation improvements, community outreach, 10 letters of recommendation, and proof of completing continuing education. In his Petition, as well as his testimony at hearing, petitioner explained the circumstances surrounding the events that gave rise to the discipline imposed on his license and his rehabilitation and corrective efforts from that time.

5. Petitioner is currently in compliance with the terms and conditions of his Board probation. Petitioner has completed over half of his probation term, which ends on or about September 1, 2023. He completed the required continuing education and ethics course, and paid the ordered investigation and enforcement costs. Petitioner is compliant with all probation terms and conditions.

6. Petitioner explained that he took immediate corrective action on the day that he was notified in 2015 of the matters that led to disciplinary action against his pharmacist license and pharmacy permit. He noted that his entire team at Central Drugs Pharmacy "has been diligently working on adding safety measures into our practice ever since the inspection" and that he accepts full responsibility and sincerely regrets that "I allowed my judgment to lapse when interpreting regulations related to sterile compounding." Petitioners have discontinued sterile compounding since 2018 and the practice is now focused on non-sterile compounds. He explained that he has been practicing pharmacy for 24 years and considers compounding to be his calling. At hearing, he confirmed that compounding comprises approximately 80 percent of his business, that he engages in no sterile compounding and that he has no intention of doing so in the future. Petitioner provides instruction in both sterile and non-sterile compounding at the University of Southern California, School of Pharmacy.

7. Petitioner noted that Central Drugs has been a part of the La Habra community since 1954. As a direct result of being placed on probation, Central Drugs lost many insurance contracts and is no longer able to serve many local patients in the community who have relied on its services. This includes low-income Medicaid patients. The COVID-19 lockdown made consumer access to pharmacy services even more difficult this past year.

8. Petitioner submitted documents and testified regarding the continuing systematic efforts he has undertaken to exceed regulatory requirements for compounding pharmacies. His efforts to mitigate past deficiencies include retaining outside consultants, expanding his regulatory compliance staff, providing extensive training to compounding personnel, and maintaining his professional skills by attendance at conferences and participating in various continuing education activities.

Petitioner has also engaged in community service by organizing educational events, health fairs, health screening services, and donations of protective equipment to first responders during the COVID-19 pandemic.

9. Petitioner has ceased sterile compounding since August 2018, and canceled his sterile compounding license. He has no intention of resuming sterile compounding. The majority of the violations leading to disciplinary action related to sterile compounding. Accordingly, there will be little or no opportunity for repetition of the sterile compounding issues in this case.

Central Drugs Pharmacy is licensed in 29 states, including California, and petitioner is licensed in six states, including California. At least 10 states initiated disciplinary action solely on the grounds of discipline imposed by the Board. Petitioner believes most, if not all, of the disciplinary restrictions imposed by other states will be removed upon termination of California discipline.

Probation also resulted in cancellation of many third-party payer contracts, most notably Medicaid. This has resulted in a substantial reduction in business, one consequence being that petitioner was forced to reduce his workforce. Petitioner is requesting early termination of his probation so that he can return to full and unrestricted pharmacy practice. Petitioner believes his safety and compliance record over the past five years demonstrates his full rehabilitation, as well that of Central Drugs Pharmacy. He acknowledges and regrets past deficiencies, is committed to meet or exceed all applicable regulatory compliance standards, and to hold his pharmacy operations to the highest professional standards. He believes full restoration of his license and pharmacy permit will not pose any appreciable risk of repetition of past errors.

Recommendations

10. Pursuant to Business and Professions Code section 4309, subdivision (b),[1] petitioner submitted six letters of recommendation from individuals licensed by the Board and four letters of recommendation from private citizens. Six of the letters were verified. Those verified letters whose authors were aware of the discipline imposed on petitioner's license uniformly support early termination of his probation. A sample of letter comments follow:

a. Jonathan Fujimoto, Pharm.D., worked with petitioner from May 2017 to November 2019. Dr. Fujimoto was the lead pharmacist at Auro Pharmacies, Inc., the "sister site" to Central Drugs. He noted that petitioner was "both personally and fiscally very supportive of all quality improvement efforts to support a compliant operation." Dr. Fujimoto has no concerns even were petitioner to resume sterile compounding operations. He believes petitioner has learned from past mistakes and now has an

[1] Business and Professions Code section 4309, subdivision (b), provides:

> The petition shall state any facts required by the Board, and the petition shall be accompanied by two or more verified recommendations from holders of licenses issued by the Board to which the petition is addressed, and two or more recommendations from citizens, each having personal knowledge of the disciplinary penalty imposed by the Board and the activities of the petitioner since the disciplinary penalty was imposed.

exceptionally strong commitment to upholding a high level of compliance and patient safety going forward.

b. Dr. Mario A. Jimenez is a licensed pharmacist with the College of Pharmacy, Western University of Health Sciences. He confirmed that petitioner speaks to fourth year students on compounding and draws on his personal experience with Board discipline to teach students about the critical importance of regulatory compliance in compounding. Petitioner is a member of the school's Dean's Advisory Committee.

c. Raffi Swadjian is an Assistant Professor, USC School of Pharmacy. He has known petitioner for 15 years and confirmed that he is an excellent resource for the School of Pharmacy who has lectured extensively on the topic of sterile and non-sterile compounding, and that Central Drugs Pharmacy has served as an Advanced Pharmacy Practice site as part of a third-year elective course on pharmacy ownership. Dr. Swadjian described petitioner as a "humble and honest pharmacist who recognized his past mistakes and I do not hesitate in expressing my support for ending his probation early."

d. Tom Beamish is the Mayor of the City of La Habra. He confirmed the many community contributions made by petitioner and Central Drugs Pharmacy to the city through outreach efforts including Healthy Kids Program, health fairs and community emergency preparedness events. He expressed appreciation for petitioner's devotion to the wellbeing of their community, particularly since the COVID-19 pandemic.

Analysis

11. Petitioner has completed over half of his five-year Board probation. He is fully compliant with all terms and conditions of his probation, and has engaged in a process of continuing systematic efforts to meet or exceed regulatory requirements for compounding pharmacies. Petitioner has accepted full responsibility for past mistakes and failures to comply with the Board's laws and regulations. He has not served as a pharmacist-in-charge since 2015, and sees no need to do so in the future. Importantly, he has not engaged in sterile compounding since August 2018, and does not expect to do so again.

Being placed on Board probation has caused hardship for petitioner, both professional and financial. Petitioner expressed regret for allowing past regulatory deficiencies, has since demonstrated his ability to safely and responsibly practice pharmacy, and is firmly committed to continuously holding his pharmacy operation to the highest professional standards going forward.

12. When all the evidence is considered, no further public interest will be served by continuing petitioner on probation. Petitioner demonstrated that he and Central Drugs Pharmacy are capable of practicing as a pharmacist and pharmacy without restrictions, and without harm to the public.

LEGAL CONCLUSIONS

1. In a proceeding for reinstatement of a license, including early termination of probation, the burden at all times is on the petitioner to establish rehabilitation. (See *Flanzer v. Board of Dental Examiners* (1990) 220 Cal.App.3d 1392, 1398, citing *Housman v. Board of Medical Examiners* (1948) 84 Cal.App.2d 308, 315.) The standard

of proof is clear and convincing evidence to a reasonable certainty. (*Hippard v. State Bar* (1989) 49 Cal.3d 1084, 1091-1092; *Feinstein v. State Bar* (1952) 39 Cal.2d 541.)

2. Business and Professions Code section 4309, subdivision (d), sets forth the following factors for consideration when the Board reviews a petition for early termination of probation:

> (1) All the activities of the petitioner since the disciplinary action was taken.
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> (2) The offense for which the petitioner was disciplined.
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> (3) The petitioner's activities during the time the license was in good standing.
>
> (4) The petitioner's documented rehabilitative efforts.
>
> (5) The petitioner's general reputation for truth and professional ability.

3. When all the relevant rehabilitation criteria set forth in Business and Professions Code section 4309, subdivision (d), are considered, petitioner established that it would be consistent with the public health, safety, and welfare to terminate his probation, as well as for Central Drugs Pharmacy.

ORDER

1. The Petition for Early Termination of Probation of Naya Patel, Pharm.D., Pharmacist License No. RPH 48867, is GRANTED.

2. The Petition for Early Termination of Probation of Auro Pharmacies, Inc., dba Central Drugs, Pharmacy Permit No. PHY 49146, is GRANTED.

This Decision shall become effective at 5:00 p.m. on October 13, 2021.

It is so ORDERED on September 13, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

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

In the Matter of the Accusation Against: AURO PHARMACIES INC. d.b.a. CENTRAL DRUGS 520 W. La Habra Blvd. La Habra, CA 90631-5308 Pharmacy Permit No. PHY 49146; Licensed Sterile Compounding Permit No. LSC 99515, and NAYAN PATEL Pharmacist License No. RPH 48867, Respondents.	Case No. 5865 OAH No. 2017050577

DECISION AFTER REJECTION

Abraham M. Levy, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter on November 27 and 28, 2017, in San Diego, California. Marichelle S. Tahimic, Deputy Attorney General, Department of Justice, appeared on behalf of complainant Virginia Herold, Executive Officer of the California State Board of Pharmacy (board), Department of Consumer Affairs. Ivan Petrelzka and Tony J. Park, Attorneys at Law, appeared on behalf of respondents Nayan Patel, D.Pharm. (respondent Patel or Patel) and Auro Pharmacies Inc., dba Central Drugs (Central Drugs). On November 28, 2017, the matter was submitted.

On April 2, 2018, pursuant to section 11517 of the Government Code, the board issued an Order Rejecting Proposed Decision. The deadline for submission of written argument was set for May 31, 2018. Both parties timely submitted written argument. Complainant argues an increase in penalty is appropriate; respondent argues a decrease is appropriate.

The board, having reviewed and considered the record, including the transcript, the Proposed Decision and written arguments, now issues this decision.

SUMMARY

Complainant sought to impose discipline against respondents' licenses for unprofessional conduct based on respondents' employment of an unlicensed pharmacy technician, failure to follow the law governing injectable compounded products produced from non-sterile ingredients, and failure to include directions for use on prescription labels. For the reasons detailed in the decision, complainant established that cause exists to impose discipline against respondents' licenses and that in the interest of public protection respondents' licenses are subject to a period of probation with appropriate terms and conditions.

FACTUAL FINDINGS

Background

LICENSE AND ADMINISTRATIVE ACTION HISTORY

1. On August 14, 1996, the board issued Pharmacist License number RPH 48867 to respondent Nayan Patel. The license was in force and effect at all times relevant to the allegations in the accusation and will expire on November 30, 2019, unless renewed.

On August 21, 2008, the board issued Pharmacy Permit number PHY 49146 to Auro Pharmacies Inc., doing business as Central Drugs. Respondent Nayan Patel is and has been the President and 33 percent shareholder of Auro Pharmacies Inc. since August 21, 2008. The Pharmacy Permit was in force and effect at all times relevant to the allegations in the accusation and will expire on August 1, 2017, unless renewed. Respondent Patel was the Pharmacist-in-Charge (PIC) from August 21, 2008, to May 15, 2015. Since May 15, 2015, another pharmacist, Manisha Patel, has been the PIC.

On October 7, 2008, the board issued Sterile Compounding Permit number LSC 99515 to Auro Pharmacies, Inc. doing business as Central Drugs. The Sterile Compounding Permit was in full force and effect at all times relevant to the allegations in the accusation and will expire on August 1, 2018, unless renewed. Respondent Patel was the PIC from October 7, 2008, to May 15, 2015. Since May 15, 2015, another pharmacist, Manisha Patel, has been the PIC.

CITATIONS

2. Respondents' licenses have been subject to the following citations and fines:

Respondent Central Drugs' pharmacy license, PHY 49146, was the subject of two Citations and Fines. The first citation was issued on January 29, 2014, in Case No. CI 2012 54846; the second, a Modified Citation and Fine Issued Pursuant to Settlement, was issued on January 19, 2016, in Case No. CI 2008 39038.[1] The citations detail the factual bases of the citations and the violations of applicable laws and regulations.

a. As detailed in the 2014 citation, Citation No. CI 2012 54846, an inspection on November 27, 2012, revealed that a compounded cream was labeled with an incorrect expiration date and dispensed to four patients. Central Drugs was found in violation of California Code of Regulations (CCR), title 16, sections 1735.4, subdivision (a), and 1793.7, subdivision (b); and Business and Professions Code sections 4169, subdivision (a)(4), and 4076, subdivision (a)(9).[2] The assessed penalty was $2,500.

b. As detailed in the 2016 Modified Citation and Fine Issued Pursuant to Settlement, Case No. CI 2008 39038, Central Drugs was found to be in non-compliance or in violation of a number of regulations and applicable Business and Professions Code and Health and Safety Code sections.

First, Central Drugs was found to have violated CCR section 1761, which prohibits a pharmacist from compounding or dispensing any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration and in violation of Section 4067, subdivision (a), which prohibits a person or entity from dispensing or furnishing dangerous drugs or devises on the internet for delivery to any person in this state without a prescription issued based on a good faith prior examination if the person or entity knew, or reasonably should have known, the prescription was not issued pursuant to a good faith prior examination. The citation identified four pages of such prescriptions issued or filled in 2008 and 2009.

Second, Central Drugs was also found, under this citation, to have violated Section 4169, subdivision (a)(1), which prohibits a pharmacy from purchasing dangerous drugs from an entity that is not licensed with the board.

Third, Central Drugs was found to have violated Section 4301, subdivision (o), which prohibits a pharmacy from violating or attempting to violate, directly or indirectly, any

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[1] The License History Certification for Central Drugs' pharmacy license (number 49146) incorrectly identifies the case number for this citation as CI 2010 45127. (Ex. 2.) A copy of the 2016 citation received into evidence bears case number CI 2008 39038. (Ex. 36.) The case number identified in the certificate of licensure for Central Drugs' pharmacy license corresponds to the case number for the Modified Citation issued to respondent Patel on January 19, 2016, based on related facts and discussed below. (Exs. 3 and 38.)

[2] Unless otherwise specified, all section references are to the Business and Professions Code. All references to the California Code of Regulations (CCR) are to title 16, unless otherwise specified.

provision of applicable state and federal laws. Central Drugs was further found to have violated Section 4059.5, subdivision (e), which prohibits dispensing or delivery of dangerous drugs into a state without complying with that state's laws. Specifically, Central Drugs sold prescriptions to patients in Oregon, and the Oregon State Board of Pharmacy issued a Consent Order dated May 15, 2009, that fined Central Drugs $7,000 for sales of dangerous drugs into Oregon without licensure.

Fourth, Central Drugs was found to have violated Health and Safety Code section 11153, subdivision (a). This statute requires a prescription for a controlled substance to be issued only for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The citation identified 167 controlled substance prescriptions that were issued without a legitimate medical purpose for California patients and 11 samples of prescriptions for patients out of state.

Finally, Central Drugs was found in violation of Health and Safety Code section 111615, which provides that no person shall manufacture any drug or device in this state unless he or she has a valid license form the California Department of Public Health, Food and Drug Branch. On 248 separate occasions, Central Drugs sold an unknown number of prescriptions for a total of $2,518,724.67 from June 16, 2009, to July 30, 2009. The citation identified five pages of those sales.

The Modified Citation and Fine Issued Pursuant to Settlement assessed a total penalty of $100,000 against respondent Central Drugs.

3. a. On January 29, 2014, in Case No. CI 2013 59617, the board issued to respondent Patel a Citation and Fine for violations of CCR sections 1793.7, subdivision (b), and 1735.4, subdivision (a), and Sections 4169, subdivision (a)(4), and 4076, subdivision (a)(9). These violations involved the dispensing of the expired cream detailed in CI 2012 58846, above. Respondent Patel was assessed a total penalty of $2,500 for these violations.

b. On January 19, 2016, the board issued to respondent Patel a Modified Citation and Fine Issued Pursuant to Settlement in Case No. CI 2010 45127 for violations of CCR sections 1761, subdivision (a); Section 4033, subdivision (a)(1); Section 4067, subdivision (a); Section 4169, subdivision (a)(1), Section 4301, subdivision (o), Section 4059.5, subdivision (e); and Health and Safety Code sections 11153 and 111615. These violations involved, for the most part, the dispensing of medications detailed in CI 2008 39038 above. Respondent Patel was, further, found in violation of Section 4306.5, subdivisions (a) and (b), for his failure to exercise his best judgment as pharmacist-in-charge when he allowed the dispensing of dangerous drugs and controlled substances in 2008 and 2009 based on 205 internet prescriptions for California patients written by a Florida prescriber whose Drug Enforcement Agency (DEA) registration was surrendered.

The Modified Citation and Fine Issued Pursuant to Settlement assessed a total penalty of $75,000 against respondent Patel.

Summary of the Allegations in the Accusation

4. On March 13, 2017, complainant signed the accusation in this matter seeking to discipline respondents' licenses for unprofessional conduct. The accusation contains three causes for discipline. The First Cause for Discipline alleges that respondents violated Sections 4301, subdivision (o), and 4115, subdivision (e), because respondents aided and abetted H.S.[3] in practicing as a pharmacy technician without being licensed. The accusation asserts that H.S., as an unlicensed pharmacy technician, compounded 2,327,484 ml of specifically identified sterile products.

The Second Cause for Discipline asserts that respondents violated Section 4301, subdivisions (j) and (o), and CCR section 1751.7, subdivision (c), when respondents failed 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.[4]

The Third Cause for Discipline alleges that respondents violated Section 4301, subdivision (o), and 4040, subdivision (a)(1)(B), for failing to provide directions for use on prescription labels.

To determine any degree of discipline, the accusation cites the four citations issued to respondents as detailed above.

5. Respondents did not dispute the allegations that H.S. was unlicensed and that they violated CCR section 1751.7, subdivision (c), by 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 argued that these were technical violations that did not warrant discipline because there was little if any harm or potential harm to the public. Respondents did dispute that they failed to include directions for use on prescription labels as alleged in the Third Cause for Discipline. They asserted that the directions provided were adequate.

Compounded Medications and Changes to the Laws after NECC and CCR Section 1751.7

6. Compounded medications are pharmaceutical products that licensed pharmacies formulate for individual consumers. The compounded products may utilize both sterile and non-sterile ingredients, and licensed pharmacists and licensed technicians, under the pharmacists' supervision, formulate these products. Because tainted compounded

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[3] H.S.'s initials are used in this Decision, but all parties were aware of her identity.

[4] Notice is taken of the following definition of "pyrogens": "Pyrogens are fever-producing agents of external origin, e.g., bacterial endotoxins and other microbial products. . . ." <https://medical-dictionary.thefreedictionary.com/pyrogen> [as of December 21, 2017.]

products pose a risk to the health and safety of consumers who use these products, compounding pharmacies are subject to specific laws and regulations under the Pharmacy Law.

The risk to consumers in the distribution of tainted compounded medications is illustrated in an incident involving the New England Compounding Center (NECC) in Massachusetts in October 2012. NECC shipped contaminated product throughout the country, including products shipped to California, that caused the death of more than 40 people and resulted in 461 patients becoming ill from tainted steroid injections. NECC's compounding facility had ongoing safety violations, but continued to operate and ship products despite employee whistleblower complaints to management. The compounding facility failed to maintain its clean room. The air intake for the clean room was contaminated and shared with the neighboring furniture recycling facility, and employees discovered mold on various work and storage surfaces several times per year. Yet, NECC remained accredited and was licensed to ship sterile compounded injectable products into California. (California Senate Rules Committee Report dated September 10, 2013, on S.B. 294.)

In response to the NECC incident, in 2013, the California Legislature passed legislation that increased the board's oversight of pharmacies that compound sterile products. The specific legislative changes to the Business and Professions Code are not relevant to the issues addressed in this matter.[5] However, by this legislation, the Legislature expressed its intent to ensure the safety of compounded sterile products and increase the regulatory oversight of pharmacies that compound sterile products.

CCR section 1751.7 is part of the regulatory scheme to afford public protection relating to compounding medications and pharmaceutical products. As noted above, respondents did not dispute that they violated this regulation. They argued that the violations of this rule were technical with little or no risk of harm to the public. The pertinent section of the version of the regulation in effect during the relevant period of this matter provided as follows:

> (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.

[5] The legislation modified Section 4127 and required any pharmacy that compounds sterile drug products to possess a sterile compounding pharmacy license. Section 4127 further required the board to adopt regulations to establish policies, guidelines, and procedures to implement the statute and also required the board to review any formal revision to General Chapter 797 of the United States Pharmacopeia and The National Formulary (USP-NF) relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official, to determine whether amendments are necessary to the regulations adopted by the board pursuant to subdivision (b).

The Board's July 8, 2015, September 22, 2015, and September 24, 2015, Inspections

7. Michael Boluro-Ajayi has worked as a board Inspector for the last four years. He is a licensed pharmacist, and he previously worked for different pharmacies and for Los Angeles County. He was first licensed in 2011. He has a degree in microbiology, and prior to becoming licensed he worked for 10 years in the research and development of drugs. Inspector Boluro-Ajayi has conducted over 100 inspections of pharmacies including compounding pharmacies. He is assigned to the board's compounding team where he travels, including out of state, to inspect sterile compounding pharmacies that sell drugs in California.

Compounding pharmacists often create customized medication solutions for patients (humans and animals) whose health care needs cannot be met by manufactured medications. All licensed pharmacies may compound non-sterile drug products as long as they do so consistent with applicable laws and regulations. Some compounded drug products must be sterile to be safe for patient use (e.g., medications injected into the central nervous system). As a result of the legislation discussed above, a pharmacy compounding sterile drug products must also obtain a specialty license as a sterile compounder. Such licensees are closely monitored and inspected annually before their licenses may be renewed. (Section 4127.1.)

Respondent Central Drugs is a sterile compounding pharmacy. Sterile drug products may be compounded either from sterile or non-sterile ingredients. Central Drugs compounds drugs that are batch-produced, sterile injectable drugs. It does this from non-sterile ingredients. As explained by Inspector Boluro-Ajayi, compounding sterile drug products from non-sterile ingredients is "high risk" sterile compounding. To compensate for that risk, CCR section 1751.7, subdivision (c), requires a pharmacy to test the end products for both sterility and pyrogens (or endotoxins) for all batch-produced sterile injectable products, when such products are compounded from one or more non-sterile ingredients. Pyrogen and endotoxin testing are terms used interchangeably for tests that check for the presence of the cell wall of microbial organisms in sterile compounded drugs. Endotoxin (or pyrogen) testing is important for the safety of patients taking the drugs because the presence of endotoxins or pyrogens may make the patients sick and may even lead to death. Endotoxins can withstand sterilization, hence the importance of both sterility and endotoxin testing. And, because endotoxins, once present, cannot be eliminated, it is important to measure whether or not a sterile compounded drug product has an acceptable level of endotoxins (or pyrogens). Until the end product testing confirms sterility and acceptable levels of pyrogens, the pharmacy is required to quarantine the sterile drug products in the pharmacy.

UNLICENSED PHARMACY TECHNICIAN H.S.

8. On July 8, 2015, Inspector Boluro-Ajayi conducted a routine inspection of Central Drugs' La Habra facility. While conducting this annual inspection he initially spoke with respondent Patel. Respondent Patel told Inspector Boluro-Ajayi he had to leave and he introduced him to Chinh M. Tran, Pharm.D., who he said was in charge of sterile compounding. Before he left, respondent Patel said that the new pharmacist in charge,

Manisha Patel, Pharm.D., would soon be at the facility. Mr. Tran showed Inspector Boluro-Ajayi the compounding facility, which included the sterile room, anteroom to "gown up," an autoclave room where equipment is sterilized, and the compounding room. Mr. Tran introduced him to four personnel, including H.S. Inspector Boluro-Ajayi asked each of them what their role and job titles were, and they all told him "technicians." He advised Mr. Tran that he wanted to see their licenses after the tour.

While Inspector Boluro-Ajayi was gowning up he saw five persons in the "clean room" with one person in a supervisory role, Helen Nguyen, Pharm.D. Ms. Nguyen said she was the sterile compounding pharmacist and worked under Mr. Tran. PIC M. Patel joined the parties at this point. PIC M. Patel gave Inspector Boluro-Ajayi California Pharmacy Technicians licenses for three of the personnel. She did not give him the license of H.S. PIC M. Patel told Inspector Boluro-Ajayi that H.S. was hired in July 2014, and that she was not the PIC until March 2015. Inspector Boluro-Ajayi asked for H.S.'s employee badge, job description and employee letter. He, further, asked to speak to H.S. PIC M. Patel told Inspector Boluro-Ajayi that H.S. had already been removed from the sterile compounding area and had left for the day. She did not explain why H.S. left before Inspector Boluro-Ajayi completed his inspection.

After his July 8, 2015, inspection, PIC M. Patel gave Inspector Boluro-Ajayi a number of documents relating to H.S., including her Central Drugs employee badge. The badge identified her as a Central Drugs "Pharmacy Technician." PIC M. Patel also gave Inspector Boluro-Ajayi a card from the Pharmacy Technician Certification Board (PTCB). The card identified her name and stated that she was certified on September 6, 2013, with an expiration date of November 30, 2015. In addition, he received a copy of H.S.'s "competency log," relating to her role in compounding products; H.S.'s employee hire form; job description signed by H.S.; original compounding log of Magnesium Chloride Injection 200 mg/ml Injectable compounded by H.S.; original compounding log for Magnesium Chloride compounded by "technician" H.S. under the supervision of pharmacist H. Nguyen; original compounding log of Dexpantheol 250 mg/ml Injectable compounded by "technician" H.S. under pharmacist Nguyen's supervision; copy of technician daily schedule in the sterile compounding room for April 27, 2015, to July 31, 2015, which identified H.S. performing a variety of cleaning tasks which licensed pharmacy technicians also performed. These documents were admitted into evidence at this hearing.

Also after his July 8, 2015, inspection, Inspector-Boluro-Ajayi obtained H.S.'s signed statement dated July 11, 2015. (Ex. 15.) In her statement, H.S. said she had worked at Central Drugs Compounding Pharmacy since July 16, 2014. She worked under the supervision of pharmacists Nguyen and Tran. Her duties involved cleaning and sterilizing glassware, vials and supplies according to procedures, informing her supervisor of stock needs, effectively performing sterile compounding using aseptic techniques according to procedures and operating, calibrating and keeping daily records of all required equipment for preparing prescriptions, assisting in formulating logs and measuring and weighing chemicals. She attached to her statement a list of medications she compounded. H.S. stated that she had not been aware of the California Technician Licensing requirements and she was now aware

of those requirements. H.S. stated that she was placed on administrative leave for three days and her classification at Central Drugs was changed from Pharmacy Technician to Pharmacy Clerk beginning July 14, 2015.

Inspector Boluro-Ajayi, in addition, obtained from Central Drugs the Position Description for Pharmacy Technician, which H.S. signed on July 8, 2014. (Ex. 10.) This document identified the following essential functions of a pharmacy technician at Central Drugs: the proficient use of all computer systems, knowledge of location of medications in the pharmacy and stock of inventory and familiarity with all chemicals; knowledge of physicians' specific preparations and anticipation of scheduled orders; proficient knowledge of sterile lab and daily routines and record-keeping; the ability to build and maintain consistency and knowledge base; ability to quickly and efficiently multi-task and prioritize work; the ability to keep up with system flow; deliver consistent customer service; have excellent telephone etiquette and verbal and written communications; and adhere to company policies and procedures.

In this document, the first identified minimum qualification for a pharmacy technician at Central Drugs was that the individual must have a "current and active California Pharmacy Technician License."

9. H.S. was hired as a pharmacy technician on July 16, 2014, received three months training and began working in the compounding department at Central Drugs after this training. H.S. was not licensed in California as a Pharmacy Technician from her time of hire, on July 16, 2014, to July 8, 2015, the date of Inspector Boluro Ajayi's inspection, after which her duties were changed. During this time, H.S. performed work at Central Drugs that required her to be licensed as a pharmacy technician.[6]

After this period, H.S. applied to become a pharmacy technician and the board denied her application because she worked as a pharmacy technician without a license. She reapplied after one year and the board granted her application. Since September 15, 2017, H.S. has been a licensed pharmacy technician and continues to work at Central Drugs, though she does not compound pharmaceutical products.

TESTING OF BATCH-PRODUCED END PRODUCT WITHOUT TESTING FOR PYROGENS AND WITHOUT QUARANTINING PRODUCTS

10. On September 22, 2015, Inspector Boluro-Ajayi returned to Central Drugs with FDA Consumer Safety Officer Uttanito (Tom) Limchumroon and California

[6] The First Cause for Discipline accusation alleges that H.S. assisted in compounding drugs as an unlicensed pharmacy technician: initially, it alleges H.S. compounded certain products from November 1, 2014, to July 8, 2015; later, it alleges the comprehensive quantity of drugs compounded by H.S. from her initial hire through her change of duties. (Accusation, p. 8, lines 21-27.) Respondents did not dispute the allegation or time line as framed in the accusation.

Department of Public Health (DPH) Investigator Jaqueline Nunez.[7] They met respondent Patel and PIC M. Patel and toured the facility. During their inspection of the clean room, Inspector Boluro-Ajayi noticed an alcohol bottle labeled with H.S.'s name in large bold type. A photograph of the bottle shows H.S.'s name in large bold letters.[8]

On September 24, 2015, Inspector Boluro-Ajayi and the FDA and DPH Investigators returned to Central Drugs and talked to Mr. Tran and respondent Patel. Mr. Tran said that "Central Drugs conducts endotoxin only about 60 % of the time on batches of non-sterile to sterile injectables."[9] To ensure he understood what Mr. Tran said about endotoxin testing of non-sterile to sterile injectable products, Inspector Boluro-Ajayi asked him to repeat what he said. Mr. Tran repeated his statement. Respondent Patel then told Inspector Boluro-Ajayi that they "are doing more than the law requires." He added that as "far back as he can remember the law does not require them to test more than what Central Drugs was currently doing." In the presence of PIC M. Patel and the Investigators from the FDA and the DPH, Inspector Boluro-Ajayi asked respondent Patel if the products he was referring to were compounded from non-sterile ingredients. He said "yes." Inspector Boluro-Ajayi then read CCR section 1751.7 to respondent Patel. Respondent Patel seemed surprised that the law requires endotoxin and sterile testing for every batch-produced compounded sterile product made from non-sterile ingredients.

Inspector Boluro-Ajayi asked PIC M. Patel for the batch results of all the random selected compounded drugs and the sterile test results, and the endotoxin test and release dates associated with each prescription. On October 1, 2015, PIC M. Patel transmitted the requested compounding logs to Inspector Boluro-Ajayi.

11. The logs introduced at hearing consisted of eight sets of documents for eight different prescriptions for injectable drugs captioned "Logged Formula Worksheets" and "Microbial Log/Pyro Test." They identified non-sterile ingredients used in compounding the end products, whether the batch was pyrogen tested and the release date from quarantine of the end product. Only one log, for the product manufactured on February 20, 2015, lot number 150220/2, documented that the products were tested for pyrogens, but this test occurred after the release date of the product on March 6, 2015. These logs did not document whether the products were tested for sterility.

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[7] Inspector Boluro-Ajayi identified Mr. Limchumroon as being an FDA "Investigator." However, he identified him in the body of the report as a "Consumer Safety Officer."

[8] Inspector Boluro-Ajayi testified that the bottle with H.S.'s name on it was "significant" because it showed that H.S. continued to compound medications after July 8, 2015. His conclusion is not accepted considering H.S.'s statement and her testimony at the hearing that she stopped working as a pharmacy technician on July 8, 2015.

[9] Inspector Boluro-Ajayi testified that pyrogens are endotoxins.

12. The logs show the following compounded batch-produced injectable sterile products, compounded from non-sterile ingredients, were not tested for endotoxins 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	1502260@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	Prostril 20 mg/ml	5 ml	150218@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/50mg	3500	150220@2	H.N./H.S.
2/20/2015	Capyrilc Capric Triglycerides +10% Benzyl Alcohol	50 ml	150220@31	H.N./H.S.
2/25/2015	Chromium 200 mcg/ml	2000 ml	150225@5	H.N./E.C./H.S.

LABELING OF PRESCRIPTIONS AND DANGEROUS DRUGS

13. When Inspector Boluro-Ajayi was at Central Drugs on September 24, 2015, he requested and received duplicate labels for prescription numbers 6423900, 6441577, 6449573, 6458220, 6442478, and 6445321. Six of the prescriptions directed the patient to "bring to physician's office for administration." Prescription number 6442478 directed the patient to "Inject .3ml intramuscularly 3 times a week."[10] Inspector Boluro-Ajayi testified that the labels are deficient because they do not comply with the labeling requirements under Code section 4040, subdivision (a)(1)(B).

14. The drugs identified in this decision are "dangerous drugs" pursuant to Section 4022.

Respondent's Evidence

TESTIMONY OF NAYAN PATEL, PHARM.D.

[10] The accusation alleges incorrectly that all the labels stated, "Bring to physician's office for administration."

15. Respondent Patel graduated from the University of Southern California (USC) School of Pharmacy in 1996 and in 1999 he took over Central Drugs. He recruited a former colleague at USC, Mr. Tran, to run the compounding department at Central Drugs and Mr. Tran remains in charge of the compounding department. As noted, respondent Patel was the pharmacist in charge at Central Drugs until May 2015.

Respondent Patel testified that he is committed to safe compounding, has educated himself over the years on this subject and has lectured on the subject. Central Drugs has been compounding since 2000 without any deficient products. Since 2000, respondent Patel commented that laws governing compounding increased scrutiny of compounding pharmacies due in part to the NECC incident discussed above. He said that the NECC incident caused a major shift in thinking about the process of sterile compounding in order to ensure patient safety. The process of compounding is now extremely rigorous and Central Drugs purchases ingredients only from FDA-approved manufacturers. As a result of NECC, respondent Patel hired three industry consultants to make sure that Central Drugs' compounding processes were safe. To show his commitment to the safe compounding of sterile products, respondent provided evidence that, in 2014, he participated in a training in pharmaceutical compounding and sterile preparations offered by United States Pharmacopeial Convention's Global Education and Training Program (USP). (Ex. N.)

Respondent Patel did not dispute that Central Drugs failed to perform end product testing for the presence of pyrogens as required under CCR section 1751.7. Once he realized Central Drugs was not in compliance with CCR section 1751.7, a realization that appears triggered by the board's inspection activities in September, 2015, effective July 6, 2016, the procedure manual was changed and required end product testing for pyrogens in compliance with CCR section 1751.7.

Respondent Patel testified that regardless of the pharmacy's failure to follow CCR section 1751.7, there was "no risk" to the public due to the presence of pyrogens because of the many steps Central Drugs took to ensure the sterility of the end product. In this regard, he stressed the importance of processes Central Drugs had in place to safeguard compounded sterile products. He identified these processes as: "process validation," "equipment validation," and "raw material validation." He added that these processes ensured the sterility of the end product and were above what the law required.

He explained that the biggest threat to consumers was not from pyrogens in the end product but from products that were not sterile. As he stated, a patient can die from non-sterile ingredients in a compounded product while a pyrogen, which is the cell wall of bacteria, can cause only "flu like symptoms." Patel did not define "flu like symptoms" and he did not explain how he concluded there was no risk to the public when the presence of pyrogens in the end product can cause "flu like symptoms." His opinion, here, is not accepted.

In support of his testimony that Central Drugs' processes before July 2016 ensured the safety of the compounded sterile products, he cited United States Pharmacopeia's (USP) Chapter 797. This chapter allows for the dispensing of sterile compounded products before the results of sterility testing are known, provided certain procedures are in place. Patel candidly admitted that California has not adopted the provisions of that chapter upon which he relied. To the extent, thus, USP Chapter 797 conflicts with CCR section 1751.7, it is given no weight as a mitigating factor on respondents' behalf.[11]

Respondent Patel also suggested that CCR section 1751.7 was ambiguous because of changes to the rule effective January 1, 2017. It is not clear whether Respondent Patel was asserting that his failure to follow CCR section 1751.7 was somehow reasonable due to this asserted ambiguity. But, at any rate, the rule in effect in 2015 was not ambiguous and contained substantially similar language as the 2017 version of the rule that required end product testing for pyrogens in batch-produced sterile preparations produced from non-sterile ingredients.[12]

Regarding H.S. working as an unlicensed pharmacy technician at Central Drugs, respondent Patel did not dispute that she was hired as a pharmacy technician and performed duties when a pharmacy technician license was required. Respondent Patel blamed the human resources manager at Central Drugs for hiring H.S. because she accepted H.S.'s PTCB card as proof that she was licensed as a pharmacy technician. He was not involved in H.S.'s hiring and he relied on his human resources manager's experience to hire qualified licensed staff. As a result of this error, respondent Central Drugs implemented a check list to follow to ensure that only licensed technicians are hired.

Respondent Patel argued that H.S.'s employment as an unlicensed technician posed minimal risk to the public because she obtained a Bachelor of Pharmacy degree in India, passed the PTCB, and before she began compounding sterile products, H.S. underwent training in order to ensure that she was able to safely compound sterile products. This required training involved a 90-day Mentoring and Training program for new staff in sterile

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[11] Respondent Patel was questioned on cross examination regarding why he ignored another section of USP 797 entitled "Bacterial Endotoxin (Pyrogen) Testing" which requires testing for pyrogens of "all high-risk level compounded sterile products that are prepared in groups of 25 identical single-dose packages" or exposed to certain conditions. His answer was not responsive.

[12] The key text of the 2015 version is compared to the 2017 version of the rule here (strikeout reflects deleted text and underline shows additional text): "Batch-produced sterile ~~injectable~~ drug ~~products~~ preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), 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." The 2017 exception does not require end product testing for sterility and pyrogens for certain products not at issue in this proceeding.

compounding. This training was documented in a 13-page document entitled "90-Day Mentoring and Training/Plan for Retail Pharmacy/Sterile Compounding Technician."

Regarding the adequacy of directions for use on the prescription labels, respondent Patel testified that in his experience if a physician prescribes a drug that is not intended for self-administration the physician will direct the patient to bring the medication to the physician's office for administration. Complainant did not offer evidence to rebut respondent Patel's testimony in this regard.

Respondent Patel stressed the impact discipline would have on him and his patients. He has multiple licenses in numerous states and discipline would restrict his ability to do business in these states and provide products and medications. As a result of this restriction, he believed patients would be harmed. Respondent Patel added that if he was disciplined the board would notify state boards of any imposed discipline and this would require him to answer to these boards. His insurance would also be affected. He also said that discipline would jeopardize the jobs of his employees.

Respondent Patel's testimony was credible in some respects, but he did not, however, take responsibility for the violations at issue here although he was pharmacist-in-charge at Central Drugs until May 15, 2015, and as pharmacist-in-charge he had the duty to ensure the pharmacy's compliance with applicable laws and regulations under Section 4036.5. He blamed the human resources manager for hiring and employing H.S., an unlicensed technician, although the H.S.'s duty statement reflects that she reported to him. He, further, discounted if not dismissed, the violation of CCR section 1751.7 because, in his opinion, Central Drugs' processes ensured the safety of the end products and, in his opinion, there was no risk to patient safety despite the failure to test for pyrogens in the end products.

TESTIMONY OF JAYNE Y. HAN, PHARM.D.

16. Jayne Y. Han, Pharm.D., obtained her Doctor of Pharmacy degree in 2002 from Western University of Health Sciences and is a California licensed pharmacist. She presently works at Harbor Compounding Pharmacy in Costa Mesa as Marketing Pharmacist and Staff Pharmacist. From 2002 to 2017 she worked at California Pharmacy and Compounding Center in Newport Beach where she compounded sterile and non-sterile products. Ms. Han is familiar with the requirements for sterilization and end product testing.

Ms. Han testified that there was "low" risk to consumers of contamination from products compounded at Central Drugs from non-sterile ingredients produced in depyrogenated glassware in an ISO 5 environment even though end products were not tested for pyrogens. She reached this opinion for the following reasons: Central Drugs tested raw materials for sterility and used ingredients which manufacturers analyzed and certified for sterility. Central Drugs also used sterilized equipment and depyrogenated glassware when compounding products and technicians wore suits to help prevent the shedding of hair and skin, which can contaminate the products. Ms. Han noted that products compounded in an

ISO level 5 classified environment helped ensure that the compounded products were sterile almost to a 100 percent certainty.[13]

Despite her opinion that there was "low" risk to consumers from products compounded at Central Drugs, Ms. Han, nonetheless, recognized that pyrogens in the end product with sterile ingredients can trigger an inflammatory response in the consumer's immune system, cause high fever, and in rare cases, a high pyrogen load can result in death.

Ms. Han did not explain how she reached the conclusion that the risk was "low" to consumers from pyrogens in the end products produced at Central Drugs when pyrogens can trigger an inflammatory response and lead to flu-like symptoms and fever. Further, she offered her opinion based on her training, education and experience as a licensed pharmacist. No foundation was offered to credit her opinion as an expert in microbiology or immunology. Thus, her opinion can be given little weight.

Ms. Han also addressed whether the prescription labels directing patients to bring the products to physicians were adequate. She testified that in her experience it is common for prescriptions to direct patients to take medications to their physicians for administration. Complainant did not offer evidence that contradicted her testimony in this regard. Ms. Han's testimony in this regard was credible.

OTHER EVIDENCE

17. Respondent Patel submitted letters of support from Mitchell J. Ghen, D.O., Ph.D.; Raffi Svadjian, Pharm.D.; and Shushma Patel, RPH, MBA.

Mr. Ghen has known respondent Patel for 15 years and practices medicine in Florida. In his letter dated June 23, 2017, he stated he has worked with respondent Patel in academia and with patients. He has co-authored a textbook with respondent Patel. He described respondent Patel as committed to quality and safety in his pharmacy and he trusts that respondent Patel will treat his patients with the utmost professionalism and the medication will be of the highest quality.

Mr. Svadjian has known respondent Patel for 15 years and has interacted with him through respondent Patel's relationship with USC. In his letter dated June 30, 2017, he stated that respondent Patel is dedicated to the education of pharmacy students and has helped educate students, particularly in the area of professional compounding. Mr. Svadjian cited respondent Patel's extensive lecturing on the topic of sterile and non-sterile compounding; his company has served as a site for the Advanced Pharmacy Practice Experience clerkship for over 10 years; respondent Patel has hosted USC Pharmacy students at his pharmacy and spent many hours educating students about ownership and management

[13] As explained at the hearing, ISO level 5 refers to the clean room used in the manufacturing of compounded products where air particles that can contaminate products are removed.

of a pharmacy and regulatory affairs, compliance, financial management, human resources, and leadership/management; respondent Patel has participated in a student compounding competition; and he has served as a student panel speaker.

Shushma Patel, in a letter dated July 3, 2017, stated that he has known respondent Patel on both a personal and professional level for over 20 years. He purchased an independent community pharmacy from respondent Patel and has served with respondent Patel as a committee member of the Indian Pharmacist Association. Shushma Patel stated that respondent Patel is a highly respected and ethical pharmacist and an integral part of the health care system available to community residents. He also stated that respondent Patel has a comprehensive knowledge of compounding practice coupled with a passion for mentoring registered pharmacists.

In their letters these individuals did not state that they reviewed or were made aware of the allegations against respondent Patel in the accusation. Their opinions regarding respondent Patel's reputation and competency in the field of compounding pharmacy practice are discounted.

Costs

18. Pursuant to Business and Professions Code section 125.3, subdivision (a), the board may request an order directing a licensee "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." A certified copy of the actual costs, or a good faith estimate of costs where actual costs are not available, signed by the entity bringing the proceeding or its designated representative "shall be prima facie evidence of reasonable costs of investigation and prosecution of the case." (Bus. & Prof. Code, § 125.3, subd. (c).)

In support of the request for costs, complainant submitted: (1) a Certification of Investigative Costs, which complainant signed on November 16, 2017, for total investigative costs of $14,943.50; (2) the Declaration of Michael Boluro-Ajayi, which provided a detailed summary of the tasks involved in the 123.25 hours he expended in this matter, and which he signed on November 16, 2017; and (3) the Certification of Prosecution Costs: Declaration of Marichelle S. Tahimic, which Ms. Tahimic signed on November 21, 2017, and which incorporated a detailed summary of the time billed on the matter captioned "Matter Time Activity by Professional Type." According to this summary, the Attorney General billed the board a total of $8,085 for time spent by legal staff on this matter. This reflects a total of 46.50 attorney hours and 1.50 paralegal hours on the enforcement of this matter. Ms. Tahimic, further, made the good faith estimate that she would incur and bill seven additional hours to prepare the case up to the commencement of the hearing in the amount of $1,190. Thus, including this good faith estimate, the Attorney General billed the board a total of $9,275 for prosecution costs up to the commencement of the hearing.

Based on these declarations, complainant's request for an order for respondents to reimburse the board a total of $24,218.50 for its investigative and enforcement costs is reasonable.

LEGAL CONCLUSIONS

1. The California State Board of Pharmacy is charged with the administration and enforcement of the Pharmacy Law, Business and Professions Code section 4000, et seq. (Bus. & Prof. Code, § 4001.) In exercising its licensing, regulatory, and disciplinary functions, the board's highest priority is protection of the public. "Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount." (Bus. & Prof. Code, § 4001.1.)

2. In this action to discipline respondents' licenses, complainant bears the burden of proof of the charges alleged in the accusation. If the complainant meets the burden, respondents bear the burden of establishing any affirmative defense, including proving rehabilitation. (*Whetstone v. Board of Dental Examiners* (1927) 87 Cal.App. 156, 164.)

a. In the part of this proceeding based on the accusation against a pharmacist, the burden of proof is on Complainant to establish alleged violations by "clear and convincing proof to a reasonable certainty." (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 855-856.) The standard of proof is clear and convincing evidence to a reasonable certainty. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 855-856.) Clear and convincing evidence means the evidence is "so clear as to leave no substantial doubt" and is "sufficiently strong to command the unhesitating assent of every reasonable mind." (*Mathieu v. Norrell Corporation* (2004) 115 Cal.App.4th 1174, 1190 [citing *Mock v. Michigan Millers Mutual Ins. Co*. (1992) 4 Cal.App.4th 306, 332-333].)

b. In the part of this proceeding based on the accusation against a pharmacy's permits, the burden of proof remains on complainant, but the standard of proof is preponderance of the evidence. A pharmacy's license is not a "professional" license in that there are not extensive education, training and testing requirements to obtain such licensure. (Bus. & Prof. Code § 4113; see also §§ 4101, 4305, 4329 and 4330.) Since it is a nonprofessional license, complainant must establish cause for discipline against a pharmacy license by demonstrating cause for discipline by a preponderance of the evidence. (*Imports Performance v Dept. of Consumer Affairs, Bur. of Automotive Repair* (2011) 201 Cal.App.4th 911, 916-917; *San Benito Foods v. Veneman* (1996) 50 Cal.App.4th 1889.)

c. The distinction in the standards of proof between the license types is unnecessary in this matter, however, because each violation found was proven by clear and convincing evidence.

Applicable Business and Professions Code Sections

3. Section 4022 defines "dangerous drugs" as follows:

> "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 .

4. Section 4038 defines a "pharmacy technician" as "an individual who assists a pharmacist in a pharmacy in the performance of his or her pharmacy related duties as specified in section 4115." Section 4115 sets forth various tasks a pharmacy technician may perform. Subdivision (a) of Section 4115 provides "a pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of, a pharmacist."

Section 4115, subdivision (e), provides: "A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician."

5. Section 4301 provides as follows:

> 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, in pertinent part:
>
> [¶] . . . [¶]
>
> (j) The violation of any of the statutes of this state, of 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. . . .

6. Section 4040, subdivision (1)(B), provides as follows:

(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.

Definition of Pharmacist in Charge

7. Section 4036.5 provides the following definition of pharmacist-in-charge:

> "Pharmacist-in-charge" means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

CCR Section 1751.7

8. CCR section 1751.7, subdivision (c), which was in effect during the time period at issue in this matter, provides as follows:

> (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.

Cause Exists to Impose Discipline on Respondents' Licenses Under the First and Second Causes for Discipline

9. Complainant established by clear and convincing evidence that respondents engaged in unprofessional conduct in violation of Sections 4301, subdivision (o), and 4115, subdivision (e). Between July 16, 2014, and July 8, 2015, they aided and abetted H.S. in practicing as an unlicensed pharmacy technician when she performed work at Central Drugs that required her to be licensed as a pharmacy technician when she was not licensed. (Factual Findings 5, 8-9, & 15-16.)

Complainant established by clear and convincing evidence that respondents engaged in unprofessional conduct in violation of Section 4301, subdivisions (j) and (o), and CCR section 1751.7. Respondents failed to document end product testing for sterility and pyrogens for eight sets of batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients and failed to quarantine these products until the end product testing confirmed sterility and acceptable levels of pyrogens in violation of CCR section 1751.7, subdivision (c). (Factual Findings 5, 7, 10-12, & 15-16.)

Cause Does Not Exist to Impose Discipline on Respondents' Licenses Under the Third Cause for Discipline

10. Cause does not exist to impose discipline against respondents' licenses for failing to provide directions for use on prescription labels as alleged in the Third Cause for Discipline. Section 4040, subdivision (a)(1)(B), requires that prescription labels contain, "(t)he name and quantity of the drug or device prescribed and the directions for use." Six of the prescriptions directed the patients to "bring to physician's office for administration."[14] Such instructions are "directions for use." Drs. Patel and Han testified credibly that in their experience physicians issue such directions for prescription labels. Complainant did not offer evidence to rebut their testimony. (Factual Findings 5, 13, 15, & 16.)

Assessment of Discipline

11. The board has published disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. 10/2007)[15] (Guidelines) that are to be used in reaching a decision on a disciplinary action under the adjudicatory provisions of the Administrative Procedure Act (commencing at Government Code sections 11400 and 11500). Deviation from the guidelines "is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation – the presence of mitigating factors; the age of the case; evidentiary problems." (Cal. Code Regs., tit. 16, § 1760.)

In determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, the following factors are considered, in relevant part: the actual or potential harm to the public or to any consumer; prior disciplinary record, including level of compliance with disciplinary order(s); prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s); number and/or variety of current violations; nature and severity of the act(s), offense(s) or crime(s) under consideration; aggravating evidence; mitigating evidence; rehabilitation evidence; time passed since the act(s) or offense(s); whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another; whether the respondent had knowledge of or knowingly participated in such conduct; and the financial benefit to the respondent from the misconduct. (Guidelines, p. 3.)

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[14] The seventh prescription, prescription number 6442478, directed the patient to "Inject .3ml intramuscularly 3 times a week." This direction is also a "direction for use."

[15] Effective April 1, 2018, the board's new Disciplinary Guidelines (rev. 2/2017) became effective. (Cal. Code. Regs., tit. 16, § 1760.) The board's prior Disciplinary Guidelines (rev. 10/2007), which were in effect at the time of the hearing and granting of reconsideration, are considered here for consistency. The board notes, however, that the result would be unchanged under the new version.

No single one or combination of the above factors is required to justify the minimum and/or maximum penalty in a given case, as opposed to an intermediate one. A respondent is permitted to present mitigating circumstances at a hearing and has the burden to show any rehabilitation or corrective measures he or she has taken. (Guidelines, p. 4.)

The Guidelines contain four categories of violations and recommended penalties. For the violations of the Business and Professions Code at issue here, the level of discipline is appropriately classified as "Category II" because, consistent with the board's Guidelines, the violations posed a serious potential for harm, and respondents' conduct involved the disregard of pharmacy law and public safety, and reflected on respondents' competency and ability to take care. (Guidelines, p. 11-12, 16, 73-74, 78.) Under this classification, the minimum range of discipline is revocation, revocation stayed, three years' probation with standard terms and conditions and optional terms as appropriate. The maximum range is outright revocation.

Respondents' arguments that the violations were technical and did not pose serious potential for harm to the public were not persuasive, and are not reasonable. First, respondents failed to have injectable compounded end products produced from non-sterile ingredients tested for pyrogens before dispensing them in violation of CCR section 1751.7. CCR section 1751.7 represents the board's effort to protect the public from contaminated or tainted sterile compounded end products and the rule serves this important goal. Failure to comply could result in patient illness or even death – a greater potential harm cannot be imagined. Indeed, the NECC incident highlights the need for such regulatory protections. Respondents' violation of this rule exposed the public to serious potential harm on its face. Ms. Han's testimony that respondents' violation of this rule posed a low risk of harm to the public even when pyrogens can cause flu-like symptoms and fever was not persuasive for the reasons addressed above. Respondent Patel's similar testimony was also found not persuasive. As respondent Patel acknowledged, the board itself, through its regulation, established the standard for compounding. The board adopted the formal regulation pursuant to its authority and obligation to protect the public, because it determined such processes are for the safety of California consumers. Respondents' conduct and their failure to comply with the standard is neither a technical violation nor was it one "without risk" such that it does not warrant discipline. In sterile compounding, particularly from non-sterile ingredients, any violations are extremely concerning.

H.S.'s employment of an unlicensed pharmacy technician in sterile compounding also posed a serious potential for harm and respondents' arguments to the contrary were not persuasive. H.S. was hired in July 2014 as a pharmacy technician and her duty statement provided by Central Drugs indicated she had to hold license as a pharmacy technician. H.S. worked in this capacity upon hiring on July 16, 2014, to July 8, 2015, when she ceased as a result of the board's inspection. Even though H.S. subsequently passed the PTCB and received training, by hiring and employing H.S. as a pharmacy technician without ensuring she was licensed by the board, respondents deprived the board of the ability to ensure that H.S. was qualified and fit to practice as a pharmacy technician and remained qualified. This, by itself, posed serious potential for harm to the public. The fact that the board subsequently

licensed H.S. as a pharmacy technician on September 15, 2017, does not change this conclusion.

In addition, as further support that the violation warrants at least a Category II classification (as well as in considering the appropriate level of discipline), by their conduct, respondents disregarded the laws and regulations governing pharmacy. Notably, respondent Patel was unwilling to acknowledge his responsibility as the pharmacist-in-charge for his pharmacy's compliance with applicable laws. In his testimony, he blamed the human resources manager for hiring H.S. as a pharmacy technician. Similarly, he was unwilling to acknowledge that Central Drugs' processes of end product testing were deficient because these processes did not include pyrogen testing as required under CCR section 1751.7, even when the violations occurred when he was pharmacist-in-charge. Instead, he stressed that the processes in place ensured the safety of compounded end products even when these processes violated CCR section 1751.7. Interestingly, his testimony sounded similar to what he told Inspector Boluro-Ajayi on September 24, 2015. At that time, he said he was "doing more than the law requires" and as "far back as he can remember the law does not require them to test more than what Central Drugs was currently doing." Respondent Patel appeared to sustain this belief at the hearing. This is extremely concerning.

At this point, the question is the degree of discipline to impose under the Category II discipline level. Consistent with the factors identified in the board's Guidelines, due consideration has been given to the potential harm respondents' conduct represented, respondents' significant citation histories, and respondents' evidence of rehabilitation. In particular, respondents' subsequent implementation of policy and procedural changes to ensure compliance with CCR section 1751.7 and that pharmacy technicians hired in the future are licensed. Respondent Patel's stated commitment to safe compounding was also considered. Respondents' conduct, however, reflects a failure to follow undisputed board requirements and even Central Drugs' own policy with regard to H.S.'s licensure. Respondents' lack of diligence to identify and follow California law in performing the most risky type of sterile compounding, where errors may risk fragile patients' health and could even result in death, must be heavily weighted. As noted above, also concerning is respondent Patel's failure to fully concede his responsibility in these violations and to minimize them. Finally, respondents' history of board inspectors identifying significant practice concerns also warrants a penalty above the minimum and additional scrutiny during probation.

After considering these factors and the evidence of record as a whole, it is concluded that the maximum penalty of outright revocation of respondents' licenses is not necessary to ensure public protection, but neither is the minimum penalty for the type of violation. An intermediate term will allow the board to observe the conduct of the pharmacy over time. A five-year period of probation, subject to the terms and conditions set forth below, will adequately protect the public. Given Central Drugs' history of failing to comply with pharmacy law and regulation in significant manners, to ensure and monitor respondent Central Drugs' compliance with state and federal laws and regulations, the pharmacy will be

required to obtain a qualified and approved consultant pharmacist, and who may be required to provide written reports to the board upon request.

Assessment of Costs

12. In *Zuckerman v. Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, the California Supreme Court decided that in order to determine whether the actual costs of investigation and prosecution sought by a regulatory board under a statute substantially identical to Business and Professions Code 125.3 are "reasonable," the agency must decide: (a) Whether the licensee has been successful at hearing in getting charges dismissed or reduced; (b) the licensee's subjective good faith belief in the merits of his or her position; (c) whether the licensee has raised a colorable challenge to the proposed discipline; (d) the financial ability of the licensee to pay; and (e) whether the scope of the investigation was appropriate to the alleged misconduct.

As found above, the reasonable costs of investigation and enforcement are found to be $24,218.50. Applying the factors detailed in *Zuckerman*, *supra*, a reduction in the amount of $8,072.83 is allowed because respondents had a good faith belief in the merits of their positions and one of the three causes for discipline was dismissed. Thus, costs are awarded in the amount of $16,145.67.

ORDER

License number RPH 48867, issued to respondent Nayan Patel, and license numbers PHY 49146 and LSC 99515, issued to respondent Auro Pharmacies Inc., dba Central Drugs, are hereby revoked; however, the revocation is stayed, and these licenses are placed on probation for five (5) years upon the following terms and conditions:

A. **RESPONDENT AURO PHARMACIES INC., dba CENTRAL DRUGS', LICENSES** (PHY 49146 and LSC 99515**)** are subject to the following conditions:

1. **Obey All Laws**: Respondent owner shall obey all state and federal laws and regulations. Respondent owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;

- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment;

- a conviction of any crime;

- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. **Report to the Board:** Respondent owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**: Upon receipt of reasonable prior notice, respondent owner shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff:** Respondent owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her or its probation. Failure to cooperate shall be considered a violation of probation.

5. **Reimbursement of Board Costs**: As a condition precedent to successful completion of probation, respondent owner shall pay to the board its costs of investigation and prosecution in the amount of $16,145.67. Respondent owner shall make said payments as follows: within 3 years of the effective date of this Decision, pursuant to a reasonable payment plan agreed to by the board. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation. RESPONDENT AURO PHARMACIES IS JOINTLY AND SEVERALLY LIABLE FOR COSTS IMPOSED ON RESPONDENT PATEL, PURSUANT TO TERM B. 8.

The filing of bankruptcy by respondent owner shall not relieve respondent of his or her or its responsibility to reimburse the board its costs of investigation and prosecution.

6. **Probation Monitoring Costs:** Respondent owner shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. **Status of License:** Respondent owner shall, at all times while on probation, maintain current licensure with the board. If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. **License Surrender While on Probation/Suspension:** Following the effective date of this decision, should respondent owner discontinue business, respondent owner may tender the premises licenses to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements

applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. **Notice to Employees:** Respondent owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent owner shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. **Owners and Officers: Knowledge of the Law**: Respondent owner shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent owner or respondent owner's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. **Posted Notice of Probation:** Respondent owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. **Consultant for Owner and/or Pharmacist-In-Charge:** Respondent owner shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a quarterly basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy, including the

compliance of the pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation. The consultant may be required to submit a written report about respondent's compliance with state and federal laws and regulations as directed by the board or its designee.

13. **Violation of Probation:** If respondent owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent owner's license, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent owner violates probation in any respect, the board, after giving respondent owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent owner during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

14. **Completion of Probation:** Upon written notice by the board or its designee indicating successful completion of probation, respondent owner's license will be fully restored.

B. **RESPONDENT NAYAN PATEL'S PHARMACIST LICENSE** (No. RPH 48867) is subject to the following conditions:

1. **Obey All Laws**: Respondent shall obey all state and federal laws and regulations. Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;

- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment;

- a conviction of any crime;

- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. **Report to the Board:** Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board:** Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff:** Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate shall be considered a violation of probation.

5. **Continuing Education:** Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. **Notice to Employers:** During the period of probation, respondent shall notify all present and prospective employers of the decision in board case number 5865 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment while on probation) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in board case number 5865, and the terms and conditions imposed herein. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his or her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in board case number 5865 in advance of respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in board case number 5865 and the terms and conditions imposed herein. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present to current and/or prospective employer(s) or to cause those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. **No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant:** During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. **Reimbursement of Board Costs**: As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $16,145.67. Respondent shall make said payments as follows: within three years of the effective date of this Decision, pursuant to a reasonably payment plan agreed to by the board. RESPONDENT PATEL IS JOINTLY AND SEVERALLY LIABLE FOR COSTS IMPOSED ON RESPONDENT AURO PHARMACIES PURSUANT TO TERM A.5.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

9. **Probation Monitoring Costs:** Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

10. **Status of License:** Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. **License Surrender While on Probation/Suspension:** Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his or her pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

12. **Notification of a Change in Name, Residence Address, Mailing Address or Employment:** Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. **Tolling of Probation:** Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and must further notify the board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

14. **Violation of Probation:** If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. **Ethics Course:** Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation. Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

16. **No Supervision of Ancillary Personnel:** During the period of probation, respondent shall not supervise any ancillary personnel, including, but not limited to, pharmacy technicians or designated representatives in any entity licensed by the board.

Failure to comply with this provision shall be considered a violation of probation.

17. **No New Ownership of Licensed Premises**: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

18. **Completion of Probation:** Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

IT IS SO ORDERED this 3rd day of August, 2018.

This Decision and Order will be effective at 5 p.m. on September 3, 2018.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Victor Law, R.Ph.
Board President

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

In the Matter of the Accusation Against:	Case No. 5865
AURO PHARMACIES INC. DBA CENTRAL DRUGS AND NAYAN PATEL,	OAH No. 2017050577
Respondents.	

TO ALL PARTIES AND THEIR ATTORNEY OF RECORD:

ORDER SETTING DATE FOR SUBMISSION OF WRITTEN ARGUMENT

The administrative record of the hearing in the above-entitled matter having now become available, the parties are hereby notified of the opportunity to submit written argument in accordance with the Order Rejecting the Proposed Decision dated April 2, 2018. In addition to any arguments the parties may wish to submit, the board is interested in arguments directed to the question whether the discipline is appropriate under the circumstances.

Written argument shall be filed with the Board of Pharmacy, Attn. Susan Cappello, 1625 N. Market Blvd., Suite N-219, Sacramento, California, on or before **May 31, 2018**. **No new evidence may be submitted**.

It is so ORDERED on May 10, 2018.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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

In the Matter of the Accusation Against:	Case No. 5865
AURO PHARMACIES INC. DBA CENTRAL DRUGS AND NAYAN PATEL,	OAH No. 2017050577
Respondents.	

ORDER REJECTING PROPOSED DECISION

Pursuant to section 11517 of the Government Code, the Proposed Decision of the Administrative Law Judge in the above-entitled matter is rejected. The California State Board of Pharmacy (hereinafter "board") will decide the case upon the record, including the transcript(s) of the hearing, and upon such written argument as the parties may wish to submit.

Although the right to argue is not limited, the board is particularly interested in arguments directed to the question whether the discipline is appropriate under the circumstances. The parties will be notified of the date for submission of such argument when the transcript of the above-mentioned hearing becomes available.

The parties will be notified of the date for submission of such argument when the transcript of the above-mentioned hearing becomes available.

It is so ORDERED on April 2, 2018.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____

Amy Gutierrez, Pharm.D.
Board President

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

In the Matter of the Accusation Against: AURO PHARMACIES INC. dba CENTRAL DRUGS 520 W. La Habra Blvd. La Habra, CA 90631-5308 Pharmacy Permit No. 49146 Licensing Sterile Compounding Permit No. LSC 99515, and NAYAN PATEL Pharmacist License No. RPH 48867, Respondents.	Case No. 5865 OAH No. 2017050577

PROPOSED DECISION

Abraham M. Levy, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter on November 27 and 28, 2017, in San Diego, California.

Marichelle S. Tahimic, Deputy Attorney General, Department of Justice, appeared on behalf of complainant Virginia Herold, Executive Officer, Board of Pharmacy (Board), Department of Consumer Affairs.

Ivan Petrelzka and Tony J. Park, Attorneys at Law, appeared on behalf of respondents Nayan Patel, D.Pharm (respondent Patel or Patel) and Auro Pharmacies Inc. dba Central Drugs (Central Drugs).

On November 28, 2017, the matter was submitted.

SUMMARY

Complainant sought to impose discipline against respondents' licenses for unprofessional conduct based on respondents' employment of an unlicensed pharmacy technician, failure to follow the law governing injectable compounded products produced from non-sterile ingredients, and failure to include directions for use on prescription labels. For the reasons detailed in the decision, complainant established that cause exists to impose discipline against respondents' licenses and that in the interest of public protection respondents' licenses are subject to a period of probation with appropriate terms and conditions.

FACTUAL FINDINGS

Background

LICENSE AND ADMINISTRATIVE ACTION HISTORY

1. On August 14, 1996, the Board issued Original Pharmacist License No. RPH 48867 to respondent Nayan Patel.

On August 21, 2008, the Board issued Pharmacy Permit Number PHY 49146 to Auro Pharmacies Inc., dba Central Drugs. Respondent Nayan Patel is and has been the President and 33 percent shareholder of Auro Pharmacies, Inc. since August 21, 2008. The Pharmacy Permit was in force and effect at all times relevant to the allegations in the accusation and will expire on August 1, 2017, unless renewed. Respondent Patel was the Pharmacist-in-Charge (PIC) from August 21, 2008, to May 15, 2015. Since May 15, 2015, Manisha Patel has been the PIC.

On October 7, 2008, the Board issued License Sterile Compounding Permit Number LSC 99515 to Auro Pharmacies, Inc. doing business as Central Drugs. The Licensed Sterile Compounding Permit was in full force and effect at all times relevant to the allegations in the accusation and will expire on August 1, 2018, unless renewed. Respondent Patel was also identified as the PIC in charge from October 7, 2008, to May 15, 2015.

CITATIONS

1. Respondents' licenses have been subject to the following citations and fines:

Respondent Central Drugs's PHY 49146 License was the subject of two Citations and Fines issued on January 29, 2014, in Case No. CI 2012 54846, and a Stipulated Settlement of Citations with a Modified Citation and Fine Issued on January 19, 2016, in

Case No. CI 2008 39038.[1] The citations detail the factual bases of the citations and the violations of applicable laws and regulations.

As detailed in Citation CI 2012 58846, an inspection on November 27, 2012, revealed that a compounded cream was labeled with an incorrect expiration date and dispensed to four patients. Central Drugs was found in violation of California Code of Regulations, title 22, sections 1735.4, subdivision (a), 1793.7, subdivision (b), and Business and Professions Code Sections 4169, subdivision (a)(4), and 4076, subdivision (a)(9).[2] The assessed penalty was $2,500.

As detailed in Citation CI 2008 39038, Central Drugs was found to be in non-compliance or violation of a number of regulations and applicable Business and Professions Code and Health and Safety Code sections.

First, Central Drugs was found to have violated CCR section 1761, which prohibits a pharmacist from compounding or dispensing any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration and in violation of Section 4067, subdivision (a), which prohibits a person or entity from dispensing or furnishing dangerous drugs or devises on the internet for delivery to any person in this state without a prescription issued based on a good faith prior examination if the person or entity knew or reasonably should have known the prescription was not issued pursuant to a good faith prior examination. The citation identified four pages of such prescriptions issued in 2008 and 2009.

Central Drugs was also found, under this citation, to have violated Section 4169, subdivision (a)(1), which prohibits a pharmacy from purchasing dangerous drugs from an entity that is not licensed with the board.

Further, Central Drugs was found to have violated Section 4301, subdivision (o), which prohibits a pharmacy from violating or attempting to violate, directly or indirectly, any provision of applicable state and federal laws. Central Drugs was further found to have violated Section 4059.5, subdivision (3), which prohibits dispensing or delivery of dangerous drugs into a state without complying with that state's laws. Specifically, Central Drugs sold prescriptions to patients in Oregon, and the Oregon State Board of Pharmacy issued a Consent Order dated May 15, 2009, that fined Central Drugs $7,000 for sales of dangerous drugs into Oregon without licensure.

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[1] The certificate of licensure identifies the case number for this citation as CI 2010 45127. This appears to be incorrect. According to a copy of the citation received into evidence the case number for this citation is CI 2008 39038. The case number identified in the certificate of licensure is the same case number for the Modified Citation issued to respondent Patel on January 19, 2016.

[2] All further references are to the Business and Professions Code and to Title 16 of the California Code of Regulations (CCR) unless otherwise stated.

In addition, Central Drugs was found to have violated Health and Safety Code section 11153, subdivision (a). This statute requires a prescription for a controlled substance to be issued only for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The Citation identified 167 controlled substance prescriptions that were issued without a legitimate medical purpose for California patients and 11 samples of prescriptions for patients out of state.

Finally, under this Citation, Central Drugs was found in violation of Health and Safety Code section 111615, which provides that no person shall manufacture any drug or device in this state unless he or she has a valid license form the California Department of Public Health, Food and Drug Branch. On 248 separate occasions Central Drugs sold an unknown number of prescriptions for a total of $2,518,724.67 from June 16, 2009 to July 30, 2009. The Citation identified five pages of those sales.

For those violations, the Citation assessed a total penalty of $100,000.

3. On January 29, 2014, in Case No. CI 2013 59617, the Board issued to respondent Patel a Citation and Fine for violations of CCR sections 1793.7, subdivision (b) and 1735.4, subdivision (a), and Code sections 4169, subdivision (a)(4), 4076, subdivision (a)(9). These violations involved the dispensing of the expired cream detailed in CI 2012 58846, above. Respondent Patel was assessed a total penalty of $2,500 for these violations.

On January 19, 2016, the Board issued to respondent Patel Modified Citation No. CI 2010 45127 for violations of CCR sections 1761, subdivision (a), Sections 4033, subdivision (a)(1), 4067, subdivision (a), 4169, subdivision (a)(1), 4301, subdivision (o), 4059.5, subdivision (e), and Health and Safety Code sections 11153 and 111615. These violations involved, for the most part, the dispensing of medications detailed in CI 2008 39038 above. Respondent Patel was, further, found in violation of Section 4306.5, subdivisions (a) and (b), for his failure to exercise his best judgment as pharmacist in charge when he allowed the dispensing of dangerous drugs and controlled substances in 2008 and 2009 based on 205 internet prescriptions for California patients written by a Florida prescriber whose Drug Enforcement Agency (DEA) registration was surrendered.

Respondent was assessed a total penalty of $75,000 for these violations.

Summary of the Allegations in the Accusation

4. On March 13, 2017, complainant signed the accusation in this matter seeking to discipline respondents' licenses for unprofessional conduct. The accusation contains three causes for discipline. The First Cause for Discipline alleges that respondents violated Code sections 4301, division (o), and 4115, subdivision (e), because respondents aided and abetted H.S. in practicing as a pharmacy technician without being licensed. The accusation asserts that H.S., as an unlicensed pharmacy technician, compounded 2,327,484 ml of specifically identified sterile products.

The Second Cause for Discipline asserts that respondents violated Section 4301 and CCR section 1751.7, subdivision (c), when respondents failed 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.[3]

The Third Cause for Discipline alleges that respondents violated Code section 4301, subdivision (o), and 4040, subdivision (1)(B), for failing to provide directions for use on prescription labels.

To determine any degree of discipline, the accusation cites the four citations issued to respondents as detailed above.

5. Respondents did not dispute the allegations that H.S. was unlicensed and that they violated CCR section 1751.7, subdivision (c), by 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 argued that these were technical violations that did not warrant discipline because there was little if any harm or potential harm to the public. Respondents did dispute that they failed to include directions for use on prescription labels as alleged in the Third Cause for Discipline. They asserted that the directions provided were adequate.

Compounded Medications and Changes to the Laws after NECC and CCR Section 1751.7

6. Compounded medications are pharmaceutical products that licensed pharmacies formulate for individual consumers. The compounded products utilize both sterile and non-sterile ingredients, and licensed pharmacists and licensed technicians, under the pharmacists' supervision, formulate these products. Because tainted compounded products pose a risk to the health and safety of consumers who use these products, compounding pharmacies are subject to specific laws and regulations under the Pharmacy Law.

The risk to consumers in the distribution of tainted compounded medications is illustrated in an incident involving the New England Compounding Center (NECC) in Massachusetts in October 2012. NECC shipped contaminated product throughout the country, including products shipped to California, that caused the death of more than 40 people and resulted in 461 patients becoming ill from tainted steroid injections. NECC's compounding facility had ongoing safety violations, but continued to operate and ship products despite employee whistleblower complaints to management. The compounding

[3] Notice is taken of the following definition of "pyrogens": "Pyrogens are fever-producing agents of external origin, e.g., bacterial endotoxins and other microbial products. . . ." <https://medical-dictionary.thefreedictionary.com/pyrogen> [as of December 21, 2017.]

facility failed to maintain its clean room. The air intake for the clean room was contaminated and shared with the neighboring furniture recycling facility, and employees discovered mold on various work and storage surfaces several times per year. Yet, NECC remained accredited and was licensed to ship sterile compounded injectable products into California. (California Committee Report dated September 10, 2013, on S.B. 294.)

In response to the NECC incident, in 2013, the California Legislature passed legislation that increased the Board's oversight of pharmacies that compound sterile products. The specific legislative changes to the Business and Professions Code are not relevant to the issues addressed in this matter.[4] However, by this legislation, the Legislature expressed its intent to ensure the safety of compounded sterile products and increase the regulatory oversight of pharmacies that compound products from non-sterile ingredients.

CCR section 1751.7 is part of the regulatory scheme to afford public protection relating to compounding medications and pharmaceutical products. As noted above, respondents did not dispute that they violated this regulation. They argued that the violations of this rule were technical with little or no risk of harm to the public. The pertinent section of the version of the regulation in effect during the relevant period of this matter provided as follows:

> (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.

The Board's July 8, 2015, September 22, 2015, and September 24, 2015, Inspections

7. Michael Boluro-Ajayi has worked as a Board inspector for the last four years. He is a licensed pharmacist, and he previously worked for different pharmacies and for Los Angeles County. He was first licensed in 2011. He has a degree in microbiology, and prior to becoming licensed he worked for 10 years in the research and development of drugs. Inspector Boluro-Ajayi has conducted over 100 inspections of pharmacies including compounding pharmacies. He is assigned to the Board's compounding team where he travels out of state to inspect pharmacies that send drugs into California.

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[4] The legislation modified Section 4127 and required any pharmacy that compounds sterile drug products to possess a sterile compounding pharmacy license. Section 4127 further required the Board to adopt regulations to establish policies, guidelines, and procedures to implement the statute and also required the Board to review any formal revision to General Chapter 797 of the United States Pharmacopeia and The National Formulary (USP-NF) relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official, to determine whether amendments are necessary to the regulations adopted by the Board pursuant to subdivision (b).

As he explained, compounding pharmacies create products that fit the needs of individual patients. Compounding pharmacies include pharmacies that outsource products out of state and are "503B" entities.[5] These pharmacies must register with the Food and Drug Administration (FDA). Sterile compounding pharmacies are another type of compounding pharmacy and create products without microorganisms. Respondent Central Drugs is a sterile compounding pharmacy. Central Drugs makes sterile compounds from non-sterile products. According to Inspector Boluro-Ajayi, this involves a "high risk" of contamination.

UNLICENSED PHARMACY TECHNICIAN H.S.

8. On July 8, 2015, Inspector Boluro-Ajayi conducted a routine inspection of Central Drugs's La Habra facility. While conducting this annual inspection he initially spoke with respondent Patel. Respondent Patel told Inspector Boluro-Ajayi he had to leave and he introduced him to Chinh M. Tran, Pharm.D., who he said was in charge of sterile compounding. Before he left, respondent Patel said that the new pharmacist in charge, Manisha Patel, Pharm.D., would soon be at the facility. Mr. Tran showed Inspector Boluro-Ajayi the compounding facility, which included the sterile room, anteroom to "gown up," an autoclave room where equipment is sterilized, and the compounding room. Mr. Tran introduced him to four personnel, including H.S. Inspector Boluro-Ajayi asked each of them what their role and job titles were, and they all told him "technicians." He advised Mr. Tran that he wanted to see their licenses after the tour.

While Inspector Boluro-Ajayi was gowning up he saw five persons in the "clean room" with one person in a supervisory role, Helen Nguyen, Pharm.D. Ms. Nguyen said she was the sterile compounding pharmacist and worked under Mr. Tran. PIC M. Patel joined the parties at this point. PIC M. Patel gave Inspector Boluro-Ajayi California Pharmacy Technicians licenses for three of the personnel. She did not give him the license of H.S. PIC M. Patel told Inspector Boluro-Ajayi that H.S. was hired in July 2014, and that she was not the PIC until March 2015. Inspector Boluro-Ajayi asked for H.S.'s employee badge, job description and employee letter. He, further, asked to speak to H.S. PIC M. Patel told Inspector Boluro-Ajayi that H.S. had already been removed from the sterile compounding area and had left for the day. She did not explain why H.S. left before Inspector Boluro-Ajayi completed his inspection.

After his July 8, 2015, inspection, PIC M. Patel gave Inspector Boluro-Ajayi a number of documents relating to H.S., including her Central Drugs employee badge. The badge identified her as a Central Drugs "Pharmacy Technician." PIC M. Patel also gave Inspector Boluro-Ajayi a card from the Pharmacy Technician Certification Board (PTCB). The card identified her name and stated that she was certified on September 6, 2013, with an expiration date of November 30, 2015. In addition, he received a copy of H.S.'s "competency log," relating to her role in compounding products; H.S.'s employee hire form;

[5] "503B refers to Section 503B of the Federal Food, Drug, and Cosmetic Act and regulates pharmacies that compound sterile products and are "outsourcing" facilities.

job description signed by H.S.; original compounding log of Magnesium Chloride Injection 200 mg/ml Injectable compounded by H.S.; original compounding log for Magnesium Chloride compounded by "technician" H.S. under the supervision of pharmacist H. Nguyen; original compounding log of Dexpantheol 250 mg/ml Injectable compounded by "technician" H.S. under pharmacist Nguyen's supervision; copy of technician daily schedule in the sterile compounding room for April 27, 2015, to July 31, 2015, which identified H.S. performing a variety of cleaning tasks which licensed pharmacy technicians also performed. These documents were admitted into evidence at this hearing.

Also after his July 8, 2015, inspection, Inspector-Boluro-Ajayi obtained H.S.'s signed statement dated July 11, 2015. In her statement, H.S. said she had worked at Central Drugs Compounding Pharmacy since July 16, 2014. She worked under the supervision of pharmacists Nguyen and Tran. Her duties involved cleaning and sterilizing glassware, vials and supplies according to procedures, informing her supervisor of stock needs, effectively performing sterile compounding using aseptic techniques according to procedures and operating, calibrating and keeping daily records of all required equipment for preparing prescriptions, assisting in formulating logs and measuring and weighing chemicals. She attached to her statement a list of medications she compounded. H.S. stated that she had not been aware of the California Technician Licensing requirements and she was now aware of those requirements. H.S. stated that she was placed on administrative leave for three days and her classification at Central Drugs was changed from Pharmacy Technician to Pharmacy Clerk beginning July 14, 2015.

Inspector Boluro-Ajayi, in addition, obtained from Central Drugs the Position Description for Pharmacy Technician, which H.S. signed on July 8, 2014. This document identified the following essential functions of a pharmacy technician at Central Drugs: the proficient use of all computer systems, knowledge of location of medications in the pharmacy and stock of inventory and familiarity with all chemicals; knowledge of physicians' specific preparations and anticipation of scheduled orders; proficient knowledge of sterile lab and daily routines and record-keeping; the ability to build and maintain consistency and knowledge base; ability to quickly and efficiently multi-task and prioritize work; the ability to keep up with system flow; deliver consistent customer service; have excellent telephone etiquette and verbal and written communications; and adhere to company policies and procedures.

In this document, the first identified minimum qualification for a pharmacy technician at Central Drugs was that the individual must have a current and active pharmacy technician license.

9. H.S was not licensed in California as a Pharmacy Technician from November 1, 2014, to July 8, 2015. During this time, H.S. performed work at Central Drugs that required her to be licensed as a pharmacy technician.[6]

[6] H.S. was hired as a pharmacy technician on July 8, 2014, received three months training as discussed below, and as also discussed below, began working in the compounding

After this period H.S. applied to become a pharmacy technician and the Board denied her application because she worked as a pharmacy technician without a license. She reapplied after one year and the Board granted her application. Since September 15, 2017, H.S. has been a licensed pharmacy technician and continues to work at Central Drugs, though she does not compound pharmaceutical products.

TESTING OF BATCH END PRODUCT WITHOUT TESTING FOR PYROGENS

10. On September 22, 2015, Inspector Boluro-Ajayi returned to Central Drugs with FDA Consumer Safety Officer Uttanito (Tom) Limchumroon and California Department of Public Health (DPH) Investigator Jaqueline Nunez.[7] They met respondent Patel and PIC M. Patel and toured the facility. During their inspection of the clean room, Inspector Boluro-Ajayi noticed an alcohol bottle labeled with H.S.'s name in large bold type. A photograph of the bottle shows H.S.'s name in large bold letters.[8]

On September 24, 2015, Inspector Boluro-Ajayi and the FDA and DPH Investigators returned to Central Drugs and talked to Mr. Tran and respondent Patel. Mr. Tran said that "Central Drugs conducts endotoxin only about 60 % of the time on batches of non-sterile to sterile injectables."[9] To ensure he understood what Mr. Tran said about endotoxin testing of non-sterile to sterile injectable products, Inspector Boluro-Ajayi asked him to repeat what he said. Mr. Tran repeated his statement. Respondent Patel then told Inspector Boluro-Ajayi that they "are doing more than the law requires." He added that as "far back as he can remember the law does not require them to test more than what Central Drugs was currently doing." In the presence of PIC M. Patel and the Investigators from the FDA and the DPH, Inspector Boluro-Ajayi asked respondent Patel if the products he was referring to were compounded from non-sterile ingredients. He said "yes." Inspector Boluro-Ajayi then read CCR section 1751.7 to respondent Patel. Respondent Patel seemed surprised that the law requires endotoxin and sterile testing for every batch of compounded sterile products made from non-sterile ingredients.

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department at Central Drugs after this training. The accusation alleges that H.S. worked as an unlicensed pharmacy technician from November 1, 2014, to July 8, 2015, the date of Inspector Boluro-Ajayi's inspection. Respondents did not dispute the allegation or time line as framed in the accusation.

[7] Inspector Boluro-Ajayi identified Mr. Limchumroon as being an FDA "Investigator." However, he identified him in the body of the report as a "Consumer Safety Officer."

[8] Inspector Boluro-Ajayi testified that the bottle with her name on it was "significant" because it showed that H.S. continued to compound medications after July 8, 2015. His conclusion is not accepted considering H.S.'s statement and her testimony at the hearing that she stopped working as a pharmacy technician on July 8, 2015.

[9] Inspector Boluro-Ajayi testified that pyrogens are endotoxins.

Inspector Boluro-Ajayi asked PIC M. Patel for the batch results of all the random selected compounded drugs and the sterile test results, and the endotoxin test and release dates associated with each prescription. On October 1, 2015, PIC M. Patel transmitted the requested compounding logs to Inspector Boluro-Ajayi.

11. The logs introduced at hearing consisted of eight sets of documents for eight different prescriptions for injectable drugs captioned "Logged Formula Worksheets" and "Microbial Log/Pyro Test." They identified non-sterile ingredients used in compounding the end products, whether the batch was pyrogen tested and the release date from quarantine of the end product. Only one log, for the product manufactured on February 20, 2015, lot number 150220/2, documented that the products were tested for pyrogens, but this test occurred after the release date of the product on March 6, 2015. These logs did not document whether the products were tested for sterility.

12. The logs show the following compounded batch produced injectable sterile products, compounded from non-sterile ingredients, were not tested for endotoxins 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	1502260@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	Prostril 20 mg/ml	5 ml	150218@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/50mg	3500	150220@2	H.N./H.S.
2/20/2015	Capyrilc Capric Triglycerides +10% Benzyl Alcohol	50 ml	150220@31	H.N./H.S.
2/25/2015	Chromium 200 mcg/ml	2000 ml	150225@5	H.N./E.C./H.S.

LABELING OF PRESCRIPTIONS AND DANGEROUS DRUGS

13. When Inspector Boluro-Ajayi was at Central Drugs on September 24, 2015, he requested and received duplicate labels for prescription nos. 6423900, 6441577, 6449573, 6458220, 6442478, and 6445321. Six of the prescriptions directed the patient to "bring to

physician's office for administration." Prescription RX No. 6442478 directed the patient to "Inject .3ml intramuscularly 3 times a week."[10] Inspector Boluro-Ajayi testified that the labels are deficient because they do not comply with the labeling requirements under Code section 4040, subdivision (1)(B).

14. The drugs identified in this decision are "dangerous drugs" pursuant to Section 4022.

Respondent's Evidence

TESTIMONY OF NAYAN PATEL, PHARM.D.

15. Respondent Patel graduated from the University of Southern California (USC) School of Pharmacy in 1996 and in 1999 he took over Central Drugs. He recruited a former colleague at USC, Mr. Tran, to run the compounding department at Central Drugs and Mr. Tran remains in charge of the compounding department. As noted, respondent Patel was the pharmacist in charge at Central Drugs until May 2015.

Respondent Patel testified that he is committed to safe compounding, has educated himself over the years on this subject and has lectured on the subject. Central Drugs has been compounding since 2000 without any deficient products. Since 2000, respondent Patel commented that laws governing compounding increased scrutiny of compounding pharmacies due in part to the NECC incident discussed above. He said that the NECC incident caused a major shift in thinking about the process of sterile compounding in order to ensure patient safety. The process of compounding is now extremely rigorous and Central Drugs purchases ingredients only from FDA-approved manufacturers. As a result of NECC, respondent Patel hired three industry consultants to make sure that Central Drugs's compounding processes were safe. As proof of his commitment to the safe compounding of sterile products, in 2014 he attended a training in pharmaceutical compounding and sterile preparations at the United States Pharmacopeial Convention (USP).

Respondent Patel did not dispute that Central Drugs failed to perform end product testing for the presence of pyrogens as required under CCR section 1751.7. Once he realized Central Drugs was not in compliance with CCR section 1751.7, effective July 6, 2016, the procedure manual was changed and required end product testing for pyrogens in compliance with CCR section 1751.7.

Respondent Patel testified that regardless of the pharmacy's failure to follow CCR section 1751.7, there was "no risk" to the public due to the presence of pyrogens because of the many steps Central Drugs took to ensure the sterility of the end product. In this regard, he stressed the importance of processes Central Drugs had in place to safeguard compounded sterile products. He identified these processes as: "process validation," "equipment

[10] The accusation alleges incorrectly that all the labels stated, "Bring to physician's office for administration."

validation," and "raw material validation." He added that these processes ensured the sterility of the end product and were above what the law required.

He explained that the biggest threat to consumers was not from pyrogens in the end product but from products that were not sterile. As he stated, a patient can die from non-sterile ingredients in a compounded product while a pyrogen, which is the cell wall of bacteria, can cause only "flu like symptoms." Patel did not define "flu like symptoms" and he did not explain how he concluded there was no risk to the public when the presence of pyrogens in the end product can cause "flu like symptoms." His opinion, here, is not accepted.

In support of his testimony that Central Drugs's processes before July 2016 ensured the safety of the compounded sterile products, he cited United States Pharmacopeial Convention section 797. This section allows for the dispensing of sterile compounded products before the results of sterility testing are known, provided certain procedures are in place. Patel candidly admitted that California has not adopted this section. To the extent, thus, it conflicts with CCR section 1751.7, it is given no weight as a mitigating factor on respondents' behalf.[11]

Respondent Patel also suggested that CCR section 1751.7 was ambiguous because of changes to the rule effective January 1, 2017. It is not clear whether Respondent Patel was asserting that his failure to follow CCR section 1751.7 was somehow reasonable due to this asserted ambiguity. But, at any rate, the rule in effect in 2015 was not ambiguous and contained the same language as the 2017 version of the rule that required end product testing for pyrogens in batch-produced sterile preparations produced from non-sterile ingredients.[12]

Regarding H.S. working as an unlicensed pharmacy technician at Central Drugs, respondent Patel did not dispute that she was hired as a pharmacy technician and performed duties when a pharmacy technician license was required. Respondent Patel blamed the human resources manager at Central Drugs for hiring H.S. because she accepted H.S.'s PTCB card as proof that she was licensed as a pharmacy technician. He was not involved in H.S.'s hiring and he relied on this human resources manager's experience to hire qualified

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[11] Respondent Patel was questioned on cross examination regarding why he ignored another section of USP 797 entitled "Bacterial Endotoxin (Pyrogen) Testing" which requires testing for pyrogens of "all high-risk level compounded sterile products that are prepared in groups of 25 identical single-dose packages" or exposed to certain conditions. His answer was not responsive.

[12] The following language is the same in the 2015 and 2017 versions of the rule: "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." The 2017 version does not require end product testing for sterility and pyrogens for certain products not at issue in this proceeding.

licensed staff. As a result of this error, respondent Central Drugs implemented a check list to follow to ensure that only licensed technicians are hired.

Respondent Patel argued that H.S.'s employment as an unlicensed technician posed minimal risk to the public because she obtained a Bachelor of Pharmacy degree in India, passed the PTCB, and before she began compounding sterile products, H.S. underwent training in order to ensure that she was able to safely compound sterile products. This required training involved a 90-day Mentoring and Training program for new staff in sterile compounding. This training was documented in a 13-page document entitled "90-Day Mentoring and Training/Plan for Retail Pharmacy/Sterile Compounding Technician."

Regarding the adequacy of directions for use on the prescription labels, respondent Patel testified that in his experience if a physician prescribes a drug that is not intended for self-administration the physician will direct the patient to bring the medication to the physician's office for administration. Complainant did not offer evidence to rebut respondent Patel's testimony in this regard.

Respondent Patel stressed the impact discipline would have on him and his patients. He has multiple licenses in numerous states and discipline would restrict his ability to do business in these states and provide products and medications. As a result of this restriction, he believed patients would be harmed. Respondent Patel added that if he was disciplined the Board would notify state boards of any imposed discipline and this would require him to answer to these boards. His insurance would also be affected. He also said that discipline would jeopardize the jobs of his employees.

Respondent Patel's testimony was mostly credible. He did not, however, take responsibility for the violations at issue here although he was pharmacist in charge at Central Drugs until May 15, 2015, and as pharmacist in charge he had the duty to ensure the pharmacy's compliance with applicable laws and regulations under Section 4036.5. He blamed the human resources manager for hiring and employing H.S., an unlicensed technician. He, further, discounted if not dismissed, the violation of CCR section 1751.7 because, in his opinion, Central Drugs' processes ensured the safety of the end products and, in his opinion, there was no risk to patient safety despite the failure to test for pyrogens in the end products.

TESTIMONY OF JAYNE Y. HAN, PHARM.D.

16. Jayne Y. Han, Pharm.D., obtained her Doctor of Pharmacy degree in 2002 from Western University of Health Sciences and is a California licensed pharmacist. She presently works at Harbor Compounding Pharmacy in Costa Mesa as Marketing Pharmacist and Staff Pharmacist. From 2002 to 2017 she worked at California Pharmacy and Compounding Center in Newport Beach where she compounded sterile and non-sterile products. Ms. Han is familiar with the requirements for sterilization and end product testing.

Ms. Han testified that there was "low" risk to consumers of contamination from products compounded at Central Drugs from non-sterile ingredients produced in depyrogenated glassware in an ISO 5 environment even though end products were not tested for pyrogens. She reached this opinion for the following reasons: Central Drugs tested raw materials for sterility and used ingredients which manufacturers analyzed and certified for sterility. Central Drugs also used sterilized equipment and depyrogenated glassware when compounding products and technicians wore suits to help prevent the shedding of hair and skin, which can contaminate the products. Ms. Han noted that products compounded in an ISO level 5 classified environment helped ensure that the compounded products were sterile almost to a 100 percent certainty.[13]

Despite her opinion that there was "low" risk to consumers from products compounded at Central Drugs, Ms. Han, nonetheless, recognized that pyrogens in the end product with sterile ingredients can trigger an inflammatory response in the consumer's immune system, cause high fever, and in rare cases, a high pyrogen load can result in death.

Ms. Han did not explain how she reached the conclusion that the risk was "low" to consumers from pyrogens in the end products produced at Central Drugs when pyrogens can trigger an inflammatory response and lead to flu-like symptoms and fever. Further, she offered her opinion based on her training, education and experience as a licensed pharmacist. No foundation was offered to credit her opinion as an expert in microbiology or immunology. Thus, her opinion can be given little weight.

Ms. Han also addressed whether the prescription labels directing patients to bring the products to physicians were adequate. She testified that in her experience it is common for prescriptions to direct patients to take medications to their physicians for administration. Complainant did not offer evidence that contradicted her testimony in this regard.

Except as noted, Ms. Han's testimony was credible.

OTHER EVIDENCE

17. Respondent Patel submitted letters of support from Mitchell J. Ghen, D.O., Ph.D.; Raffi Svadjian, Pharm.D.; and Shushma Patel, RPH, MBA.

Mr. Ghen has known respondent Patel for 15 years and practices medicine in Florida. In his letter dated June 23, 2017, he stated he has worked with respondent Patel in academia and with patients. He has co-authored a textbook with Patel. He described respondent Patel as committed to quality and safety in his pharmacy and he trusts that respondent Patel will treat his patients with the utmost professionalism and the medication will be of the highest quality.

[13] As explained at the hearing, ISO level 5 refers to the clean room used in the manufacturing of compounded products where air particles that can contaminate products are removed.

Mr. Svadjian has known respondent Patel for 15 years and has interacted with him through respondent Patel's relationship with USC. In his letter dated June 30, 2017, he stated that respondent Patel is dedicated to the education of Pharmacy students and has helped educate students, particularly in the area of professional compounding. Mr. Svadjian cited respondent Patel's extensive lecturing on the topic of sterile and non-sterile compounding; his company has served as a site for the Advanced Pharmacy Practice Experience clerkship for over 10 years; respondent Patel has hosted USC Pharmacy students at his pharmacy and spent many hours educating students about ownership and management of a pharmacy and regulatory affairs, compliance, financial management, human resources, and leadership/management; respondent Patel has participated in a student compounding competition; and he has served as a student panel speaker.

Shushma Patel, in a letter dated July 3, 2017, stated that he has known respondent Patel on both a personal and professional level for over 20 years. He purchased an independent community pharmacy from respondent Patel and has served with respondent Patel as a committee member of the Indian Pharmacist Association. Shushma Patel stated that respondent Patel is a highly respected and ethical pharmacist and an integral part of the health care system available to community residents. He also stated that respondent Patel has a comprehensive knowledge of compounding practice coupled with a passion for mentoring registered pharmacists.

In their letters these individuals did not state that they reviewed or were made aware of the allegations against respondent Patel in the accusation. Their opinions regarding respondent Patel's reputation and competency in the field of compounding pharmacy practice are discounted.

Costs

18. Pursuant to Business and Professions Code section 125.3, subdivision (a), the Board may request an order directing a licensee "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." A certified copy of the actual costs, or a good faith estimate of costs where actual costs are not available, signed by the entity bringing the proceeding or its designated representative "shall be prima facie evidence of reasonable costs of investigation and prosecution of the case." (Bus. & Prof. Code, § 125.3, subd. (c).)

In support of the request for costs, complainant submitted: (1) a Certification of Investigative Costs, which complainant signed on November 16, 2017, for total investigative costs of $14,943.50; (2) the Declaration of Michael Boluro-Ajayi, which provided a detailed summary of the tasks involved in the 123.25 hours he expended in this matter, and which he signed on November 16, 2017; and (3) the Certification of Prosecution Costs: Declaration of Marichelle S. Tahimic, which Ms. Tahimic signed on November 21, 2017, and which incorporated a detailed summary of the time billed on the matter captioned "Matter Time Activity by Professional Type." According to this summary, the Attorney General billed the Board a total of $8,085 for time spent by legal staff on this matter. This reflects a total of

46.50 attorney hours and 1.50 paralegal hours on the enforcement of this matter. Ms. Tahimic, further, made the good faith estimate that she would incur and bill seven additional hours to prepare the case up to the commencement of the hearing in the amount of $1,190. Thus, including this good faith estimate, the Attorney General billed the Board a total of $9,275 for prosecution costs up to the commencement of the hearing.

Based on these declarations, complainant's request for an order for respondents to reimburse the Board a total of $24,218.50 for its investigative and enforcement costs is reasonable.

LEGAL CONCLUSIONS

1. The California State Board of Pharmacy is charged with the administration and enforcement of the Pharmacy Law, Business and Professions Code section 4000, et seq. (Bus. & Prof. Code, § 4001.) In exercising its licensing, regulatory, and disciplinary functions, the Board's highest priority is protection of the public. "Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount." (Bus. & Prof. Code, § 4001.1.)

2. In this action to discipline respondents' licenses, complainant bears the burden of proof of the charges alleged in the Accusation. The standard of proof is clear and convincing evidence to a reasonable certainty. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 855-856.) Clear and convincing evidence means the evidence is "so clear as to leave no substantial doubt" and is "sufficiently strong to command the unhesitating assent of every reasonable mind." (*Mathieu v. Norrell Corporation* (2004) 115 Cal.App.4th 1174, 1190 [citing *Mock v. Michigan Millers Mutual Ins. Co.* (1992) 4 Cal.App.4th 306, 332-333].) If the Board meets its burden, respondents bear the burden of establishing any affirmative defense, including proving rehabilitation. (*Whetstone v. Board of Dental Examiners* (1927) 87 Cal.App. 156, 164.)

Applicable Business and Professions Code Sections

3. Section 4022 defines "dangerous drugs" as follows:

> "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 .

4. Section 4038 defines a "pharmacy technician" as "an individual who assists a pharmacist in a pharmacy in the performance of his or her pharmacy related duties as specified in section 4115." Section 4115 sets forth various tasks a pharmacy technician may perform. Subdivision (a) of Section 4115 provides "a pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of, a pharmacist."

Section 4115, subdivision (e), provides: "A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician."

5. Section 4301 provides as follows:

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, in pertinent part:

[¶] . . . [¶]

(j) The violation of any of the statutes of this state, of 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. . . .

6. Section 4040, subdivision (1)(B), provides as follows:

(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.

Definition of Pharmacist in Charge

7. Section 4036.5 provides the following definition of pharmacist in charge:

"Pharmacist-in-charge" means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

CCR Section 1751.7

8. CCR Section 1751.7, subdivision (c), which was in effect during the time period at issue in this matter, provides as follows:

> (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.

Cause Exists to Impose Discipline on Respondents' Licenses Under the First and Second Causes for Discipline

9. Complainant established by clear and convincing evidence that respondents engaged in unprofessional conduct in violation of Sections 4031, subdivision (o), and 4115, subdivision (e). Between November 1, 2014, and July 8, 2015, they aided and abetted H.S. in practicing as an unlicensed pharmacy technician when she performed work at Central Drugs that required her to be licensed as a pharmacy technician when she was not licensed.

Complainant established by clear and convincing evidence that respondents engaged in unprofessional condition in violation of Section 4031, subdivisions (j) and (o), and CCR section 1751.7. Respondents failed to document end product testing for sterility and pyrogens for eight sets of batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients and failed to quarantine these products until the end product testing confirmed sterility and acceptable levels of pyrogens in violation of CCR section 1751.7, subdivision (c).

Cause Does Not Exist to Impose Discipline on Respondents' Licenses Under the Third Cause for Discipline

10. Cause does not exist to impose discipline against respondents' licenses for failing to provide directions for use on prescription labels as alleged in the Third Cause for Discipline. Section 4040, subdivision (1)(B), requires that prescription labels contain, "(t)he name and quantity of the drug or device prescribed and the directions for use." Six of the prescriptions directed the patients to "bring to physician's office for administration."[14] Such instructions are "directions for use." Drs. Patel and Han testified credibly that in their experience physicians issue such directions for prescription labels. Complainant did not offer evidence to rebut their testimony.

[14] The seventh prescription, Prescription RX No. 6442478, directed the patient to "Inject .3ml intramuscularly 3 times a week." This direction is also a "direction for use."

Assessment of Discipline

11. The Board has published disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. 10/2007) (Guidelines) that are to be used in reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.). Deviation from these guidelines "is appropriate where the Board, in its sole discretion, determines that the facts of the particular case warrant such a deviation-the presence of mitigating factors; the age of the case; evidentiary problems." (Cal. Code Regs., tit. 16, § 1760.)

In determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, the following factors are considered, in relevant part: the actual or potential harm to the public; prior disciplinary record, including level of compliance with disciplinary order(s); prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s); number and/or variety of current violations; nature and severity of the act(s), offense(s) or crime(s) under consideration; aggravating evidence; mitigating evidence; rehabilitation evidence; time passed since the act(s) or offense(s); whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another; whether the respondent had knowledge of or knowingly participated in such conduct; and the financial benefit to the respondent from the misconduct.

No single one or combination of the above factors is required to justify the minimum and/or maximum penalty in a given case, as opposed to an intermediate one. A respondent is permitted to present mitigating circumstances at a hearing and has the burden to show any rehabilitation or corrective measures he or she has taken.

The Guidelines contain four categories of violations and recommended penalties. For the violations of the Business and Professions Code at issue here, the level of discipline is appropriately classified as "Category II" because, consistent with the board's Guidelines, the violations posed a serious potential for harm, and respondents' conduct involved the disregard of pharmacy law and public safety, and reflected on respondents' competency and ability to take care. Under this classification, the minimum range of discipline is revocation, revocation stayed, three years' probation with standard terms and conditions and optional terms as appropriate. The maximum range is revocation.

Respondents' arguments that the violations were technical and did not pose serious potential for harm to the public were not persuasive. First, respondents failed to have injectable compounded end products produced from non-sterile ingredients tested for pyrogens before dispensing them in violation of CCR section 1751.7. CCR section 1751.7 represents the Board's effort to protect the public from contaminated or tainted injectable compounded end products and the rule serves this important goal. Indeed, the NECC incident highlights the need for such regulatory protections. It is reasonable, thus, to conclude that respondents' violation of this rule exposed the public to serious potential harm on its face. Ms. Han's testimony that respondents' violation of this rule posed a low risk of

harm to the public even when pyrogens can cause flu-like symptoms and fever was not persuasive for the reasons addressed above. Respondent Patel's similar testimony was also found not persuasive.

H.S.'s employment as an unlicensed pharmacy technician in the compounding department also posed a serious potential for harm and respondents' arguments to the contrary were not persuasive. H.S. worked in this capacity from November 1, 2014, to July 8, 2015. Even though H.S. passed the PTCB and received training, by hiring and employing H.S. as a pharmacy technician without ensuring she was licensed by the Board, respondents deprived the Board of the ability to ensure that H.S. was qualified and fit to practice as a pharmacy technician and remained qualified. This, by itself, posed serious potential for harm to the public. The fact that the Board subsequently licensed H.S. as a pharmacy technician on September 15, 2017, does not change this conclusion.

In addition, as a further factor in support of the Category II classification, by their conduct respondents disregarded the laws governing pharmacy law. Notably, respondent Patel was unwilling to acknowledge his responsibility as the pharmacist in charge for his pharmacy's compliance with applicable laws. In his testimony, he blamed the human resources manager for hiring H.S. as a pharmacy technician. Similarly, he was unwilling to acknowledge that Central Drugs's processes of end product testing were deficient because these processes did not include pyrogen testing as required under CCR section 1751.7, even when the violations occurred when he was pharmacist in charge. Instead, he stressed that the processes in place ensured the safety of compounded end products even when these processes violated CCR section 1751.7. Interestingly, his testimony sounded similar to what he told Inspector Boluro-Ajayi on September 24, 2015. At that time, he said he was "doing more than the law requires" and as "far back as he can remember the law does not require them to test more than what Central Drugs was currently doing." Respondent Patel appeared to sustain this belief at the hearing.

At this point, the question is the degree of discipline to impose under the Category II discipline level. Consistent with the factors identified in the Board's Guidelines, due consideration has been given to the potential harm respondents' conduct represented, respondents' citation histories, and respondents' evidence of rehabilitation, in particular, respondents' implementation of policy and procedural changes to ensure compliance with CCR section 1751.7 and that pharmacy technicians hired in the future are licensed. Respondent Patel's stated commitment to safe compounding was also considered. In addition, the conduct at issue was not intentional.

After considering these factors and the evidence of record as a whole, it is concluded that revocation of respondents' licenses is not necessary to ensure public protection. Respondents presented sufficient evidence of rehabilitation such that a three-year period of probation, subject to the terms and conditions set forth below, will adequately protect the public.

Assessment of Costs

12. In *Zuckerman v. Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, the California Supreme Court decided that in order to determine whether the actual costs of investigation and prosecution sought by a regulatory board under a statute substantially identical to Business and Professions Code 125.3 are "reasonable," the agency must decide: (a) Whether the licensee has been successful at hearing in getting charges dismissed or reduced; (b) the licensee's subjective good faith belief in the merits of his or her position; (c) whether the licensee has raised a colorable challenge to the proposed discipline; (d) the financial ability of the licensee to pay; and (e) whether the scope of the investigation was appropriate to the alleged misconduct.

As found above, the reasonable costs of investigation and enforcement are found to be $24,218.50. Applying the factors detailed in *Zuckerman, supra*, a reduction in the amount of $8,072.83 is allowed because respondents had a good faith belief in the merits of their positions and one of the three causes for discipline was dismissed. Thus, costs are awarded in the amount of $16,145.67.

ORDER

License number RPH 48867, issued to respondent Nayan Patel, and Permit Number PHY 49146 and License Number LSC 99515, issued to respondent Auro Pharmacies Inc. dba Central Drugs, are hereby revoked; however, the revocation is stayed, and these licenses are placed on probation for three (3) years upon the following terms and conditions:

A. **RESPONDENT AURO PHARMACIES'S dba CENTRAL DRUGS'S LICENSES** are subject to the following standard conditions:

1. **Obey All Laws**: Respondent owner shall obey all state and federal laws and regulations. Respondent owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime;

- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. **Report to the Board:** Respondent owner shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board:** Upon receipt of reasonable prior notice, respondent owner shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff:** Respondent owner shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her or its probation. Failure to cooperate shall be considered a violation of probation.

5. **Reimbursement of Board Costs**: As a condition precedent to successful completion of probation, respondent owner shall pay to the Board its costs of investigation and prosecution in the amount of $16,145.67. Respondent owner shall make said payments as follows: within 3 years of the effective date of this Decision, pursuant to a reasonable payment plan agreed to by the Board. There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation. RESPONDENT AURO PHARMACIES IS JOINTLY AND SEVERALLY LIABLE FOR COSTS IMPOSED ON RESPONDENT PATEL, PURSUANT TO TERM B. 8.

The filing of bankruptcy by respondent owner shall not relieve respondent of his or her or its responsibility to reimburse the Board its costs of investigation and prosecution.

6. **Probation Monitoring Costs:** Respondent owner shall pay any costs associated with probation monitoring as determined by the Board each and every year of

probation. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. **Status of License:** Respondent owner shall, at all times while on probation, maintain current licensure with the Board. If respondent owner submits an application to the Board, and the application is approved, for a change of location, change of permit or change of ownership, the Board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the Board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. **License Surrender While on Probation/Suspension:** Following the effective date of this decision, should respondent owner discontinue business, respondent owner may tender the premises licenses to the Board for surrender. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and renewal license to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer.

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, respondent owner shall provide a copy of the written notice to the Board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner may not apply for any new licensure from the Board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board.

Respondent owner further stipulates that he or she shall reimburse the Board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. **Notice to Employees:** Respondent owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent owner shall submit written notification to the Board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the Board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. **Owners and Officers: Knowledge of the Law**: Respondent owner shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent owner or respondent owner's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. **Posted Notice of Probation:** Respondent owner shall prominently post a probation notice provided by the Board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. **Violation of Probation:** If respondent owner has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over respondent owner's license, and probation shall be automatically extended until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent owner violates probation in any respect, the Board, after giving respondent owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent owner during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

13. **Completion of Probation:** Upon written notice by the Board or its designee indicating successful completion of probation, respondent owner's license will be fully restored.

B. **RESPONDENT NAYAN PATEL'S LICENSE** is subject to the following conditions:

1. **Obey All Laws**: Respondent shall obey all state and federal laws and regulations. Respondent shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime;
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. **Report to the Board:** Respondent shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not

made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

3. **Interview with the Board:** Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff:** Respondent shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate shall be considered a violation of probation.

5. **Continuing Education:** Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

6. **Notice to Employers:** During the period of probation, respondent shall notify all present and prospective employers of the decision in OAH case number 2017050577 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment while on probation) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in OAH case number 2017050577, and the terms and conditions imposed herein. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his or her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in OAH case number 2017050577 in advance of respondent commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that he or she has read the decision in OAH case number 2017050577 and the terms and conditions imposed herein. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

Failure to timely notify present to current and/or prospective employer(s) or to cause those employer(s) to submit timely acknowledgments to the Board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. **No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant:** During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the Board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. **Reimbursement of Board Costs**: As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $16,145.67. Respondent shall make said payments as follows: within three years of the effective date of this Decision, pursuant to a reasonably payment plan agreed to by the Board. RESPONDENT PATEL IS JOINTLY AND SEVERALLY LIABLE FOR COSTS IMPOSED ON RESPONDENT AURO PHARMACIES PURSUANT TO TERM A.5.

There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the Board its costs of investigation and prosecution.

9. **Probation Monitoring Costs:** Respondent shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

10. **Status of License:** Respondent shall, at all times while on probation, maintain an active, current license with the Board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or

otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. **License Surrender While on Probation/Suspension:** Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the Board for surrender. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the Board.

Upon acceptance of the surrender, respondent shall relinquish his or her pocket and wall license to the board within ten (10) days of notification by the Board that the surrender is accepted. Respondent may not reapply for any license from the Board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

12. **Notification of a Change in Name, Residence Address, Mailing Address or Employment:** Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the Board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the Board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. **Tolling of Probation:** Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, respondent must notify the Board in writing within ten (10) days of the cessation of practice, and must further notify the Board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

14. **Violation of Probation:** If a respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the Board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. **Ethics Course:** Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the Board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation. Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

16. **No Supervision of Ancillary Personnel:** During the period of probation, respondent shall not supervise any ancillary personnel, including, but not limited to, pharmacy technicians or designated representatives in any entity licensed by the Board.

Failure to comply with this provision shall be considered a violation of probation.

17. **No New Ownership of Licensed Premises**: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the Board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the Board, respondent may continue to serve in such capacity or hold

that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

18. **Completion of Probation:** Upon written notice by the Board or its designee indicating successful completion of probation, respondent's license will be fully restored.

DATED: December 26, 2017

DocuSigned by:
Abraham Levy
C84194237D2243C...

ABRAHAM M. LEVY
Administrative Law Judge
Office of Administrative Hearings

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

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

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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