

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

In the Matter of the Accusation Against:¹

JEFFERSON PLAZA PHARMACY
Pharmacy Permit No. PHY 11062, and

JOHNNY PINGHON CHAN
Pharmacist License No. RPH 32261, and

MARICON PAYTE ESMABE,
Pharmacy Technician Registration No.
TCH 124483,

Respondents.

Case No. 5113

OAH No. 2015010397

**DECISION
AFTER REJECTION OF PROPOSED DECISION**

Administrative Law Judge Perry O. Johnson, Office of Administrative Hearings, State of California, heard this matter on June 8 and June 9, 2015, in Oakland, California. Deputy Attorney General Kim M. Settles, Department of Justice, State of California, along with the assistance of Mr. Chris Collins, represented complainant Virginia K. Herold, Executive Officer, Board of Pharmacy (the board), Department of Consumer Affairs, State of California. Attorney at Law Natallia Mazina represented respondent Jefferson Plaza Pharmacy (respondent pharmacy or respondent Jefferson Plaza Pharmacy) and Johnny Pinghon Chan (respondent Chan). Respondent Chan was present for all phases of the administrative adjudication proceeding.

The record was held open to afford opportunities to the parties to file written arguments regarding the reasonableness and appropriateness of the board's recovery of the costs of investigation. On June 11, 2015, respondent pharmacy and respondent Chan, through their counsel, filed a document titled "Motion to Reduce Investigative Costs," which was marked as exhibit "W," and received as argument. On June 16, 2015, complainant, through her counsel, filed correspondence titled "Response to Motion to Reduce Investigative Costs,"

¹ The allegations pertaining to Maricon P. Esmabe (TCH 124483) were resolved by a separate Decision and Order of the Board prior to the hearing in this case. This Decision does not pertain to that license.

which was marked as exhibit "5," and received as argument. On June 16, 2015, the parties were deemed to have submitted the matter for decision, and the record closed. On July 16, 2015, the Administrative Law Judge issued his Proposed Decision in this matter.

Pursuant to section 11517 of the Government Code, on October 7, 2015, the California State Board of Pharmacy (hereinafter "board") issued an Order rejecting the Proposed Decision in this matter. On December 2, 2015, the parties were notified that the transcript had been received and the deadline for the parties to submit written argument was set for January 4, 2016. Written argument was timely received from the complainant. No argument was received from respondent.

The board, having reviewed and considered the entire record, including the transcript, exhibits and written argument, now issues this decision.

FACTUAL FINDINGS

Jurisdictional Matters

1. On July 27, 2014, complainant Virginia K. Herold, in her official capacity as the board's Executive Officer (complainant), signed the Accusation in Case No. 5113, which was served thereafter on respondent pharmacy and respondent Chan.

Respondents timely filed a Notice of Defense and the hearing in this matter ensued.

License Histories

2. On August 8, 1978, the board issued Pharmacist License Number RPH 32261 to respondent Chan. Respondent Chan's license is renewed until May 31, 2016.

3. There is no history of any prior discipline having been executed against respondent Chan's pharmacist license.

4. On May 4, 1981, the board issued Pharmacy Permit Number PHY 11062 to Medical Plaza Pharmacies, Inc., to engage in business under the fictitious business name of "Jefferson Plaza Pharmacy." The license issued to respondent Medical Plaza Pharmacies, Inc., doing business as Jefferson Plaza Pharmacy, is renewed until October 1, 2015.

5. Since May 4, 1981, the corporation, which owns respondent Jefferson Plaza Pharmacy, has had as its president Ruth Fung Chan. Mrs. Fung Chan holds board issued Pharmacist License Number RPH 32217. And, she is the wife of respondent Chan.

6. On March 1, 1986, respondent Chan became the Pharmacist-in-Charge for respondent Jefferson Plaza Pharmacy.

7. There is no history of any prior discipline having been perfected against respondent Jefferson Plaza Pharmacy's permit.

8. Respondent Jefferson Plaza Pharmacy is a community pharmacy situated at 3137 Jefferson Avenue in Redwood City, San Mateo County, California.

A Citizen Complaint

9. On approximately January 30, 2012, a medical doctor, identified herein as Dr. N.A., filed a Consumer Complaint Form with complainant's personnel regarding suspected unprofessional acts of respondent Jefferson Plaza Pharmacy and its agents or employees. The medical doctor's consumer complaint asserted that individuals at the subject pharmacy had dispensed five different narcotic drugs within a ten-day period to the medical doctor's patient, who was under the complaining medical doctor's care and treatment for opioid dependence.² Complainant's personnel commenced an investigation into respondent Jefferson Plaza Pharmacy's policies, practices, and methods for dispensing³ narcotics, as well as the acts and omissions of respondent Chan as the Pharmacist-in-Charge for respondent Jefferson Plaza Pharmacy.

The Inspection and Investigative Findings and Conclusions

10. Manisha Patel Shafir (Inspector Shafir) offered reliable and persuasive evidence at the hearing of this matter. By her demeanor while testifying, her attitude toward the proceeding, her clear and unhesitating presentation of evidence as well as her solemn, sincere and conscientious attitude toward the proposed action against respondents, Inspector Shafir established herself to be a credible,⁴ exceedingly knowledgeable, and trustworthy witness at the hearing of this matter.

11. As part of complainant's investigation, which resulted from the consumer complaint made by Dr. A.N., Manisha Patel Shafir (Inspector Shafir), a Pharmacy Board Inspector, on July 12, 2013, conducted an inspection of the business premises of respondents; and, she crafted a detailed investigative report containing summaries of findings and conclusions resulting from the inspection. The findings and determinations made by Inspector

² Opioid dependence is a manifestation of brain changes resulting from chronic opioid abuse ... Brain abnormalities resulting from chronic use of heroin, oxycodone, and other morphine-derived drugs are underlying causes of opioid dependence (the need to keep taking drugs to avoid a withdrawal syndrome) ... The abnormalities that produce dependence ... appear to resolve after detoxification, within days or weeks after opioid use stops ... " (www.ncbl.nim.hin.gov. (U.S. National Library of Medicine).)

³ As defined in Health and Safety Code section 11010, "dispense" means "to deliver a controlled substance to an ultimate user ... pursuant to the lawful order of a practitioner, including the prescribing, furnishing, packaging, labeling, or compounding necessary to prepare the substance for that delivery."

⁴ Government Code section 11425.5, subdivision (b), third sentence.

Shafir are found to be reliable and accurate. The investigative report, which consists of more than 40 pages, along the inspector's testimony at the hearing, underpin Factual Findings 12 through 22:

INVESTIGATIVE FINDINGS AND CONCLUSIONS - FIRST CAUSE FOR DISCIPLINE

12. Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, possessed pharmaceutical preparations and drugs that did not conform with the standards and tests for quality and strength for prescription medications, as established by, or provided in, the latest edition of the United States Pharmacopeia⁵ or the National Formulary.⁶ Moreover, the pharmaceutical preparations and drugs possessed by respondent Jefferson Plaza Pharmacy, as controlled, directed and supervised by respondent Chan, violated provisions of the Sherman Food, Drug and Cosmetic Law (Health & Saf. Code, § 109875, et seq.).

On July 12, 2013, Inspector Shafir detected, and documented in detail, that respondent Chan enabled, facilitated, and permitted such poor control of supply records and inventory control measures so that numerous outdated drug products, on the premises of respondent Jefferson Plaza Pharmacy, were not only included in compounding bulk ingredients but also were stored as part of the general inventory of respondent pharmacy.

In these regards, respondents' acts and omissions violated the Pharmacy Law. (Bus. & Prof. Code, § 4000 et seq.)

INVESTIGATIVE FINDINGS AND CONCLUSIONS - SECOND CAUSE FOR DISCIPLINE

13. Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, failed to maintain the subject pharmacy's facilities, spaces, fixtures and equipment items in a manner that drugs could be safely and

⁵ The U.S. Pharmacopeial Convention (USP) is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the Food and Drug Administration, and these standards are used in more than 140 countries. (www.usp.org)

⁶ The National Formulary has as its full name, "United States Pharmacopeia and National Formulary" (USP-NF). It is an official publication, issued first by the American Pharmaceutical Association and now yearly by the United States Pharmacopeial Convention, that gives the composition, description, method of preparation, and dosage for drugs. The book contains two separate official compendia, which are identified as the USP and the N F. The United States Pharmacopeia (USP), established in 1820, contains legally recognized standards of identity, strength, quality, purity, packaging, and labeling for drug substances, dosage forms, and other therapeutic products, including nutritionals and dietary supplements. The National Formulary (NF), established in 1888 by the American Pharmaceutical Association, includes standards for excipients, botanicals, and other similar products. USP purchased the NF in 1975, combining the two publications under one cover, creating the USP-NF. (www.medicines.net)

properly prepared, maintained, secured and dispensed. Also, respondent Jefferson Plaza Pharmacy, together with, and under the control, direction and supervision of respondent Chan, failed to maintain the subject pharmacy's fixtures and equipment in a clean and orderly condition.

On July 12, 2013, Inspector Shafir detected, and documented in detail, that the general pharmacy premises, as well as the drug prescription compounding areas, at respondent Jefferson Plaza Pharmacy were extremely disorganized, dirty and excessively cluttered with equipment, papers and other objects. Moreover, Inspector Shafir observed that the drug stock at the premises of respondent Jefferson Plaza Pharmacy included an inordinate number of outdated products. During an overview sampling of medications on shelves and in drawers at the premises of respondent Jefferson Plaza Pharmacy, in her review of both compounding bulk ingredients and regular drug inventories, Inspector Shafir identified over 50 (fifty) expired drugs. And, some outdated drugs, as located inside a pharmacy storage drawer, had no label showing clear indications that the drugs had been quarantined for destruction. The identified drugs, which did show expiration dates, ranged from November 2007 to the inspection date on July 12, 2013.

In these regards, respondents' acts and omissions violated the Pharmacy Law.

INVESTIGATIVE FINDINGS AND CONCLUSIONS - THIRD CAUSE FOR DISCIPLINE

14. Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, failed to maintain a written policy and procedures manual for compounding. Respondents failed to maintain clearly defined compounding policy and procedures to reflect the compounding activities of the pharmacy.

On July 12, 2013, Inspector Shafir detected, and documented in detail, that respondent Chan failed to assure that respondent Jefferson Plaza Pharmacy maintained on the premises current written compounding policies and procedures.

In these regards, respondents' acts and omissions violated the Pharmacy Law.

INVESTIGATIVE FINDINGS AND CONCLUSIONS - FOURTH CAUSE FOR DISCIPLINE

15. Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, failed to maintain written documentation sufficient to demonstrate that respondents' pharmacy personnel had the skills and training to perform compounding activities. Respondents failed to develop and maintain an on-going competency evaluation process.

On July 12, 2013, Inspector Shafir detected, and documented in detail, that respondent Chan failed to possess any form of board approved training records for the pharmacy staff who engaged in compounding activities at and for respondent Jefferson Plaza Pharmacy. The investigator's discovery was of particular concern in that respondents employed a person (Ms. Esmabe), who did not hold a valid pharmacy technician registration; yet, that person who did not possess a valid technician registration performed, each month,

many acts of compounding of prescriptions. There was no record that Ms. Esmabe had received training by, or through, respondents.

In these regards, respondents' acts and omissions violated the Pharmacy Law.

INVESTIGATIVE FINDINGS AND CONCLUSIONS - FIFTH CAUSE FOR DISCIPLINE

16. Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, failed to maintain a written policy and procedure designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

On July 12, 2013, Inspector Shafir detected, and documented in detail, that respondent Chan failed to assure that Jefferson Plaza Pharmacy possessed on its premises clearly defined compounding policies and procedures so as to document and reflect all compounding activities performed at the subject pharmacy. Respondents failed to possess on the premises of the subject pharmacy any written quality assurance plans for compounded prescriptions. And, respondent Jefferson Plaza Pharmacy's inadequately crafted compounding log reflected that Ms. Esmabe had compounded a majority of prescriptions each month for, at least, the period of January 19, 2013, to July 9, 2013.

In these regards, respondents' acts and omissions violated the Pharmacy Law.

INVESTIGATIVE FINDINGS AND CONCLUSIONS – SEVENTH⁷ CAUSE FOR DISCIPLINE

17. Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, allowed Ms. Esmabe to compound prescriptions without possessing either a pharmacist license or a valid pharmacy technician⁸ registration.

On July 12, 2013, Inspector Shafir detected, and documented in detail, that respondent Chan allowed, enabled and assured that on the premises of respondent Jefferson Plaza Pharmacy, Ms. Esmabe engaged in the activities constituting the process of compounding numerous prescriptions without possessing a license or registration. Ms. Esmabe engaged in unlicensed activity regarding the duties,⁹ functions and responsibilities reserved for a holder

⁷ By reason of the stipulated settlement between complainant and respondent Esmabe, the Accusation's Sixth Cause of Discipline is subject to dismissal.

⁸ California Code of Regulations, title 16, section 1793, defines "Pharmacy technician" to mean "an individual who, under the direct supervision and control of a registered pharmacist, performs packaging, manipulative, repetitive, or other nondiscretionary tasks related to the processing of a prescription in a licensed pharmacy, but who does not perform duties restricted to a registered pharmacist under section 1793.1."

⁹ California Code of Regulations, title 16, section 1793.2, sets forth that a holder of valid pharmacy technician registration "may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting, and while under the direct supervision and control of, a

of a valid pharmacy technician registration. Ms. Esmabe performed unlicensed and therefore unlawful activities, over, at the very least, the time frame of January 19, 2013, to July 9, 2013.

Although on January 11, 2010, the board had issued an intern pharmacist license (INT 25497) to Ms. Esmabe, that intern license was cancelled effective January 31, 2012. And, the board did not issue Ms. Esmabe a pharmacy technician registration (TCH 124483) until August 23, 2013. At the time of Inspector Shafir's site investigation, Ms. Esmabe possessed neither a license nor a registration.

In these regards, respondents' acts and omissions violated the Pharmacy Law.

INVESTIGATIVE FINDINGS AND CONCLUSIONS - EIGHTH CAUSE FOR DISCIPLINE

18. Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, failed to comply with respondents' corresponding responsibility to ensure that controlled substances¹⁰ were dispensed for a legitimate medical purpose. When respondents dispensed or furnished prescriptions for controlled substances, they did so despite the presence of numerous "red flags," which reasonable prudent and vigilant pharmacy licensees would have warned to either refuse to fill the prescription or to acquire explicit input from a medical treatment licensee as to the basis for the frequent, large or unusual request for the controlled substance.

On July 12, 2013, Inspector Shafir detected, and documented in detail, that respondent Chan and other personnel of respondent Jefferson Plaza Pharmacy dispensed controlled substances in accordance with prescriptions written by prescribers, and for patients on a refill basis, who had either offices or residences outside of the subject pharmacy's expected, or normal, service area. Respondents or their personnel filled prescriptions without positively verifying whether the prescriptions for consumers were issued by medical care providers for legitimate medication purposes. Moreover, respondents

registered pharmacist." Further, 'Nondiscretionary tasks' as used in Business and Professions Code section 4115, include: (a) removing the drug or drugs from stock; (b) counting, pouring, or mixing pharmaceuticals; (c) placing the product into a container; (d) affixing the label or labels to the container; [and] (e) packaging and repackaging."

¹⁰ Controlled Substance means any substance listed in Chapter 2 (commencing with section 11053) of Division 10 of the Health and Safety Code. And the phrase "dangerous drug" is defined, in pertinent part, at Business and Profession Code section 4022 to mean: "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.

and especially respondent Chan failed to use pharmacy-industry tools or programs, such as the Prescription Drug Monitoring Program, so as to verify early, or duplicate, dispensing requests by patients, who were either “doctor shopping” or “pharmacy shopping.” Inspector Shafir pointed to the records for patients such as Camilla H. and approximately nine other individuals for whom respondents violated the Pharmacy Law in the way respondents failed to scrupulously adhere to the corresponding responsibility law and doctrine.

Furthermore, Inspector Shafir detected, and documented in detail, that over the time frame of July 11, 2010, to July 11, 2013, respondent Jefferson Plaza Pharmacy, as controlled and supervised by respondent Chan, dispensed large number of prescriptions (in an amount of 25,261 doses) of controlled substances. Of that number of prescriptions for narcotics, 4,178 prescriptions were written by Bernard Wilcosky, M.D., who prescribed large quantities of “drug cocktails” of controlled substances. Respondents honored many early refills for patients of Dr. Wilcosky in an excessive number as shown by CURES¹¹ data that pertained to that medical doctor’s patients. In addition, the investigation revealed that respondents refilled prescription “too soon,” that is the prescriptions were filled well before the a previously dispensed supply of controlled substance had been exhausted according to industry standards for consumption of the prescribed medications. Also, respondent’s practice exhibited “therapeutic duplications,” that is, respondents dispensed narcotics to the same individual for various strengths of a narcotic or narcotic combination so as to provide a suspect “drug cocktail.” Respondents dispensed controlled substances to various patients, who were using multiple pharmacies to fill prescriptions. And, respondents dispensed controlled substances to patients who were using different doctors to act as prescribers of narcotics. Inspector Shafir, who had limited time to review respondents’ records and she was, therefore, unable to account for the vast number of prescription records, created tables regarding nine consumers for whom respondents violated, at a minimum, the basic precepts of the corresponding responsibility law or doctrine.¹² By neglecting to use CURES, respondents dispensed

¹¹ CURES is the “Controlled Substance Utilization Review and Evaluation System,” part of a California’s prescription drug monitoring program. The program began in 1998. It is a mandatory monthly pharmacy reporting program for dispensed Schedule II drugs. The program was amended in January 2005 so as to include mandatory weekly reporting of Schedule II through IV drugs. The data is collected statewide and such data can be used by health care professionals, including pharmacists and drug prescribers, to evaluate and to determine whether patients are utilizing prescribed controlled substances lawfully and correctly.

¹² For the time span of July 11, 2010, to July 11, 2013, respondents dispensed controlled substances, for example, as follows:

Consumer Alan S. was allowed to fill with respondents a total of 303 prescriptions for various controlled substances, which were all issued by Dr. Wilcosky. Consumer Alan S. filled prescriptions through 28 different pharmacies, which were located in 22 different cities; but, respondent Jefferson Plaza Pharmacy filled 41 percent of the prescriptions for Alan S. For the time studied by the inspector, Alan S. obtained a total of 30,479 tablets of various strengths of Oxycontin ER and oxycodone IR.

Consumer Lisa B. was allowed to fill with respondents a total of 134 prescriptions for various controlled substances. Over the period studied, she used 10 different pharmacies in six different cities as well as prompted five different physicians in five separate cities to enable her to procure narcotics. Among other things, over a 35-day period (July 5 through August 9, 2012), Consumer Lisa B. was allowed to fill three prescriptions for oxycodone (30 mg), for a total of 780 tablets that is ordinarily a 60-day supply. And, over a 22-day period (May 20 through June 11, 2013), Consumer Lisa B. was

controlled substances to patients whose conduct demonstrated "doctor shopping" and "pharmacy shopping." Respondent ignored well-recognized "red flags," which required respondent to verify that a prescription was issued for a legitimate medical purpose. The "red flags" were ignored because of respondents' gross dereliction of the corresponding responsibility doctrine, which included respondents:

- Filling prescriptions for consumers who came from well outside the pharmacy service area. And honoring prescriptions written by health care providers having offices well outside respondents' service area;
- Accepting cash payment tendered by consumers. Respondent Jefferson Plaza Pharmacy accepted cash, as opposed to third-party insurance payment, for nearly 26 percent of its sales of narcotics. (Comparable pharmacies accept cash in less than 15 percent of sales of controlled substances versus receiving insurance payments for the sale.);
- Failing to use PDMP to evaluate whether consumers were procuring prescriptions for legitimate purposes;
- Filling prescriptions for many consumers who traveled significant distances from residences to the premises of respondent Jefferson Plaza Pharmacy;
- Early dispensing of controlled substances for various consumers, which were explicitly noted in CURES data as well as respondents' computer data.

In these regards, respondents' acts and omissions violated not only the Pharmacy Law but also Health and Safety Code section 11153, subdivision (a). (Extensive discussion of the cited Health and Safety Code provision is set out, below, under Legal Conclusions.)

allowed to fill three prescriptions for hydrocodone/APAP for a total of 780 tablets that is ordinarily a 70-day supply. For the narcotics procuring by Lisa B., respondent filled one prescription on May 20, 2013, and another prescription 15 days later on June 5, 2013. All of the prescriptions were paid for with cash.

Consumer Charles B. was allowed to fill with respondents and other pharmacies a total of 201 prescriptions for various controlled substances. He used nine different pharmacies, but the majority of the prescriptions were filled by respondent Jefferson Plaza Pharmacy. Consumer Charles B. used four different physicians located in three different cities.

Consumer Brian D. was allowed to fill 173 prescriptions for various controlled substances. He used five pharmacies located in three cities, but 87 percent of the prescriptions for Consumer Brian D. were filled by respondent Jefferson Plaza Pharmacy.

Consumer Nancy G. was allowed to fill 181 prescriptions for various controlled substances. She used 25 different pharmacies located in 16 different cities, but respondent Jefferson Plaza Pharmacy filled in excess of 20 percent of the prescriptions presented by Consumer Nancy G. She used 23 different physicians located in 16 cities during the subject time span.

INVESTIGATIVE FINDINGS AND CONCLUSIONS - NINTH CAUSE FOR DISCIPLINE

19. Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, from July 11, 2010, through July 11, 2013, furnished excessive amounts of controlled substances in violation of Health and Safety Code section 11153, subdivision (a). In particular, from July 11, 2010, through July 11, 2013, respondents dispensed to consumers 25,261 prescriptions for various controlled substances. Respondents dispensed to consumers 204,195 doses of Hydrocodone/APAP 10/325 milligrams, and 528,718 tablets of Oxycodone¹³ 30 milligrams. The amounts of the controlled substances sold by respondents far exceeded the volumes of the same type of narcotics dispensed by other pharmacies, which were located in close proximity to the premises of respondent Jefferson Plaza Pharmacy. And those other pharmacies maintained longer hours of operation than respondents' business premises.

For the time period studied by Inspector Shafir, the hours of operation of respondent Jefferson Plaza Pharmacy were 9:00 a.m. until 6:30 p.m. on Mondays through Fridays; and, 9:00 a.m. until 5:00 p.m. on Saturdays, but the pharmacy was closed on Sundays. Within 1.4 miles of respondents' premises, a Safeway Store's pharmacy is located. That Safeway pharmacy operated Monday through Fridays from 9:00 a.m. until 8:00 p.m., and was open on both Saturdays and Sundays from 9:00 a.m. until 5:00 p.m. And at a distance of 1.3 miles from respondent Jefferson Plaza Pharmacy, a Rite Aid Pharmacy operated from 8:00 a.m. until 10:00 p.m. on Monday through Friday as well as on Saturday from 9:00 a.m. until 6:00 p.m., and on Sundays from 10:00 a.m. until 6:00 p.m. And, at a distance of 0.3 miles from respondent Jefferson Plaza Pharmacy another Rite Aid Store's pharmacy operated from 9:00 a.m. until 9:00 p.m. on Monday through Friday as well as on Saturday from 9:00 a.m. until 6:00 p.m., and on Sundays from 10:00 a.m. until 6:00 p.m.

While respondent Jefferson Plaza Pharmacy dispensed 205,195 tabs of Hydrocodone, and 528,718 tabs of Oxycodone, the three neighboring pharmacies, over the period of July 11, 2010, until July 11, 2013, dispensed those controlled substances as follows:

| <i>Pharmacy</i> | <i>Hydrocodone/APAP (10/325 mg)</i> | <i>Oxycodone (30mg)</i> |
|---------------------|-------------------------------------|-------------------------|
| Safeway Pharmacy | 112,357 tabs | 56,501 tabs |
| Rite Aid (No. 5892) | 190,960 tabs | 41,727 tabs |
| Rite Aid (No. 5893) | 120,268 tabs | 15,530 tabs |

In these regards, respondents' acts and omissions violated the Pharmacy Law.

¹³ Oxycodone is a semi-synthetic narcotic analgesic with multiple actions qualitatively similar to those of Morphine. It is a Schedule II controlled substance and narcotic as designated by Health and Safety Code section 11055, subdivision (b) (1). And, oxycodone is a dangerous drug under Business and Professions Code section 4022. Oxycodone can produce drug dependence and has the potential for being abused.

INVESTIGATIVE FINDINGS AND CONCLUSIONS - TENTH CAUSE FOR DISCIPLINE

20. Respondent Chan failed to use his education, training, and experience as a pharmacist when he filled prescriptions for large quantities of narcotics for consumers, who used multiple prescribers so that those consumers could obtain early refills at and through respondent Jefferson Plaza Pharmacy.

When respondent Chan executed 25,251 prescriptions and dispensed controlled substances under that number of prescriptions, so as to dispense 204,195 doses of Hydrocodone/APAP¹⁴ 10/325 mg and 528,718 tablets of Oxycodone 30 mg, he failed to properly, professionally or ethically use his education, training and experience as a licensed pharmacist. Also, respondent Chan failed to use his education, training and experience as a licensed pharmacist when he filled prescriptions for large quantities of narcotics for patients who used multiple prescribers or obtained early refills through the facilities of Jefferson Plaza Pharmacy.

In these regards, respondents' acts and omissions violated the Pharmacy Law.

INVESTIGATIVE FINDINGS AND CONCLUSIONS - ELEVENTH CAUSE FOR DISCIPLINE

21. Respondent Chan failed to exercise or implement his best professional judgement or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services authorized by his pharmacist's license. In particular, from July 11, 2010, through July 11, 2013, respondent Chan filled prescriptions for large quantities of narcotics for patients who used multiple prescribers, paid cash, and obtained early refills at and through respondent Jefferson Plaza Pharmacy. Respondent Chan engaged in those practices without taking proper or thorough measures to confirm the prescriptions through explicit inquiries of the medical care providers who purportedly issued the prescriptions. Accordingly, respondent's failure to confirm the proper, correct and appropriate extent of prescriptions did not verify or assure that large quantities of narcotics were prescribed for legitimate medical purposes.

When respondent Chan executed 25,251 prescriptions and dispensed controlled substances under that number of prescriptions so as to dispense 204,195 doses of Hydrocodone/APAP 10/325 mg and 528,718 tablets of Oxycodone 30 mg, he failed to exercise corresponding responsibility by filling prescriptions for large quantities of narcotics for patients who used multiple prescribers and obtained early refills at Jefferson Plaza Pharmacy. When respondent Chan committed such acts or omissions he failed to take measures to confirm the prescriptions, and the large quantities of narcotics, were prescribed for legitimate medical purposes.

¹⁴ Hydrocodone with APAP is also known by brand names of Vicodin and Lortab. Hydrocodone is a Schedule III controlled substance under Health and Safety Code section 11056, subdivision (e). Hydrocodone with APAP is a dangerous drug as defined by Business and Professions Code section 4022.

In these regards, respondents' acts and omissions violated the Pharmacy Law.

TWELFTH CAUSE FOR DISCIPLINE – UNPROFESSIONAL CONDUCT

22. By virtue of the violations established in Factual Findings 12 through 21 above, Respondent Jefferson Plaza Pharmacy and respondent Chan engaged in unprofessional conduct, as established by the clear and convincing evidence, as alleged under the Twelfth Cause of Discipline in complainant's Accusation.

Finding Regarding Effect of Respondents' Cross Examination of Complainant's Inspector

23. Respondents' cross-examination of complainant's sole witness did not establish that Inspector Shafir's testimony or her investigative conclusions were unclear or less than convincing regarding respondents' unprofessional acts and omissions as set out in Factual Findings 12 through 21.

Respondents' Case-in-Chief

RESPONDENTS' WITNESSES IN MITIGATION

BERNARD R. WILCOSKY

24. Bernard R. Wilcosky (Dr. Wilcosky) offered extensive testimonial evidence at the hearing.

Dr. Wilcosky is a physician who, over a career of 30 years, has focused upon a medical practice oriented towards pain management. He is a board-certified anesthesiologist. In 1993, he took the very first examination for the pain practitioner-specialists. Dr. Wilcosky is a member of American Academy of Pain Medicine and the American Academy of Pain Management. And, he is recognized as an Advanced Practitioner through the American Academy of Pain Management.

At the hearing of this matter, Dr. Wilcosky presented testimony regarding his provision of treatment to patients having grave pain or disabling physical discomfort, which must be primarily attended to with strong pain medication therapy.

25. Over a period of approximately five years, Dr. Wilcosky has known respondent Chan. As a pain treatment specialist, Dr. Wilcosky thinks highly of respondents' capabilities and facilities. And, Dr. Wilcosky notes that respondents have made it "easy" for his pain-impaired patients to acquire narcotics, which are necessary to control pain.

26. Despite his favorable estimation of respondents, Dr. Wilcosky offered no testimonial evidence to refute complainant's Accusation's First through Fifth and Seventh through Eleventh Causes, which resulted in Factual Findings 12 through 21, above.

Dr. Wilcosky was not persuasive with his testimony regarding the needs of patients to fill numerous narcotics through many prescriptions. And, Dr. Wilcosky was not credible when he asserted at the hearing that he did not recommend that his patients, who consume significant doses of controlled substances, seek out respondents, without those board licensees adhering to corresponding responsibility principles. Dr. Wilcosky did not establish that he has examined the computer records, or other data, pertaining to respondents' methods and practices for dispensing controlled substances and respondents' efforts to document verifying with prescribing medical treatment providers the supporting information for the level of controlled substances sold through respondents' pharmacy business.

27. On cross-examination, Dr. Wilcosky was shown not to have as close a working relationship with respondent Chan. Among other things, Dr. Wilcosky believed that respondent Chan's name was "Chang." And, Dr. Wilcosky was not believable when he suggested that he held necessary communications with respondent Chan regarding most prescriptions written by the physician for his patients to acquire controlled substances through respondents.

Dr. Wilcosky was shown to hold disdain for the so-called chain pharmacies, that is, the large corporate pharmacies. He has views that his opioid-using patients have been made uncomfortable in attempting to fill prescriptions at the large chain pharmacies. Dr. Wilcosky has concluded that respondents have shown great accommodations toward his patients who must take significant amounts of narcotics to control pain.

GEORGE PON

28. George Pon gave testimonial evidence at the hearing of this matter.

Mr. Pon is a registered pharmacist. He has been licensed for "forty-something" years. Although he is retired from a day-to-day practice, Mr. Pon maintains an active license with the board.

Mr. Pon graduated in 1970 from the University of Idaho with a bachelor's of science degree in pharmacy science. His first professional employment position in California was as a pharmacist for the Payless Drug Stores. But, most of his career as a pharmacist was spent with Kaiser Permanente Medical facilities, where he had a long-term assignment in Redwood City, San Mateo County.

Mr. Pon has known respondent Chan for "about 30 years."

Mr. Pon has been president of the San Mateo County Pharmacists Association, as well as a member of the board of directors for that organization. Mr. Pon is aware that respondent has served as treasurer of the San Mateo County Pharmacists Association for the last few years. Currently, respondent Chan provides services to the association as not only treasurer but also as the volunteer organization's member who files reports with state and federal government entities due to the association's "501(c)(3)" status. Mr. Pon reviews respondent Chan as having great qualities consistent with being a "detailed, on-time"

individual. Mr. Pon views respondent Chan as a person who makes important suggestions regarding the association's use of its financial resources.

On approximately five occasions as a "relief pharmacist," Mr. Pon has worked for respondents on the premises of Jefferson Plaza Pharmacy. And, he interacted with Ms. Esmabe within the pharmacy.

Mr. Pon pointed out that respondent Chan has been the recipient of William Dugoni Memorial Lifetime Achievement Award as granted by the San Mateo County Pharmacists Association. The award is a synthesis of the organization's members' collective respect and admiration for respondent's commitment to the association as well as an appreciation for his knowledge of pharmacy. Also, respondent received the association's "Pharmacist of the Year" Award on more than one occasion.

Mr. Pon advanced that complainant's allegation of unprofessional conduct on respondents' part, "just cannot be" a reality. Mr. Pon asserts that over the years he has known respondent Chan to have only exhibited great professionalism as a pharmacist. He asserts the Accusation's allegations "make no sense" because Mr. Pon has observed respondent in work settings, and Mr. Pon is aware that respondent Chan has provided great services to elderly and infirm consumers.

29. Despite his high estimation of respondents, Mr. Pon did not show that he has engaged in an audit, or other detailed review of the actual practices and procedures executed by respondents.

Mr. Pon offered no testimonial evidence to refute complainant's Accusation's First through Fifth and Seventh through Eleventh Causes for Discipline, which resolved in Factual Findings 12 through 21, above.

TERESA LOUISE BITTNER

30. Teresa Louise Bittner (Dr. Bittner) offered compelling testimony at the hearing.

Dr. Bittner is currently a college mathematics professor. She once occupied a position as a chief executive officer for an educational textbook services publishing company.

Approximately 16 years ago, Dr. Bittner was impacted by the adverse effects of debilitating disease. The disease process had incapacitating abdominal pain as one of the manifestations of the disorder. She spent a year as an inpatient in a hospital because of the disease.

Dr. Bittner has been a customer of respondents for 20 years. And with the intensification of the disease that impacts her, Dr. Bittner greatly relies on respondents' services. In her view, respondents operate a community-based pharmacy, which is greatly appreciated by Dr. Bittner and her family.

To manage the illnesses and disease, Dr. Bittner acquires, at this time, no less than three controlled substances from respondents. She has two prescribers, both a rheumatologist and a pain management physician, who issue prescriptions for her to acquire the narcotics from respondent.

Dr. Bittner notes she has a complicated case, which includes her allergies to various substances. She observes that respondent Chan has "always watched out" for her particular needs with regard to her acquiring controlled substances.

As recently as the day prior to her testimony, Dr. Bittner had heard from her treating rheumatologist that that medical doctor receives telephone inquiries from respondent Chan regarding the prescriptions presented to Dr. Bittner through respondent Jefferson Plaza Pharmacy. According to Dr. Bittner, her treating medical doctor has reported being impressed with respondent Chan, and the physician views respondent Chan as being "a very good pharmacist," who works with Dr. Bittner's treating physician so as to solve problems with prescriptions.

Dr. Bittner is impressed with the physical plant that makes up the premises of respondent Jefferson Plaza Pharmacy. She understands respondents have a good system to assure that expired drugs are not distributed to the public.

Should respondent Jefferson Plaza Pharmacy close because of license revocations, Dr. Bittner does not know what she will do to readily fill her prescription for pain relief medications. She fears that the "big box" pharmacies may not expeditiously fill the level of prescriptions for controlled substances that she requires to comfortably live with her various disease processes.

31. Notwithstanding the poignant, heart-felt statements from Dr. Bittner, some aspects of her testimony were not plausible. She did not state, for example, that on any occasion when a corporate pharmacy has denied the filling of a prescription for her to acquire a controlled substance that she has filed a complaint with the board based on the large pharmacy's violation of Business and Professions Code section 733.¹⁵ And even though it might be inconvenient for a family member of Dr. Bittner to drive one or two miles to a large, corporate-oriented pharmacy, Dr. Bittner was not believable that the revocation of respondents' licensure status would result in a grave hardship to her or other consumers who have procured narcotics from respondent.

¹⁵ Business and Professions Code section 733 sets out, in part:

(a) A licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

RESPONDENT CHAN'S BACKGROUND AND MATTERS IN MITIGATION

32. In 1978, respondent Chan graduated from University of the Pacific in Stockton, California with a doctorate degree in Pharmacy. Earlier in his advanced formal education years in the United States, he spent one year (1975) in studies at the University of Wisconsin, School of Medicine, but he did not earn a degree from that university.

33. Respondent Chan has been a licensed pharmacist for 35 years. He was first employed by Thrifty Drugs before working as the pharmacist-in-charge at Jefferson Plaza Pharmacy.

Respondent Chan views respondent Jefferson Plaza Pharmacy as a family-owned pharmacy, which for 30 years has been owned, in part, by his wife.

34. Jefferson Plaza Pharmacy employs five individuals, including respondent Chan and his wife. As a local, community pharmacy, respondent Jefferson Plaza Pharmacy serves several retirement homes and elderly people. And, the pharmacy provides services to local hospice facilities and other medical treatment institutions in proximity to the premises of the pharmacy.

Unlike the large corporate pharmacy enterprises, respondent Jefferson Plaza Pharmacy makes home delivery of narcotics and controlled substances used by patients to treat disabling pain and grave physical discomfort.

35. Respondent Chan asserts that respondent Jefferson Plaza Pharmacy is very consumer oriented and that consumers pay relatively lower prices for drugs when compared to large corporate-owned pharmacies. Cash paying consumers receive price discounts under the policy established by respondent Chan. And, respondent Jefferson Plaza Pharmacy operates as a "fast and efficient" pharmacy.

Respondent Chan claims that respondent Jefferson Plaza Pharmacy receives very good reviews in various rating guides for consumers. He produced pages from the Yelp internet site's set of glowing and very complimentary consumer reviews for respondents, especially of Jefferson Plaza Pharmacy as compared with large corporate pharmacies.

RESPONDENTS' PROGRESS TOWARDS REHABILITATION

36. Respondent Chan has the respect of individual health care providers. At the hearing, respondent offered five letters.¹⁶ Those letters, which supplement and explain¹⁷ other evidence, especially respondent's testimony, include remarks such as:

¹⁶ A letter, dated October 2, 2014, by Sagee Thirucote, president-elect, San Mateo County Pharmacists Association; a letter, dated October 1, 2014, by David A. Jacoby, M.D.; a letter, dated October 1, 2014, by Chau Phan, M.S., Pharm.D., president, San Mateo County Pharmacists Association; a letter, dated June 1, 2015, by R. Elaine Lambert, M.D., Adjunct Clinical Professor of

As a member of [San Mateo County Pharmacists Association, respondent Chan] has been serving as treasurer for over 10 years. As ...treasurer, he has displayed stellar professionalism, great motivational skills and accuracy. In addition ... he volunteered his time to help lobby for the passage of several pharmacy bills, at senior health care centers, sponsor[ed] pharmacy students for various events (letter by Sagee Thirucote)

[Respondents] have been uniformly responsive and helpful to my patients, as well as to my staff and me. [¶]...[¶] ... [Respondents] give excellent service ... (letter by David A. Jacoby, M.D.)

[Respondent Chan] is one of the oldest and most trusted member in the [San Mateo county Pharmacists Association] Throughout the years, I have not had any reasons to doubt [respondent Chan's] integrity as a person or as our fellow member who handles our finances (letter by Chau Phan, M.S., Pharm.D.)

Since I moved to private practice, I have had many patients who have filled their medications regularly at Jefferson Plaza Pharmacy and have interacted with [respondent Chan]. I have had numerous conversations with [respondent Chan] regarding patients of mine who fill medications, as well as he has initiated calls to me when he had concerns about patients' usage of their opioids. I have never been aware of any instances when [respondent Chan] did not fill any prescription accurately or provide the medication to patients in a timely manner. [¶¶] It is very important that independent pharmacists, who have a special interest in dealing with chronic pain patients, such as [respondent Chan], be allowed to remain in independent pharmacy practice. [¶...¶.] I give [respondent Chan] my full support as a qualified and compassionate pharmacist in my area ... (letter by R. Elaine Lambert, M.D.)

After several months of frustration at getting my prescriptions needs met, my pain management physician recommended I see [respondent Chan] at Jefferson Plaza Pharmacy [¶ ... ¶] What a relief from all the nonsense and negativity I experienced at [three named national pharmacy chains]! [Respondent Chan] and his team were a breath of fresh air, always ready with a smile and a pleasant, 'can do' attitude even the most complex script requests. [¶]... I've gone nowhere else since discovering this hidden gem and I always recommend Jefferson Plaza Pharmacy whenever I get the chance... (letter by Jeff Wasel, Ph.D.)

Medicine (Rheumatology) Stanford School of Medicine; and, a letter, dated September 20, 2014, by Jeff Wasel, Ph.D.

¹⁷ Government Code section 11513, subdivision (d).

37. Since the date that respondent Chan became aware of Inspector Shafir's Investigative Report, which described the clutter, disorganization, and dirty, unhealthy appearance of the pharmacy's premises and compounding work area, the pharmacist-in-charge has caused respondent Jefferson Plaza Pharmacy's premises to be thoroughly cleaned. Respondent Chan directed that the work areas within the pharmacy, including the compounding space, be remodeled. The remodeling has included adding shelves and removing many previously unsightly features at Jefferson Plaza Pharmacy. (At the hearing of this matter, respondents presented recent photographs (taken in approximately June 2015) of the interior of Jefferson Plaza Pharmacy that show images of the conditions that are dramatically improved relative to the July 2013 images, which are included in complainant's Investigative Report as prepared by Inspector Shafir.)

38. Currently, respondent Chan is actively using a "Compounding Self Assessment" questionnaire to meet the requirements of the board's regulations (Cal. Code Regs., tit. 16, §§ 1735 & 1735.1) for a community pharmacy engaged in crafting compounds for prescriptions. Also, respondent Chan has created for respondent Jefferson Plaza Pharmacy a two-page document titled "Compounding Policies and Procedures."

39. Respondent Chan has developed, for use in assessing personnel of Jefferson Plaza Pharmacy a form titled, "Pharmacist/ Pharmacy Technician Performance Evaluation." The evaluation form has been used, according to respondent Chan, every three months so as to assure the professionalism of board licensees working at Jefferson Plaza Pharmacy.

40. Since the Investigative Report by Inspector Shafir, respondent Chan has authored a document titled, "Standard Operating Procedure Manual" for Jefferson Plaza Pharmacy. The manual's pages set out impressive goals and performance standards that are to be executed by personnel working for respondent Jefferson Plaza Pharmacy.

41. Both respondent Chan and Ms. Esmabe, who is working as a pharmacist trainee, have taken several continuing professional education courses in subjects pertaining to: (i) "compounding" as well as (ii) handling and dispensing controlled substances. Respondent Chan's recent continuing education courses, which have been amassed in the immediately-aforestated two critical areas, include:

| <i>Course Name</i> | <i>Date</i> |
|--|-----------------|
| "Drugs, Drugs and More Drugs" | August 18, 2013 |
| "California Board of Pharmacy Update" | August 18, 2013 |
| "Combating Pharmacy Diversion" | August 18, 2013 |
| "Drug Theft Prevention" | August 18, 2013 |
| "Management of Common Pain Conditions Encountered by Osteoarthritis" | August 26, 2013 |
| "Regulatory and Ethical Issues in Pain Management" | August 26, 2013 |

42. Since the findings and conclusion as set out in complainant's Investigative Report regarding the custom within Jefferson Plaza Pharmacy for the compounding of suspected medications within the pharmacy's premises, respondent Chan has implemented a practice of sending, every three months, various drugs for independent analysis. At the hearing, respondent produced sample Certificate(s) of Analysis by Analytical Research Laboratories that have tested drugs compounded at Jefferson Plaza Pharmacy. Respondent Chan proclaims that the independent testing results have consistently shown the high quality of the products compounded by, or under the direction of, respondent Chan.

43. With regard to respondents having used respondent Maricon Payte Esmabe (Ms. Esmabe) as an unlicensed pharmacy technician, respondent Chan provided a poignant account of the young woman's struggles and the aid given her by respondent Chan.

Ms. Esmabe graduated from a pharmacy college in the Philippines. Respondents hired her as a pharmacy technician and potential intern. Ms. Esmabe experienced difficulty in passing the board's pharmacist licensing examination, which she failed on two attempts. When she did not pass the pharmacist examination, respondent Chan encouraged Ms. Esmabe to apply to gain registration as a pharmacy technician. Before she acquired the pharmacy technician registration, respondent Chan hired Ms. Esmabe as "an intern" because of her abilities in working with "retirement home" customers. In addition to working with the pharmacy's durable equipment and other supplies for the elderly, Ms. Esmabe did aid respondent Chan in compounding under his supervision. Respondent Chan noted that Ms. Esmabe's problem with passing the board's pharmacist's examination was her weakness in executing calculations for compounding, which is not an area of study in the pharmacist education regime in the Philippines. In order to gain strength with calculations, respondent Chan oversaw Ms. Esmabe's calculations for compounding. Ms. Esmabe signed the "compounding log" as directed by respondent Chan; but according to the uncorroborated testimony, respondent Chan was the only worker at Jefferson Plaza Pharmacy who actually engaged in compounding prescriptions. In time, Ms. Esmabe passed the board's examination for her registration as pharmacy technician, but due to a board requirement that she present a high school diploma from the Philippines a delay occurred for her to acquire actual registration. The delay in the registration for Ms. Esmabe occurred at the time of the on-site inspection (July 2013) by Inspector Shafir, which happened at a time before the board granted Ms. Esmabe's pharmacy technician registration on August 23, 2013. As of the date of the hearing (June 2015), Ms. Esmabe continued to work at Jefferson Plaza Pharmacy. (Respondent Chan observed that Ms. Esmabe has passed the board's examination for licensure as a pharmacist; but the actual licensure had been "held up" by the board due to the Accusation in this matter.)

Respondents did not call Ms. Esmabe to testify on matters advanced by respondent Chan. Hence, the after-the-fact rationalizations offered at the hearing cannot be given much weight as being credible and reliable.

44. Respondent Chan vividly asserts that he is a dedicated professional. He has been, and continues, to be an active member in the San Mateo Pharmacist Association. Respondent Chan promotes high professional standards for pharmacists, including traveling with a delegation of other licensees to Sacramento to meet with legislators on laws important to the pharmacy profession. Respondent Chan has been an organizer of such programs as "Talk to a Pharmacist Day" as held in Hillsdale Mall, where he offers free services to the public. Respondent Chan asserts that he has not misused his education in that he has sought to promote the role of a pharmacist.

45. Respondent Chan claims that he and respondent Jefferson Plaza Pharmacy are currently very diligent with the use of the CURES program. And, respondent Chan has devoted himself to daily use of the program's system to check the dispensing of controlled substances to all patients. He has not been "locked out" of the system for any measurable amount of time since the occurrence of the inspection by Inspector Shafir.

MATTERS THAT CAST NEGATIVE LIGHT UPON RESPONDENT CHAN

46. Respondent Chan was not credible when he described the inspection performed in July 2013 as "pretty confrontational." He was not persuasive when he testified that upon being confronted by Inspector Shafir he became nervous. Compellingly, respondent Chan asserted at the hearing that when he is confronted with conflicts he tends to "withdraw," and he cannot think very well. Hence, he wishes to imply that the supposed disagreeable, or purported hostile, disposition of the inspector resulted in respondent Chan's poor performance during the inspection so that he made inexact statements that resulted in the adverse findings and conclusions as to unprofessionalism by respondents.

Respondent Chan's unbelievable, after-the-fact rationalization for respondents' unprofessional acts and omissions, as revealed during Inspector Shafir's inspection, cannot be attributed to the inspector's supposed mean disposition or confrontational attitude, even if accurate, which is doubtful. Respondent Chan's testimony on this matter must be wholly discounted and deemed to be without merit.

Complainant's inspector made findings and reached determinations that were based upon close scrutiny of the objectively discernible poor conditions and disorganization of respondents' physical plants, which comprised of respondents' pharmacy and compounding areas; the compilation and analysis of records and documents furnished by respondent Chan; and, extensive study of the facts gathered over many hours following July 12, 2013. The bulk of the findings and determinations by Inspector Shafir were made well after the date, time and place of the actual inspection.

47. Respondent Chan was not accurate with his testimony that during the past year's board inspection, another inspector made no adverse findings against respondents. On cross-examination, complainant established that the immediate past inspection was actually deferred to a future date. And, the immediate past year's inspection did not necessarily give complimentary findings to respondents.

49. Respondent Chan's explanation at the hearing was wholly unbelievable regarding respondents' past limited use or reliance upon the CURES program's data to verify whether a patient was engaged in "pharmacy shopping," or otherwise improperly seeking to acquire narcotics. Despite his education and experience, respondent Chan unpersuasively claimed at the hearing that the use of the CURES)¹⁸ computerized system was very complex and that the program was not very reliable. Respondent Chan gave no evidence that the CURES system was "not very good" with the process of uploading data and that the CURES software program's requirement for frequent changes of passwords was a barrier for him to use that program.

50. During his direct testimony, respondent Chan falsely testified that expired medications were not used for the compounding of prescriptions at the licensed facility of respondent Jefferson Plaza Pharmacy. But, on cross-examination, respondent made an admission that, at least, on February 26, 2013, an ingredient number 2 (Gapapentin), used in compounding prescriptions, was an expired medication because it had an expiration date of May 30, 2011.

51. Respondent Chan unpersuasively sought to refute the determination by Inspector Shafir that an industry wholesale drug vendor, which sells controlled substances, had suspended its business with Jefferson Plaza Pharmacy in the way of delivering controlled substances to respondent because of the supposed excessive ordering of narcotics for dispensing through respondents. Respondent Chan produced at the hearing an invoice, dated June 8, 2015, issued by AmerisourceBergen that shows delivery to Jefferson Plaza Pharmacy of controlled substances including: Fentanyl; Methadone HCL; Oxycodone 30 mg.

Respondent Chan proclaimed that Inspector Shafir misunderstood his comments regarding the relationship between the drug whole sellers and Jefferson Plaza Pharmacy on the matter of a suspension of the narcotics supply due to respondents' inordinate volume of purchases of controlled substances.

Respondent Chan declared that respondents have never suffered an interruption or delay in delivery of controlled substances from any supplier. During the months of April 2015 and May 2015, respondent Jefferson Plaza Pharmacy received each month approximately 20 separate deliveries of controlled substances from the AmerisourceBergen company.

But, respondent Chan did not produce either a witness from, or a declaration under oath by, a representative of AmerisourceBergen company to correct or refute that the matter of the diminished supply of drugs to respondent, which was set out in the Investigative Report.

¹⁸ Notice is taken that California doctors and pharmacies must report to the California Department of Justice every schedule II, III and IV drug prescription that is written or dispensed within seven days. Pharmacies are required to do so under Health and Safety Code section 11165, subdivision (d). The information provided establishes the CURES database, which includes information about the drug dispensed, drug quantity and strength, patient name, address, prescriber name, and prescriber authorization number including DEA number and prescription number.

52. At the hearing of this matter, respondent was not credible when he attempted to retract a prior inconsistent statement made to Inspector Shafir on the date of the July 2013 inspection. Respondent Chan's statement is included in the Investigative Report. As noted above, the statement was that AmerisourceBergen had diminished or limited the shipment by that drug wholesale company of controlled substances to respondent Jefferson Plaza Pharmacy. On cross-examination, respondent Chan was shown to have either engaged in making false statements to the board inspector or to a physician specializing in pain management medicine about respondents experiencing a diminution of a supply of narcotics from a drug supplier due to limits placed on respondents because of the past large orders for controlled substances by respondent Jefferson Plaza Pharmacy.

53. At the hearing of this matter, respondent Chan failed, or refused, to acknowledge the potential harm to the public through the array of unprofessional acts and omissions detected by the board Inspector Shafir's investigation. Respondent Chan's attitude suggests an ethical lapse on his part.

54. The number and variety of recently detected violations of the Pharmacy Law by respondent were significant as established by the findings and determinations in complainant's Investigative Report and the testimony of Inspector Shafir.

55. Respondents' acts and omissions must be viewed as serious violations of the Pharmacy Law.

56. Respondents' violations as detected in the investigation by Inspector Shafir are very recent in time.

57. Due to the large volume of controlled substances sold by, or through, respondents, it is not difficult to infer that there were substantial financial benefits received by respondents from the collective misconduct and unprofessional acts and omissions as revealed by the weight of the evidence in this matter. Respondents' sale of tens of thousands of doses of controlled substances, more likely than not, translated into great profits for respondents.

Complainant's Request for Recovery of Costs of Investigation and Prosecution and Respondent's Objection to Imposition of Costs

58. Complainant requests that respondents be ordered to pay the board the costs of prosecution under Business and Professions Code section 125.3. In support of the request for cost recovery, complainant offers a declaration, dated June 2, 2015, by Inspector Manisha Shafir of the board, as well as complainant's personal declaration, also dated June 2, 2015, which supported the Certification of Investigative Costs. Also, the declaration, dated June 3, 2015, by Deputy Attorney General Settles was filed in support of the Certification of Prosecution Costs. The declarations state that the board has incurred the following costs in connection with the investigation and enforcement of complainant's accusation as follows:

| | |
|--|--------------------|
| California Department of Justice, Office of Attorney General | |
| Costs of Prosecution | \$15,940.00 |
| Complainant's Inspector's | |
| Investigative Costs | <u>\$13,846.30</u> |
| Total Costs of Investigation and Prosecution | \$29,786.30 |

59. The declarations by Inspector Shafir, complainant, and Deputy Attorney General Settles fairly present requisite information by which the reasonableness of the costs may be determined and weighed for the board's recovery for the investigation and prosecution activities before June 8, 2015, which was the commencement date for the hearing in this matter. The declarations and their attachments set forth general, yet clear, descriptions of the tasks performed during the investigation and prosecution of this matter, as well as the time spent in attending to such tasks, and the methods of tabulating the hours involved in calculating the costs, as required by California Code of Regulations, title 1, section 1042.

The comprehensive nature of the declarations, and the supporting documents, for the certifications of costs establish that the board is entitled to the total measure of its costs of investigation and enforcement. The time expended by personnel of the Department of Justice is well within reason and was justified and necessary to establish the extent of respondent's negligence, incompetence, and unprofessional conduct. The facts developed at the hearing indicate that the deputy attorney general devoted a reasonable amount of time, which is found to have been of a prudent nature, for the prosecution of this matter.

Complainant's investigative costs, as incurred through the in depth analysis, data gathering, requisite travel, and thorough report writing, support the expenses incurred. First, Inspector Shafir exerted time in nine distinct areas relating to the investigation, including: reviewing and prioritizing her assignments upon receipt of the investigative file; communicating with complainant, namely the board's executive officer; contacting and interviewing witnesses as well as the licensees; preparing correspondence; collecting, organizing and evaluating documentation; performing audits of documents created or possessed by respondents; researching various topics of a complex and specialized nature; and conferring with agency supervisors. Such investigation entailed recording 48.50 hours, which is approximately six to eight full days of work. She then spent 48.75 hours, or approximately another six to eight full days, in preparing the detailed investigative report and its attachments. (The investigative report covers 42 pages, and when the attachments are added the entire investigative work product is made up of more than 500 pages.) It is not unreasonable for Inspector Shafir to have billed 36 hours, or four and one-half days to six days, in "hearing preparation," which necessarily means detailed study of the investigative report and its attachments so as to intelligently and collaboratively interact with the deputy attorney general, and then to refocus in order to come into the administrative hearing.

Importantly, at the hearing Inspector Shafir demonstrated her thorough, erudite knowledge of all aspects of the investigation. The board's inspector rendered unhesitating responses to all inquiries directed at her during the hearing. And, she offered reliable, trustworthy and persuasive testimonial evidence, which must be credited to the energy and time expended by her before the hearing date.

60. In this matter, respondent Chan and respondent Jefferson Plaza Pharmacy did not advance a meritorious defense in the exercise of respondents' right to a hearing in this matter insofar as to justify any reduction of the total amount of the costs sought for recovery. And, neither respondent Chan nor respondent Jefferson Plaza Pharmacy can be seen, under the facts set out above, to have committed slight or inconsequential misconduct in the context of the Accusation. Also, respondents did not raise a "colorable challenge" to the Accusation's paramount causes for discipline, namely respondent's unprofessional conduct, as manifested through breaching professional standards, such as the corresponding responsibilities doctrine, the requirement that pharmacies not expose consumers to the risk of receiving expired medications, and respondents' disregard of the Pharmacy Law's requirements regarding unlicensed persons being prohibited from the process of compounding prescriptions. Further, respondent Chan failed to acknowledge the seriousness of the violations of law as set out in the Accusation, which highlights several acts and omissions constituting unprofessional conduct on the part of respondents.

At the hearing of this matter, respondent Chan did not offer evidence that, at the time of the hearing, either he or Jefferson Plaza Pharmacy can be considered desperately impaired financially, or fiscally destitute, so that the imposition of an order for cost recovery will operate as a grave hardship. Respondent Chan provided no financial records or certification under oath from a certified public accountant that establishes respondents' financial liabilities are greater than their collective total assets. No balance sheets, statements of assets and liabilities or past tax returns were offered into evidence to show respondents' limited financial means.

The immediate foregoing factors indicate that the imposition upon respondents of the full costs of investigation and prosecution will not unfairly penalize either respondent. A substantial basis does not exist to warrant a reduction of the assessment against respondents for the costs of prosecution and investigation incurred by complainant.

Respondents did not provide adequate, competent evidence to establish that complainant's certifications for recovery of costs of investigation and prosecution are inappropriate.

61. Accordingly the reasonable and appropriate amount of costs owed by respondents to the Board of Pharmacy, Department of Consumer Affairs, is set at \$29,786.30

LEGAL CONCLUSIONS

The Regulation of Pharmacy

1. The Pharmacy Law governs the practice of pharmacy. Pharmacies must be licensed by the Board of Pharmacy, which has as its highest priority the protection of the public. Every pharmacy must have a "pharmacist-in-charge," an individual licensed by the board who is responsible for a pharmacy's compliance with all state and federal laws. A

pharmacist may be assisted by a pharmacy technician as specified in Business and Professions Code section 4115. (*Golden Drugs Co., Inc. v. Maxwell-Jolly* (2009) 179 Cal. App. 4th 1455, 1458-1459.)

2. The Board of Pharmacy is guided by a statute that mandates that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public must be paramount. (Bus. & Prof. Code, § 4001.1.)

The Purpose of Administrative Disciplinary Proceedings

3. A license revocation proceeding is civil in nature. Neither a criminal prosecution nor a malpractice action serves the purpose of a license revocation proceeding, which is not intended to punish the licensee, but to afford protection to the public upon the rationale that public respect and confidence is merited by eliminating dishonest, immoral, disreputable or incompetent persons from the ranks of practitioners. (*Fahmy v. Medical Bd. of California* (1995) 38 Cal. App. 4th 810, 817.)

The Burden and Standard of Proof

4. An individual who holds a license to practice a particular profession has a fundamental vested right to continue in that licensed activity. Procedural due process requires a regulatory board or agency seeking to suspend or revoke a professional license to prove the allegations of an accusation by clear and convincing evidence, rather than proof by a preponderance of the evidence. (*Owen v. Sands* (2009) 176 Cal.App.4th 985, 991-992.)

5. Clear and convincing evidence requires a finding of high probability; the evidence must be so clear as to leave no substantial doubt; it must be sufficiently strong to command the unhesitating assent of every reasonable mind. This requirement presents a heavy burden, far in excess of the preponderance of evidence standard that is sufficient for most civil litigation. (*Christian Research Institute v. Alnor* (2007) 148 Cal.App.4th 71, 84.)

6. The terms "burden of proof" and "burden of persuasion" are synonymous. A party has the burden of proof as to each fact the existence or nonexistence of which is essential to the claim for relief or defense that he is asserting except as otherwise provided by law. To prevail, the party bearing the burden of proof must present evidence sufficient to establish in the mind of the trier of fact a requisite degree of belief. The burden of proof does not shift during trial - it remains with the party who originally bears it. Unlike the burden of proof, the burden of producing evidence may shift throughout the trial. Initially, the burden of producing evidence as to a particular fact rests on the party with the burden of proof. When that party fails to produce sufficient evidence to make a prima facie case, that party risks an unfavorable determination. But, once that party produces evidence sufficient to make its prima facie case, the burden of producing evidence shifts to the other party to refute the prima facie case. Even though the burden of producing evidence shifts, a party need not offer evidence in reply, but the failure to do so risks an adverse outcome. Once a prima facie showing is made, it is for the trier of fact to say whether or not the crucial and necessary facts have been established. (*Sargent Fletcher, Inc. v. Able Corp.* (2003) 110 Cal.App.4th 1658, 1667-1668.)

7. a. As against the pharmacist's license, the burden of proof in this matter was on complainant to establish the allegations in the Accusation by clear and convincing evidence.

b. The standard of proof is different for the pharmacy's license, which is not a "professional" license in that there are not extensive education, training and testing requirements to obtain such licensure. 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.) Such distinction is unnecessary in this matter, however, because the same allegations are made against both the pharmacist and pharmacy's licenses, and clear and convincing evidence establishes each violation found.

Relevant Disciplinary Statutes and Regulations

8. Business and Professions Code section 4300 provides, in 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 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. . . .

9. Business and Professions Code section 4301, subdivision (o), provides:

The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . Unprofessional conduct shall include, but is not limited to, any of the following:

[¶] . . . [¶]

- (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.

10. Business and Professions Code section 4342, subdivision (a), sets forth:

The board may institute any action . . . as may be provided by law and that, in its discretion, are necessary, to prevent the sale

of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law . . .

11. Business and Professions Code section 4115, provides, in part:

(a) 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. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty.

(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(e) *No person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician.*

[¶]....[¶]

(h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

(Emphasis added.)

12. Business and Professions Code section 4051, subdivision (a), sets forth:

Except as otherwise provided in [Chapter 9-Pharmacy, Business and Professions Code], it is unlawful for any person to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription pursuant to Section 4040 (the meaning of "prescription" and "electronic transmission prescription") of a prescriber unless he or she is a pharmacist under this chapter.

13. Business and Professions Code section 4328 provides:

Except as otherwise provided in [Chapter 9-Pharmacy, Business and Professions Code], any person who permits the compounding or dispensing of prescriptions, or the furnishing of

dangerous drugs in his or her pharmacy, except by a pharmacist, is guilty of a misdemeanor.

14. Business and Professions Code section 4301, subdivision (j), establishes:

The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . Unprofessional conduct shall include, but is not limited to, any of the following:

[¶]....[¶]

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 ...

15. Business and Professions Code section 4301, subdivision (d), provides:

The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . Unprofessional conduct shall include, but is not limited to, any of the following:

[¶]....[¶]

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

16. Business and Professions Code section 4306.5, subdivision (a), states:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

17. Business and Professions Code section 4306.5, subdivision (b), states:

Unprofessional conduct for a pharmacist may include any of the following:

[¶]....[¶]

Acts or omissions that involve, in whole or in part, the failure to exercise or implement his . . . best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

18. California Code of Regulations, title 16, section 1714, subdivision (b), provides:

Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

19. California Code of Regulations, title 16, section 1714, subdivision (c), provides:

The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

20. California Code of Regulations, title 16, section 1735.5, sets out, in part:

- (a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.
- (b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.
- (c) The policy and procedure manual shall include the following:
 - (1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.
 - (2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
 - (3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
 - (4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
 - (5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

21. California Code of Regulations, title 16, section 1735.7, subdivisions (a), and (b), establish:

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on- going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

22. California Code of Regulations, title 16, section 1735.8, subdivision (a), sets forth:

Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

Causes for Discipline against Medical Plaza Pharmacies, Inc., d.b.a. Respondent Jefferson Plaza Pharmacy

FIRST CAUSE FOR DISCIPLINE - DRUGS LACKING QUALITY OR STRENGTH

23. The clear and convincing evidence established that respondent Jefferson Plaza Pharmacy subjected its license to discipline under Business and Professions Code section 4031, subdivision (o), in conjunction with Business and Professions Code section 4342, subdivision (a), by reason of Factual Findings 10, 11, and 12, along with Legal Conclusions 8, 9 and 10.

SECOND CAUSE FOR DISCIPLINE - OPERATIONAL STANDARDS AND SECURITY

24. The clear and convincing evidence established that respondent Jefferson Plaza Pharmacy subjected its license to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1714, subdivisions (b) and (c), by reason of Factual Findings 10, 11, and 13, along with Legal Conclusions 8, 9, 18 and 19.

THIRD CAUSE FOR DISCIPLINE - NO WRITTEN COMPOUNDING PROCEDURE AND MANUAL

25. The clear and convincing evidence established that respondent Jefferson Plaza Pharmacy subjected its license to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section

1735.5, subdivision (a) and (b), by reason of Factual Findings 10, 11, and 14, along with Legal Conclusions 8, 9, and 20.

FOURTH CAUSE FOR DISCIPLINE - TRAINING RECORDS AND COMPETENCY EVALUATION PROCESS

26. The clear and convincing evidence established that respondent Jefferson Plaza Pharmacy subjected its license to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.7, subdivision (a) and (b), by reason of Factual Findings 10, 11, and 15, along with Legal Conclusions 8, 9, and 21.

FIFTH CAUSE FOR DISCIPLINE - FAILURE TO PROVIDE COMPOUNDING QUALITY ASSURANCE

27. The clear and convincing evidence established that respondent Jefferson Plaza Pharmacy subjected its license to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.8, subdivision (a), by reason of Factual Findings 10, 11, and 16, along with Legal Conclusions 8, 9, and 22.

SEVENTH CAUSE FOR DISCIPLINE - PERMITTING AN UNLICENSED PERSON TO ENGAGE IN ACTS REQUIRING A VALID PHARMACY TECHNICIAN REGISTRATION

28. The clear and convincing evidence established that respondent Jefferson Plaza Pharmacy subject its license subject to discipline under Business and Professions Code section 4031, subdivision (o), in conjunction with Business and Professions Code section 4115, subdivision (e), section 4051, subdivision (a) and section 4328, by reason of Factual Findings 10, 11, and 17, along with Legal Conclusions 8, 9, 11, 12 and 13.

EIGHTH CAUSE FOR DISCIPLINE - FAILURE TO EXERCISE CORRESPONDING RESPONSIBILITY IN DISPENSING CONTROLLED SUBSTANCES

THE CORRESPONDING RESPONSIBILITY LAW

29. An issue of central importance is the Accusation's allegation that respondents violated the corresponding responsibility law. The corresponding responsibility law is both a standard of care and a duty recognized by statute. It is a critical doctrine in the Pharmacy Law.

The standard of care requires pharmacists and pharmacies to determine whether a prescription was issued for a legitimate medical purpose whenever the surrounding circumstances require such an inquiry. Inspector Shafir provided clear and convincing evidence establishing the existence of this standard, as shown by her clear and compelling testimony, and respondents' deviation from the corresponding responsibility standard.

Health and Safety Code section 11153 expresses a corresponding responsibility standard of care. That statute provides in part:

- (a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.
- (b) Any person who knowingly violates this section shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or in a county jail not exceeding one year, or by a fine not exceeding twenty thousand dollars (\$20,000), or by both that fine and imprisonment...

LEGISLATIVE HISTORY

The previous version of Health and Safety Code section 11153 was repealed and a new version was enacted in 1982. The new version mirrored Federal Regulations.¹⁹ Supporters of the 1982 assembly bill (AB 3376) sought to bring Health and Safety Code section 11153 in line with parallel federal regulations to facilitate state prosecutions. The change was also prompted by concerns about the growing numbers of "prescription mills" through which medical practitioners issued prescriptions for large amounts of high abuse drugs that were filled at pharmacies willing to participate in schemes that served to divert those drugs into the illegal street market. The newly enacted version of Health and Safety

¹⁹ Code of Federal Regulations, title 21, section 1306.04, subdivision (a), provides:

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

Code section 11153 clarified and strengthened the statute not only to reach practitioners who prescribed drugs for known drug addicts or habitual, unethical users, but also to target physicians and pharmacists who issued and filled high volume prescriptions for controlled substances with no legitimate medical purpose.

Health and Safety Code section 11153, subdivision (a), sets forth the statutory corresponding responsibility standard. And, Health and Safety Code section 115132, subdivision (b), sets forth the punishment that may be imposed upon "any person" who "knowingly" violates subdivision (a).

APPELLATE INTERPRETATION

Health and Safety Code section 11153, subdivision (b), uses the unambiguous and all-inclusive term "any person." The term includes everyone, regardless of whether the person is licensed or unlicensed. The term is specific, free from ambiguity, and therefore is not subject to any construction other than a literal one. (*People v. Gandotra* (1992) 11 Cal.App.4th 1355, 1363-1365 (holding that a licensed physician could not rely on medical appropriateness of unlicensed assistant's illegal prescription to escape liability for aiding and abetting unlawful furnishing of controlled substance; the statute does not require evidence establishing the medical inappropriateness of a drug to support a charge based upon unlicensed person's furnishing of controlled substance).)

In reviewing Health and Safety Code section 11153, several matters are obvious.

First, Health and Safety Code section 11153 sets forth a "corresponding responsibility" upon both the prescribing practitioner and upon the pharmacist who fills a prescription for a controlled substance. (Clear and convincing evidence is required in an administrative disciplinary proceeding alleging a violation of the statute, but proof beyond a reasonable doubt is not required. A disciplinary proceeding may be maintained even though the accused has been acquitted on criminal charges covering the same facts or has obtained a dismissal of such charges. (*Wong v. State Bar* (1975) 15 Cal.3d 528, 531.)

Second, subdivision (a) uses the term "corresponding responsibility," and not the term "identical responsibility." A pharmacist's role in filling a prescription corresponds to the prescriber's role in issuing a prescription, but it is not identical. The pharmacist's burden is to be alert, to make reasonable inquiry when circumstances require, and to refuse to fill a questionable prescription for a controlled substance when nothing establishes that the prescription at issue was issued for a legitimate medical purpose after engaging in due diligence. To paraphrase the decision in *Vermont & 110th Medical Arts Pharmacy v. Board of Pharmacy* (1981) 125 Cal.App.3d 19, 25, pharmacists, as reasonable professional persons, should obey the law, and they must refuse to dispense drugs when their suspicions are aroused by unexplained ambiguities in the prescriptions or the sheer volume of controlled substances prescribed by a single practitioner for a small number of persons.

Third, subdivision (b) imposes a "knowingly" requirement for criminal prosecution. But, the "knowingly" requirement does require a showing that a pharmacist actually knew that the prescription was not issued for a legitimate medical purpose. This is the case because

a section 11153 is a general intent crime. To constitute general criminal intent, it is not necessary to prove the intent to violate the law. When a person intentionally does that which the law declares to be a crime, he is acting with general criminal intent, even though he may not know that his act is unlawful. The requirement of acting "knowingly" is satisfied when the person committing the act has knowledge of the facts. "Knowingly" does not require knowledge of the unlawfulness of the act itself. The word "knowing" imports only an awareness of the facts that bring the act within the terms of the statute. (*People v. Lonergan* (1990) 219 Cal.App.3d 82, 95 [defining "knowingly" within the context of Health and Safety Code section 11153, subdivision (b), as indicated].)

CONCLUSIONS REGARDING CORRESPONDING RESPONSIBILITY

The corresponding responsibility law is both a standard of care and a duty imposed by statute. In both cases, pharmacists and pharmacies must determine whether a prescription for a controlled substance was issued for a legitimate medical purpose whenever the surrounding circumstances require such an inquiry. The misconduct that gives rise to this professional duty need not be as egregious as that described in *Vermont & 110th Medical Arts Pharmacy v. Board of Pharmacy*, *supra*, 125 Cal.App.3d 19. Reasonable judgment is all that is expected, but professional judgment must be exercised when required. Within the administrative disciplinary context, Health and Safety Code section 11153 applies to pharmacists, pharmacists-in-charge, and pharmacies. This interpretation promotes the statute's beneficial purpose and is consistent with the outcome reached in *Vermont & 110th Medical Arts Pharmacy v. Board of Pharmacy*, *supra*, 125 Cal.App.3d 19.

To establish a violation of the corresponding responsibility standard, complainant was not required to establish that a prescription for a controlled substance was in fact written by a prescriber for an illegitimate purpose; rather to establish a violation of the standard of care and a violation of the statute, complainant was merely required to establish that circumstances were present that would cause a reasonable and prudent pharmacist to question whether a prescription for a controlled substance was issued for a legitimate medical purpose and to show that the pharmacist failed to make the required inquiry. (*Smith v. State Board of Pharmacy* (1995) 37 Cal.App.4th 229, 246-247.) It is concluded that requiring such an inquiry to be made before dispensing a controlled substance does not violate the language or the spirit of Business and Professions Code section 733. But, when a pharmacist does nothing in the face of circumstances that require that some positive action be taken, the pharmacist is guilty of negligence, unprofessional conduct, and violates the corresponding responsibility law when he does nothing.

30. The clear and convincing evidence established that the permit issued to respondent Jefferson Plaza Pharmacy is subject to discipline under Business and Professions Code section 4301, subdivision (j), in conjunction with Health and Safety Code section 11153, subdivision (a), by reason of Factual Findings 10, 11 and 18, along with Legal Conclusions 8, 14 and 29.

NINTH CAUSE FOR DISCIPLINE - EXCESSIVE FURNISHING OF CONTROLLED SUBSTANCES

31. The clear and convincing evidence established that the permit issued to respondent Jefferson Plaza Pharmacy is subject to discipline under Business and Professions Code section 4301, subdivision (d), in conjunction with Health and Safety Code section 11153, subdivision (a), by reason of Factual Findings 10, 11 and 19, along with Legal Conclusions 8, 15 and 29.

Causes for Discipline against Pharmacist Chan's License

FIRST CAUSE FOR DISCIPLINE - DRUGS LACKING QUALITY OR STRENGTH

32. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4031, subdivision (o), in conjunction with Business and Professions Code section 4342, subdivision (a), by reason of Factual Findings 10, 11, and 12, along with Legal Conclusions 8, 9 and 10.

SECOND CAUSE FOR DISCIPLINE - OPERATIONAL STANDARDS AND SECURITY

33. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1714, subdivisions (b) and (c), by reason of by reason of Factual Findings 10, 11, and 13, along with Legal Conclusions 8, 9, 18 and 19.

THIRD CAUSE FOR DISCIPLINE - NO WRITTEN COMPOUNDING PROCEDURE AND MANUAL

34. The clear and convincing evidence established the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.5, subdivision (a) and (b), by reason of Factual Findings 10, 11, and 14, along with Legal Conclusions 8, 9, and 20.

FOURTH CAUSE FOR DISCIPLINE - TRAINING RECORDS AND COMPETENCY EVALUATION PROCESS

35. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.7, subdivision (a) and (b), by reason of Factual Findings 10, 11, and 15, along with Legal Conclusions 8, 9, and 21.

FIFTH CAUSE FOR DISCIPLINE - FAILURE TO PROVIDE COMPOUNDING QUALITY ASSURANCE

36. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.8, subdivision (a), by reason of Factual Findings 10, 11, and 16, along with Legal Conclusions 8, 9, and 22.

SEVENTH CAUSE FOR DISCIPLINE - PERMITTING AN UNLICENSED PERSON TO ENGAGE IN ACTS REQUIRING A VALID PHARMACY TECHNICIAN REGISTRATION

37. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4031, subdivision (o), in conjunction with Business and Professions Code section 4115, subdivision (e), section 4051, subdivision (a) and section 4328, by reason of Factual Findings 10, 11, and 17, along with Legal Conclusions 8, 9, 11, 12 and 13.

EIGHTH CAUSE FOR DISCIPLINE - FAILURE TO EXERCISE CORRESPONDING RESPONSIBILITY IN DISPENSING CONTROLLED SUBSTANCES

40. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4301, subdivision (j), in conjunction with Health and Safety Code section 11153, subdivision (a), by reason of Factual Findings 10, 11 and 18, along with Legal Conclusions 8, 14 and 29.

NINTH CAUSE FOR DISCIPLINE - EXCESSIVE FURNISHING OF CONTROLLED SUBSTANCES

41. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4301, subdivision (d), in conjunction with Health and Safety Code section 11153, subdivision (a), by reason of Factual Findings 10, 11 and 19, along with Legal Conclusions 8, 15 and 29.

TENTH CAUSE FOR DISCIPLINE - MISUSE OF EDUCATION

42. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4306.5, subdivision (a), by reason of Factual Findings 10, 11, and 19, along with Legal Conclusion 16.

ELEVENTH CAUSE FOR DISCIPLINE - FAILURE TO EXERCISE OR IMPLEMENT BEST PROFESSIONAL JUDGMENT OR CORRESPONDING RESPONSIBILITY

43. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4306.5, subdivision (b), by reason of Factual Findings 10, 11 and 21, along with Legal Conclusion 17.

Twelfth Cause for Discipline against Respondent Jefferson Plaza Pharmacy and Respondent Chan

TWELFTH CAUSE FOR DISCIPLINE – UNPROFESSIONAL CONDUCT

44. Business and Professions Code section 4301 specifically provides that unprofessional conduct includes this conduct specifically enumerated by statute as well as other misconduct. Unprofessional conduct is that conduct that breaches the rules or ethical code of a profession, or conduct which is unbecoming a member in good standing of a profession. (*Shea v. Board of Medical Examiners* (1978) 81 Cal.App.3d 564, 57S.)

45. Business and Professions Code section 4301, establishes, in part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

[¶...¶]

46. Complainant's Twelfth Cause for Discipline in the Accusation, which is directed against both respondents, alleges cause for disciplinary action against respondents for "unprofessional conduct" generally under Business and Professions Code section 4301. The allegation specifically references numbered paragraphs in the Accusation containing factual allegations. Such pleading is permissible pursuant to *Gillis v. Dental Bd. of California* (2012) 206 Cal.App.4th 311, 320. By virtue of Factual Findings 12 through 22, cause exists to discipline both respondent Jefferson Plaza Pharmacy's and respondent Chan's licenses for unprofessional conduct pursuant to Business and Professions Code section 4301.

Complainant's Cost Recovery Petition

47. Business and Professions Code section 125.3 prescribes that a "licentiate found to have committed a violation or violations of the licensing act" may be directed to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

California Code of Regulations, title 1, section 1042, subdivision (2), sets forth "a certificate or affidavit in support of costs incurred by the agency for services provided by regular agency employees should include sufficient information by which the ALJ can determine the costs incurred in connection with the matter and the reasonableness of such costs, for example, a general description of tasks performed, the time spent on such tasks, and the method of calculation the cost for such services."

The California Supreme Court's reasoning as to the obligation of a licensing agency to fairly and conscientiously impose costs in administrative adjudication as articulated in *Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, 45-46, is persuasive and should be considered in this matter. Scrutiny of certain factors, which pertain to the board's exercise of discretion to analyze or examine factors that might mitigate or

reduce costs of prosecution upon a licensee found to have engaged in unprofessional conduct, are set forth in Factual Finding 60.

48. By reason of Factual Findings 58, 59, and 61, the reasonable and appropriate costs of investigation and prosecution is set at \$29,786.30.

Established Guideline for Imposition of License Disciplinary Action

49. The board has promulgated "Disciplinary Guidelines," which serve as a manual of disciplinary guidelines and a set of model disciplinary orders.

The guidelines, which are authorized by California Code of Regulations, title 16, section 1760, suggest factors in mitigation, witnesses in mitigation, matters in rehabilitation, and as well as matters in aggravation should be weighed in the imposition of license disciplinary action. Accordingly, the matters set out in Factual Findings 24 through 56 have been considered in making the Orders below.

Among many topics in the board's Guidelines is the board's formulation for categories of violations of provisions under the Pharmacy Law (Bus. & Prof. Code, § 4000 et seq.). The categories correlate to recommended penalties upon finding a licensee's violations of law. The categories for violations of the law range from Category I to Category IV, that is for minor violations to the egregious violations that must result in absolute revocation without the possibility of a term of probation.

Under the factual findings, above, respondents committed numerous Category II violations. Those categories focus upon violations that pertain to: acts having greater disregard for pharmacy law; reflect poorly on the licensees' ethics; or poor care being exercised or simple incompetence being shown by respondents, their agents or employees. Such violations have as a minimum level of discipline as a stay of licensure revocation with a three-year term of probation; the maximum discipline is revocation. In this matter, respondents' Category II violations include: unprofessional conduct as defined at Business and Professions Code section 4301, subdivision (j)²⁰; violations of a pharmacist's duty of effecting vigorous supervision of a pharmacy technician under Business and Professions Code section 4115; a pharmacist's dereliction with regard to permitting impermissible compounding, dispensing or furnishing by a non-pharmacist contrary to Business and Professions Code section 4328; acts of excessive furnishing of controlled substances that constitutes unprofessional conduct under Business and Professions Code section 4301, subdivision (d); and, the misuse of a pharmacist's education as proscribed by Business and Professions Code section 4306.5, subdivision (a).

²⁰ Under the Guidelines, a violation of Business and Professions Code section 4301, subdivision (j), (violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs) may be either a Category II or a Category III violation.

In addition, in this matter, clear and convincing evidence also established respondents' commission of severe and numerous Category III violations over an extended period of time. Such violations involve such conduct as: knowingly or willfully violating laws or regulations pertaining to dispensing or distributing dangerous drugs or controlled substances; as well as, violations of a licensee's corresponding responsibility. The maximum discipline for such violations is revocation. Such violations have a minimum level of discipline to be: a stay of licensure revocation, a 90-day period of actual suspension of licensure (with corresponding cessation of practice activity and business dealings), a three to five year term of probation, along with a pharmacist taking courses of study. In this matter, respondents' Category III violations include: unprofessional conduct as defined at Business and Professions Code section 4301, subdivision (o); allowing an individual to engage in compounding prescriptions when that person does not possess either a pharmacist license or a valid pharmacy technician registration in violation of Business and Professions Code section 4051, subdivision (a); violation of a licensee's corresponding responsibility contrary to Business and Professions Code section 4301, subdivision (j).

50. It is determined that complainant established that the nature, volume and duration of respondents' violations, which fall into Category III offenses, warrant the most severe discipline prescribed in the Guidelines. Respondents' misconduct was severe and persuasive, and reflects a fundamental disregard for proper pharmacy procedures. Furthermore, as noted throughout the decision, but particularly in Factual Findings 46 through 57, respondents do not take responsibility for their actions or the potential harm to the public. There are no terms by which the board can effectively protect the public should either respondent have a continued ability to offer pharmacy services.

ORDER

1. Pharmacy License No. PHY 11062, issued to respondent Medical Center Pharmacies, Inc., with Ruth Fung Chan as President, doing business as Jefferson Plaza Pharmacy, is revoked.

- a. Respondent owner shall, by the effective date of this decision, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondent owner shall provide written proof of such disposition, submit a completed Discontinuance of Business form and return the wall and renewal license to the board within five days of disposition.
- b. 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.

2. Pharmacist License No. 32261, issued to respondent Johnny Pinghon Chan, is revoked.

3. Medical Center Pharmacies, Inc., doing business as respondent Jefferson Plaza Pharmacy, or its successor-in-interest or assignee (respondent owner), is jointly and severally liable with respondent Johnny Pinghon Chan, for the costs incurred by complainant, and both or either person shall pay to the Board of Pharmacy the costs of investigation and enforcement in the total amount of \$29,786.30.

This Decision shall become effective at 5:00 p.m. on April 8, 2016.

It is so ORDERED on March 9, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

A handwritten signature in black ink, appearing to read 'Amy Gutierrez', written over a horizontal line.

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:

JEFFERSON PLAZA PHARMACY
Pharmacy Permit No. PHY 11062

JOHNNY PINGHON CHAN
Pharmacist License No. RPH 32261, and

MARICON PAYTE ESMABE
Pharmacy Technician Registration No.
TCH 124483

Respondents.

Case No. 5113

OAH No. 2015010397

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 October 7, 2015. In addition to any arguments the parties may wish to submit, the board is interested in argument directed at the following issue: If cause for discipline exists, what penalty, if any, should be applied in this case.

Pursuant to said Order written argument shall be filed with the Board of Pharmacy, 1625 N. Market Blvd, Suite N-219, Sacramento, California, on or before January 4, 2016. **No new evidence may be submitted.**

IT IS SO ORDERED this 2nd day of December 2015.



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:

JEFFERSON PLAZA PHARMACY
Pharmacy Permit No. PHY 11062, and

JOHNNY PINGHON CHAN
Pharmacist License No. 32261, and

MARICON PAYTE ESMABE
Pharmacy Technician Registration No.
TCH 124483,

Respondents.

Case No. 5113

OAH No. 2015010397

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.

The board is particularly interested in arguments directed to the question whether the discipline should be increased. 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 October 7, 2015.

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:

JEFFERSON PLAZA PHARMACY
Pharmacy Permit No. PHY 11062,

JOHNNY PINGHON CHAN
Pharmacist License No. RPH 32261, and

MARICON PAYTE ESMABE,
Pharmacy Technician Registration No.
TCH 124483,

Respondents.

Case No. 5113

OAH No. 2015010397

PROPOSED DECISION

Administrative Law Judge Perry O. Johnson, Office of Administrative Hearings, State of California, heard this matter on June 8 and June 9, 2015, in Oakland, California.

Deputy Attorney General Kim M. Settles, Department of Justice, State of California, along with the assistance of Mr. Chris Collins, represented complainant Virginia K. Herold, Executive Officer, Board of Pharmacy (the board), Department of Consumer Affairs, State of California.

Attorney at Law Natallia Mazina¹ represented respondent Jefferson Plaza Pharmacy (respondent pharmacy or respondent Jefferson Plaza Pharmacy) and Johnny Pinghon Chan (respondent Chan). Respondent Chan was present for all phases of the administrative adjudication proceeding.

Before the commencement of the hearing of this matter, complainant and Ms. Maricon Payte Esmabe entered into a stipulated settlement agreement regarding allegations against Pharmacy Technician Registration No. TCH 124483 issued to Ms. Esmabe. Accordingly, because the disciplinary action against Ms. Maricon Payte Esmabe having been

¹ Natallia Mazina, Esq., is a lawyer with the law office of Carman and Mazina, 404 San Anselmo Avenue, San Anselmo, California 94960.

resolved, the administrative action against her registration is concluded. Hence, Ms. Esmabe is not a subject of either the Legal Conclusions or the Order to this Decision.

The record was held open to afford opportunities to the parties to file written arguments regarding the reasonableness and appropriateness of the board's recovery of the costs of investigation. On June 11, 2015, respondent pharmacy and respondent Chan, through their counsel, filed a document titled "Motion to Reduce Investigative Costs," which was marked as exhibit "W," and received as argument. On June 16, 2015, complainant, through her counsel, filed correspondence titled "Response to Motion to Reduce Investigative Costs," which was marked as exhibit "5," and received as argument.

On June 16, 2015, the parties were deemed to have submitted the matter for decision, and the record closed.

FACTUAL FINDINGS

Jurisdictional Matters

1. On July 27, 2014, complainant Virginia K. Herold, in her official capacity as the board's Executive Officer (complainant), signed the Accusation in Case No. 5113, which was served thereafter on respondent pharmacy and respondent.

Respondents timely filed a Notice of Defense and the hearing in this matter ensued.

License Histories

2. On August 8, 1978, the board issued Original Pharmacist License Number RPH 32261 to respondent Chan. Respondent Chan's license is renewed until May 31, 2016.

3. There is no history of any prior discipline having been executed against respondent Chan's pharmacist license.

4. On May 4, 1981, the board issued Original Pharmacy Permit Number PHY 11062 to Medical Plaza Pharmacies, Inc., to engage in business under the fictitious business name of "Jefferson Plaza Pharmacy." The license issued to respondent Medical Plaza Pharmacies, Inc., doing business as Jefferson Plaza Pharmacy, is renewed until October 1, 2015.

5. Since May 4, 1981, the corporation, which owns respondent Jefferson Plaza Pharmacy, has had as its president Ruth Fung Chan. Mrs. Fung Chan holds board issued Pharmacist License Number RPH 32217. And, she is the wife of respondent Chan.

6. On March 1, 1986, respondent Chan became the Pharmacist-in-Charge for respondent Jefferson Plaza Pharmacy

7. There is no history of any prior discipline having been perfected against respondent Jefferson Plaza Pharmacy's permit.

8. Respondent Jefferson Plaza Pharmacy is a community pharmacy situated at 3137 Jefferson Avenue in Redwood City, San Mateo County, California.

A Citizen Complaint

9. On approximately January 30, 2012, a medical doctor, identified herein as Dr. N.A., filed a Consumer Complaint Form with complainant's personnel regarding suspected unprofessional acts of respondent Jefferson Plaza Pharmacy and its agents or employees. The medical doctor's consumer complaint asserted that individuals at the subject pharmacy had dispensed five different narcotic drugs within a ten-day period to the medical doctor's patient, who was under the complaining medical doctor's care and treatment for opioid dependence.² Complainant's personnel commenced an investigation into respondent Jefferson Plaza Pharmacy's policies, practices, and methods for dispensing³ narcotics, as well as the acts and omissions of respondent Chan as the Pharmacist-in-Chief for respondent Jefferson Plaza Pharmacy.

The Inspection and Investigative Findings and Conclusions

10. Manisha Patel Shafir (Inspector Shafir) offered reliable and persuasive evidence at the hearing of this matter. By her demeanor while testifying, her attitude toward the proceeding, her clear and unhesitating presentation of evidence as well as her solemn, sincere and conscientious attitude toward the proposed action against respondents, Inspector Shafir established herself to be a credible,⁴ exceedingly knowledgeable, and trustworthy witness at the hearing of this matter.

² Opioid dependence is a manifestation of brain changes resulting from chronic opioid abuse Brain abnormalities resulting from chronic use of heroin, oxycodone, and other morphine-derived drugs are underlying causes of opioid dependence (the need to keep taking drugs to avoid a withdrawal syndrome) The abnormalities that produce dependence . . . appear to resolve after detoxification, within days or weeks after opioid use stops" (www.ncbl.nim.hin.gov. (U.S. National Library of Medicine).)

³ The term "dispense" is defined in Health and Safety Code section 11010 as follows:

"Dispense" means to deliver a controlled substance to an ultimate user . . . pursuant to the lawful order of a practitioner, including the prescribing, furnishing, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

⁴ Government Code section 11425.5, subdivision (b), third sentence.

11. As part of complainant's investigation, which resulted from the consumer complaint made by Dr. A.N., Manisha Patel Shafir, (Inspector Shafir), a Pharmacy Board Inspector, on July 12, 2013, conducted an inspection of the business premises of respondents; and, she crafted a detailed investigative report containing summaries of findings and conclusions resulting from the inspection. The findings and determinations made by Inspector Sharfir are found to be reliable and accurate. The investigative report, which consists of more than 40 pages, along the inspector's testimony at the hearing, underpin Factual Findings 12 through 20:

INVESTIGATIVE FINDINGS AND CONCLUSIONS - FIRST CAUSE FOR DISCIPLINE

12. Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, possessed pharmaceutical preparations and drugs that did not conform with the standards and tests for quality and strength for prescription medications, as established by, or provided in, the latest edition of the United States Pharmacopeia⁵ or the National Formulary.⁶ Moreover, the pharmaceutical preparations and drugs possessed by respondent Jefferson Plaza Pharmacy, as controlled, directed and supervised by respondent Chan, violated provisions of the Sherman Food, Drug and Cosmetic Law (Health & Saf. Code, § 109875, et seq.).

On July 12, 2013, Inspector Shafir detected, and documented in detail, that respondent Chan enabled, facilitated, and permitted such poor control of supply records and inventory control measures so that numerous outdated drug products, on the premises of

⁵ The U.S. Pharmacopeial Convention (USP) is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the Food and Drug Administration, and these standards are used in more than 140 countries. (www.usp.org)

⁶ The National Formulary has as its full name, "United States Pharmacopeia and National Formulary" (USP-NF). It is an official publication, issued first by the American Pharmaceutical Association and now yearly by the United States Pharmacopeial Convention, that gives the composition, description, method of preparation, and dosage for drugs. The book contains two separate official compendia, and are identified as the USP and the NF. The United States Pharmacopeia (USP), established in 1820, contains legally recognized standards of identity, strength, quality, purity, packaging, and labeling for drug substances, dosage forms, and other therapeutic products, including nutritional and dietary supplements. The National Formulary (NF), established in 1888 by the American Pharmaceutical Association, includes standards for excipients, botanicals, and other similar products. USP purchased the NF in 1975, combining the two publications under one cover, creating the USP-NF. (www.medicines.net)

respondent Jefferson Plaza Pharmacy, were not only included in compounding bulk ingredients but also were stored as part of the general inventory of respondent pharmacy.

In these regards, respondents' acts and omissions violated the Pharmacy Law. (Bus. & Prof. Code, § 4000 et seq.)

INVESTIGATIVE FINDINGS AND CONCLUSIONS - SECOND CAUSE FOR DISCIPLINE

13. Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, failed to maintain the subject pharmacy's facilities, spaces, fixtures and equipment items in a manner that drugs could be safely and properly prepared, maintained, secured and dispensed. Also, respondent Jefferson Plaza Pharmacy, together with, and under the control, direction and supervision of respondent Chan, failed to maintain the subject pharmacy's fixtures and equipment in a clean and orderly condition.

On July 12, 2013, Inspector Shafir detected, and documented in detail, that the general pharmacy premises, as well as the drug prescription compounding areas, at respondent Jefferson Plaza Pharmacy were extremely disorganized, dirty and excessively cluttered with equipment, papers and other objects. Moreover, Inspector Sharfir observed that the drug stock at the premises of respondent Jefferson Plaza Pharmacy included an inordinate number of outdated products. During an overview sampling of medications on shelves and in draws at the premises of respondent Jefferson Plaza Pharmacy, in her review of both compounding bulk ingredients and regular drug inventories, Inspector Shafir identified over 50 (fifty) expired drugs. And, some outdated drugs, as located inside a pharmacy storage drawer, had no label showing clear indications that the drugs had been quarantined for destruction. The identified drugs, which did show expiration dates, ranged from November 2007 to the inspection date on July 12, 2013.

In these regards, respondents' acts and omissions violated the Pharmacy Law.

INVESTIGATIVE FINDINGS AND CONCLUSIONS - THIRD CAUSE FOR DISCIPLINE

14. Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, failed to maintain a written policy and procedures manual for compounding. Respondents failed to maintain clearly defined compounding policy and procedures to reflect the compounding activities of the pharmacy.

On July 12, 2013, Inspector Shafir detected, and documented in detail, that respondent Chan failed to assure that respondent Jefferson Plaza Pharmacy maintained on the premises current written compounding policies and procedures.

In these regards, respondents' acts and omissions violated the Pharmacy Law.

INVESTIGATIVE FINDINGS AND CONCLUSIONS - FOURTH CAUSE OF DISCIPLINE

15. Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, failed to maintain written documentation sufficient to demonstrate that respondents' pharmacy personnel had the skills and training to perform compounding activities. Respondents failed to develop and maintain an on-going competency evaluation process.

On July 12, 2013, Inspector Shafir detected, and documented in detail, that respondent Chan failed to possess any form of board approved training records for the pharmacy staff who engaged in compounding activities at and for respondent Jefferson Plaza Pharmacy. The investigator's discovery was of particular concern in that respondents employed a person (Ms. Esmabe), who did not hold a valid pharmacy technician registration; yet, that person who did not possess a valid technician registration performed, each month, many acts of compounding of prescriptions. There was no record that Ms. Esmabe had received training by, or through, respondents.

In these regards, respondents' acts and omissions violated the Pharmacy Law.

INVESTIGATIVE FINDINGS AND CONCLUSIONS - FIFTH CAUSE OF DISCIPLINE

16. Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, failed to maintain a written policy and procedure designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

On July 12, 2013, Inspector Shafir detected, and documented in detail, that respondent Chan failed to assure that Jefferson Plaza Pharmacy possessed on its premises clearly defined compounding policies and procedures so as to document and reflect all compounding activities performed at the subject pharmacy. Respondents failed to possess on the premises of the subject pharmacy any written quality assurance plans for compounded prescriptions. And, respondent Jefferson Plaza Pharmacy's inadequately crafted compounding log reflected that Ms. Esmabe had compounded a majority of prescriptions each month for, at least, the period of January 19, 2013, to July 9, 2013.

In these regards, respondents' acts and omissions violated the Pharmacy Law.

INVESTIGATIVE FINDINGS AND CONCLUSIONS - SEVENTH⁷ CAUSE OF DISCIPLINE

⁷ By reason of the stipulated settlement between complainant and respondent Esmabe, the Accusation's Sixth Cause of Discipline is subject to dismissal.

17. Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, allowed Ms. Esmabe to compound prescriptions without possessing either a pharmacist license or a valid pharmacy technician⁸ registration.

On July 12, 2013, Inspector Shafir detected, and documented in detail, that respondent Chan allowed, enabled and assured that on the premises of respondent Jefferson Plaza Pharmacy, Ms. Esmabe engaged in the activities constituting the process of compounding numerous prescriptions without possessing a license or registration. Ms. Esmabe engaged in unlicensed activity regarding the duties,⁹ functions and responsibilities reserved for a holder of a valid pharmacy technician registration. Ms. Esmabe performed unlicensed, and therefore unlawful activities, over, at the very least, the time frame of January 19, 2013, to July 9, 2013.

Although on January 11, 2010, the board had issued an intern pharmacist license (INT 25497) to Ms. Esmabe, that intern license was cancelled effective January 31, 2012. And, the board did not issue Ms. Esmabe a pharmacy technician registration (TCH 124483) until August 23, 2013. At the time of Inspector Shaifir's site investigation, Ms. Esmabe possessed neither a license nor a registration.

In these regards, respondents' acts and omissions violated the Pharmacy Law.

INVESTIGATIVE FINDINGS AND CONCLUSIONS - EIGHTH CAUSE OF DISCIPLINE

18 Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, failed to comply with respondents' corresponding responsibility to ensure that controlled substances¹⁰ were dispensed for a

⁸ California Code of Regulations, title 16, section 1793 defines "Pharmacy technician" to mean "an individual who, under the direct supervision and control of a registered pharmacist, performs packaging, manipulative, repetitive, or other nondiscretionary tasks related to the processing of a prescription in a licensed pharmacy, but who does not perform duties restricted to a registered pharmacist under section 1793.1."

⁹ California Code of Regulations, title 16, section 1793.2, set forth that a holder of valid pharmacy technician registration "may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting, and while under the direct supervision and control of, a registered pharmacist." Further, 'Nondiscretionary tasks' as used in Business and Professions Code section 4115, include: (a) removing the drug or drugs from stock; (b) counting, pouring, or mixing pharmaceuticals; (c) placing the product into a container; (d) affixing the label or labels to the container; [and] (e) packaging and repackaging."

¹⁰ Controlled Substance means any substance listed in Chapter 2 (commencing with section 11053) of Division 10 of the Health and Safety Code. And the phrase

legitimate medical purpose. When respondents dispensed or furnished prescriptions for controlled substances, they did so despite the presence of numerous "red flags," which reasonable prudent and vigilante pharmacy licensees would have warned to either refuse to fill the prescription or to acquire explicit input from a medical treatment licensee as to the basis for the frequent, large or unusual request for the controlled substance.

On July 12, 2013, Inspector Sharif detected, and documented in detail, that respondent Chan and other personnel of respondent Jefferson Plaza Pharmacy dispensed controlled substances in accordance with prescriptions written by prescribers, and for patients on a refill basis, who had either offices or residences outside of the subject pharmacy's expected, or normal, service area. Respondents or their personnel filled prescriptions without positively verifying whether the prescriptions for consumers were issued by medical care providers for legitimate medication purposes. Moreover, respondents and especially respondent Chan failed to use pharmacy-industry tools or programs, such as the Prescription Drug Monitoring Program, so as to verify early, or duplicate, dispensing requests by patients, who were either "doctor shopping" or "pharmacy shopping. Inspector Sharif pointed to the records for patients such as Camilla H. and approximately nine other individuals for whom respondents violated the Pharmacy Law in the way respondents failed to scrupulously adhere to the corresponding responsibility law and doctrine.

Furthermore, Inspector Sharif detected, and documented in detail, that over the time frame of July 11, 2010, to July 11, 2013, respondent Jefferson Plaza Pharmacy, as controlled and supervised by respondent Chan, dispensed large number of prescriptions (in an amount of 25,261 doses) of controlled substances. Of that number of prescriptions for narcotics, 4,178 prescriptions were written by Bernard Wilcosky, M.D., who prescribed large quantities of "drug cocktails" of controlled substances. Respondents honored many early refills for patients of Dr. Wilcosky in an excessive number as shown by CURES¹¹ data that pertained to

"dangerous drug" is defined, in pertinent part, at Business and Profession Code section 4022 to mean: "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.

¹¹ CURES signifies "The Controlled Substance Utilization Review and Evaluation System" program. The program began in 1998. It is a mandatory monthly pharmacy reporting program for dispensed Schedule CII drugs. The program was amended in January

that medical doctor's patients. In addition, the investigation revealed that respondents refilled prescription "too soon," that is the prescriptions were filled well before the a previously dispensed supply of controlled substance had been exhausted according to industry standards for consumption of the prescribed medications. Also, respondent's practice exhibited "therapeutic duplications," that is, respondents dispensed narcotics to the same individual for various strengths of a narcotic or narcotic combination so as to provide a suspect "drug cocktail." Respondents dispensed controlled substances to various patients, who were using multiple pharmacies to fill prescriptions. And, respondents dispensed controlled substances to patients who were using different doctors to act as prescribers of narcotics. Inspector Sharif, who had limited time to review respondents' records and she was, therefore, unable to account for the vast number of prescription records, created tables regarding nine consumers for whom respondents violated, at a minimum, the basic precepts of the corresponding responsibility law or doctrine.¹² By neglecting to use CURES,

2005 so as to include mandatory weekly reporting of Schedule CII through IV drugs. The data is collected statewide and such data can be used by health care professionals, including pharmacists and drug prescribers, to evaluate and to determine whether patients are utilizing prescribed controlled substances lawfully and correctly.

¹² For the time span of July 11, 2010, to July 11, 2013, respondents dispensed controlled substances, for example, as follows:

Consumer Alan S was allowed to fill with respondents a total of 303 prescriptions for various controlled substances, which were all issued by Dr. Wilcosky. Consumer Alan S filled prescriptions through 28 different pharmacies, which were located in 22 different cities; but, respondent Jefferson Plaza Pharmacy filled 41 percent of the prescriptions for Alan S. For the time studied by the inspector, Alan S. obtained a total of 30,479 tablets of various strengths of Oxycontin ER and oxycodone IR.

Consumer Lisa B was allowed to fill with respondents a total of 134 prescriptions for various controlled substances. Over the period studied, she used 10 different pharmacies in six different cities as well as prompted five different physicians in five separate cities to enable her to procure narcotics. Among other things, over a 35-day period (July 5 through August 9, 2012), Consumer Lisa B was allowed to fill three prescriptions for oxycodone (30 mg), for a total of 780 tablets that is ordinarily a 60-day supply. And, over a 22-day period (May 20 through June 11, 2013), Consumer Lisa B was allowed to fill three prescriptions for hydrocodone/APAP for a total of 780 tablets that is ordinarily a 70-day supply. For the narcotics procuring by Lisa B, respondent filled one prescription on May 20, 2013, and another prescription 15 days later on June 5, 2013. All of the prescriptions were paid with cash.

Consumer Charles B was allowed to fill with respondents and other pharmacies a total of 201 prescriptions for various controlled substances. He used nine different pharmacies, but the majority of the prescriptions were fill by respondent Jefferson Plaza

respondents dispensed controlled substances to patients whose conduct demonstrated “doctor shopping” and “pharmacy shopping.” Respondent ignored well-recognized “red flags,” which required respondent to verify that a prescription was issued for a legitimate medical purpose. The “red flags” were ignored because of respondents’ gross dereliction of the corresponding responsibility doctrine included respondents:

- Filling prescriptions for consumers who came from well outside the pharmacy service area. And honoring prescriptions written by health care providers having offices well outside respondents’ service area;
- Accepting cash payment tendered by consumers. Respondent Jefferson Plaza Pharmacy accepted cash, as opposed to third-party insurance payment, for nearly 26 percent of its sales of narcotics. (Comparable pharmacies accept cash in less than 15 percent of sales of controlled substances versus receiving insurance payments for the sale.);
- Failed to use PDMP to evaluate whether consumers were procuring prescriptions for legitimate purposes;
- Filling prescriptions for many consumers who traveled significant distances from residences to the premises of respondent Jefferson Plaza Pharmacy;
- Early dispensing of controlled substances for various consumers, which were explicitly noted in CURES data as well as respondents’ computer data.

In these regards, respondents’ acts and omissions violated not only the Pharmacy Law but also Health and Safety Code section 11153, subdivision (a). (Extensive discussion of the cited Health and Safety Code provision is set out, below, under Legal Conclusions.)

Pharmacy. Consumer Charles B used four different physicians located in three different cities.

Consumer Brian D was allowed to fill 173 prescriptions for various controlled substances. He used five pharmacies located in three cities, but 87 percent of the prescriptions for Consumer Brian D were filled by respondent Jefferson Plaza Pharmacy.

Consumer Nancy G was allowed to fill 181 prescriptions for various controlled substances. She used 25 different pharmacies located in 16 different cities, but respondent Jefferson Plaza Pharmacy filled in excess of 20 percent of the prescriptions presented by Consumer Nancy G. She used 23 different physicians located in 16 cities during the subject time span.

INVESTIGATIVE FINDINGS AND CONCLUSIONS - NINTH CAUSE OF DISCIPLINE

19. Respondent Jefferson Plaza Pharmacy, together with, and under the control, direction, and supervision of respondent Chan, from July 11, 2010, through July 11, 2013, furnished excessive amounts of controlled substances in violation of Health and Safety Code section 11153, subdivision (a). In particular, from July 11, 2010, through July 11, 2013, respondents dispensed to consumers 25,261 prescriptions for various controlled substances. Respondents dispensed to consumers 204,195 doses of Hydrocodone/APAP 10/325 milligrams, and 528,718 tablets of Oxycodone¹³ 30 milligrams. The amounts of the controlled substances sold by respondents far exceeded the volumes of the same type of narcotics dispensed by other pharmacies, which were located in close proximity to the premises of respondent Jefferson Plaza Pharmacy. And those other pharmacies maintained longer hours of operation than respondents' business premises.

For the time period studied by Inspector Shafir, the hours of operation of respondent Jefferson Plaza Pharmacy were 9:00 a.m. until 6:30 p.m. on Mondays through Fridays; and, 9:00 a.m. until 5:00 p.m. on Saturdays, but the pharmacy was closed on Sundays. Within 1.4 miles of respondents' premises, a Safeway Store's pharmacy is located. That Safeway pharmacy operated Monday through Fridays from 9:00 a.m. until 8:00 p.m., and was open on both Saturdays and Sundays from 9:00 a.m. until 5:00 p.m. And at a distance of 1.3 miles from respondent Jefferson Plaza Pharmacy, a Rite Aid Pharmacy operated from 8:00 a.m. until 10:00 p.m. on Monday through Friday as well as on Saturday from 9:00 a.m. until 6:00 p.m., and on Sundays from 10:00 a.m. until 6:00 p.m. And, at a distance of 0.3 miles from respondent Jefferson Plaza Pharmacy another Rite Aid Store's pharmacy operated from 9:00 a.m. until 9:00 p.m. on Monday through Friday as well as on Saturday from 9:00 a.m. until 6:00 p.m., and on Sundays from 10:00 a.m. until 6:00 p.m.

While respondent Jefferson Plaza Pharmacy dispensed 205,195 tabs of Hydrocodone, and 528,718 tabs of Oxycodone, the three neighboring pharmacies, over the period of July 11, 2010, until July 11, 2013, dispensed those controlled substances as follows:

| <i>Pharmacy</i> | <i>Hydrocodone/APAP (10/325 mg)</i> | <i>Oxycodone (30 mg)</i> |
|----------------------|-------------------------------------|--------------------------|
| Safeway Pharmacy | 112,357 tabs | 56,501 tabs |
| Rite Aid (No. 5892) | 190,960 tabs | 41,727 tabs |
| Rite Aide (No. 5893) | 120,268 tabs | 15,530 tabs |

In these regards, respondents' acts and omissions violated the Pharmacy Law.

¹³ Oxycodone is a semi-synthetic narcotic analgesic with multiple actions qualitatively similar to those of Morphine. It is a Schedule II controlled substance and narcotic as designated by Health and Safety Code section 11055, subdivision (b)(1). And, oxycodone is a dangerous drug under Business and Professions Code section 4022. Oxycodone can produce drug dependence and has the potential for being abused.

INVESTIGATIVE FINDINGS AND CONCLUSIONS - TENTH CAUSE FOR DISCIPLINE

20. Respondent Chan failed to use his education, training, and experience as a pharmacist when he filled prescriptions for large quantities of narcotics for consumers, who used multiple prescribers so that those consumers could obtain early refills at and through respondent Jefferson Plaza Pharmacy.

When respondent Chan executed 25,251 prescriptions and dispensed controlled substances under that number of prescriptions, so as to dispense 204,195 doses of Hydrocodone/APAP¹⁴ 10/325 mg and 528,718 tablets of Oxycodone 30 mg, he failed to properly, professionally or ethically use his education, training and experience as a licensed pharmacist. Also, respondent Chan failed to use his education, training and experience as a licensed pharmacist when he filled prescriptions for large quantities of narcotics for patients who used multiple prescribers or obtained early refills through the facilities of Jefferson Plaza Pharmacy.

In these regards, respondents' acts and omissions violated the Pharmacy Law.

INVESTIGATIVE FINDINGS AND CONCLUSIONS - ELEVENTH CAUSE FOR DISCIPLINE

21. Respondent Chan failed to exercise or implement his best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services authorized by his pharmacist's license. In particular, from July 11, 2010, through July 11, 2013, respondent Chan filled prescriptions for large quantities of narcotics for patients who used multiple prescribers, paid cash, and obtained early refills at and through respondent Jefferson Plaza Pharmacy. Respondent Chan engaged in those practices without taking proper or thorough measures to confirm the prescriptions through explicit inquiries of the medical care providers who purportedly issued the prescriptions. Accordingly, respondent's failure to confirm the proper, correct and appropriate extent of prescriptions did not verify or assure that large quantities of narcotics were prescribed for legitimate medical purposes.

When respondent Chan executed 25,251 prescriptions and dispensed controlled substances under that number of prescriptions so as to dispense 204,195 doses of Hydrocodone/APAP 10/325 mg and 528,718 tablets of Oxycodone 30 mg, he failed to exercise corresponding responsibility by filling prescriptions for large quantities of narcotics for patients who used multiple prescribers and obtained early refills at Jefferson Plaza Pharmacy. When respondent Chan committed such acts or omissions he failed to take

¹⁴ Hydrocodone with APAP is also known by brand names of Vicodin and Lortab. Hydrocodone is a Schedule III controlled substance under Health and Safety Code section 11056, subdivision (e). Hydrocodone with APAP is a dangerous drug as defined by Business and Professions Code section 4022

measures to confirm the prescriptions, and the large quantities of narcotics, were prescribed for legitimate medical purposes.

In these regards, respondents' acts and omissions violated the Pharmacy Law.

TWELFTH CAUSE FOR DISCIPLINE

22. Neither respondent Jefferson Plaza Pharmacy nor respondent Chan engaged in unprofessional conduct, as established by the clear and convincing evidence through complainant's case-in-chief at the hearing of this matter, to the extent or degree as alleged under the Twelfth Cause of Discipline in complainant's Accusation.

Finding Regarding Affect of Respondents' Cross Examination of Complainant's Inspector

23. Respondents' cross-examination of complainant's sole witness did not establish that Inspector Shafir's testimony or her investigative conclusions were unclear or less than convincing regarding respondents' unprofessional acts and omissions as set out in Factual Findings 12 through 21.

Respondents' Case in Chief

RESPONDENTS' WITNESSES IN MITIGATION

BERNARD R. WILCOSKY

24. Bernard R. Wilcosky (Dr. Wilcosky) offered extensive testimonial evidence at the hearing.

Dr. Wilcosky is a physician, who over a career of 30 years, has focused upon a medical practice oriented towards pain management. He is a board-certified anesthesiologist. In 1993, he took the very first examination for the pain practitioner-specialists. Dr. Wilcosky is a member of American Academy of Pain Medicine and the American Academy of Pain Management. And, he is recognized as an Advanced Practitioner through the American Academy of Pain Management.

At the hearing of this matter, Dr. Wilcosky presented testimony regarding his provision of treatment to patients having grave pain or disabling physical discomfort, which must be primarily attended to with strong pain medication therapy.

25. Over a period of approximately five years, Dr. Wilcosky has known respondent Chan. As a pain treatment specialist, Dr. Wilcosky thinks highly of respondents' capabilities and facilities. And, Dr. Wilcosky notes that respondents have made it "easy" for his pain-impaired patients to acquire narcotics, which are necessary to control pain.

26. Despite his favorable estimation of respondents, Dr. Wilcosky offered no testimonial evidence to refute complainant's Accusation's First through Eleventh Cause for Discipline, which resulted in Factual Findings 12 through 21, above.

Dr. Wilcosky was not persuasive with his testimony regarding the needs of patients to fill numerous narcotics through many prescriptions. And, Dr. Wilcosky was not credible when he asserted at the hearing that he did not recommend that his patients, who consume significant doses of controlled substances, seek out respondents, without those board licensees adhering to corresponding responsibility principles. Dr. Wilcosky did not establish that he has examined the computer records, or other data, pertaining to respondents' methods and practices for dispensing controlled substances and respondents' efforts to document verifying with prescribing medical treatment providers the supporting information for the level of controlled substances sold through respondents' pharmacy business.

27. On cross-examination, Dr. Wilcosky was shown not to have as close a working relationship with respondent Chan. Among other things, Dr. Wilcosky believed that respondent Chan's name was "Chang." And, Dr. Wilcosky was not believable when he suggested that he held necessary communications with respondent Chan regarding most prescriptions written by the physician for his patients to acquire controlled substances through respondents.

Dr. Wilcosky was shown to hold disdain for the so-called chain pharmacies, that is the large corporate pharmacies. He has views that his opioid-using patients have been made uncomfortable in attempting to fill prescriptions at the large chain pharmacies. Dr. Wilcosky has concluded that respondents have shown great accommodations toward his patients who must take significant amounts of narcotics to control pain.

GEORGE PON

28. George Pon gave testimonial evidence at the hearing of this matter

Mr. Pon is a registered pharmacist. He has been licensed for "forty-something" years. Although he is retired from a day-to-day practice, Mr. Pon maintains an active license with the board.

Mr. Pon graduated in 1970 from the University of Idaho with a bachelor's of science degree in pharmacy science. His first professional employment position in California was as a pharmacist for the Payless Drug Stores. But, most of his career as a pharmacist was spent with Kaiser Permanente Medical facilities, where he had a long-term assignment in Redwood City, San Mateo County.

Mr. Pon has known respondent Chan for "about 30 years."

Mr. Pon has been president of the San Mateo County Pharmacists Association, as well as a member of the board of directors for that organization. Mr. Pon is aware that

respondent has served as treasurer of the San Mateo County Pharmacists Association for the last few years. Currently, respondent Chan provides services to the association as not only treasurer but also as the volunteer organization's member who files reports with state and federal government entities due to the association's "501(c)(3)" status. Mr. Pon reviews respondent Chan as having great qualities consistent with being a "detailed, on-time" individual. Mr. Pon views respondent Chan as a person who makes important suggestions regarding the association's use of its financial resources.

On approximately five occasions as a "relief pharmacist," Mr. Pon has worked for respondents on the premises of Jefferson Plaza Pharmacy. And, he interacted with Ms. Esmabe within the pharmacy.

Mr. Pon pointed out that respondent Chan has been the recipient of William Dugoni Memorial Lifetime Achievement Award as granted by the San Mateo County Pharmacists Association. The award is a synthesis of the organization's members' collective respect and admiration for respondent's commitment to the association as well as an appreciation for his knowledge of pharmacy. Also, respondent received the association's "Pharmacist of the Year" Award on more than one occasion.

Mr. Pon advanced that complainant's allegation of unprofessional conduct on respondents' part, "just cannot be" a reality. Mr. Pon asserts that over the years he has known respondent Chan to have only exhibited great professionalism as a pharmacist. The Accusation's allegations "make no sense" because Mr. Pon has observed respondent in work settings, and Mr. Pon is aware that respondent Chan has provided great services to elderly and infirmed consumers.

29. Despite his high estimation of respondents, Mr. Pon did not show that he has engaged in an audit, or other detailed review of the actual practices and procedures executed by respondents.

Mr. Pon offered no testimonial evidence to refute complainant's Accusation's First through Eleventh Cause for Discipline, which resulted in Factual Findings 12 through 21, above.

TERESA LOUISE BITTNER

30. Teresa Louise Bittner (Dr. Bittner) offered compelling testimony at the hearing.

Dr. Bittner is currently a college mathematics professor. She once occupied a position as a chief executive officer for an educational textbook services publishing company.

Approximately 16 years ago, Dr. Bittner was impacted by the adverse affects of debilitating disease. The disease process had incapacitating abdominal pain as one of the

manifestations of the disorder. She spent a year as an inpatient in a hospital because of the disease.

Dr. Bittner has been a customer of respondents for 20 years. And with the intensification of the disease that impacts her, Dr. Bittner greatly relies on respondents' services. In her view, respondents operate a community-based pharmacy, which is greatly appreciated by Dr. Bittner and her family.

To manage the illnesses and disease, Dr. Bittner acquires, at this time, no less than three controlled substances from respondents. She has two prescribers, both a rheumatologist and a pain management physician, who issue prescriptions for her to acquire the narcotics from respondent.

Dr. Bittner notes she has a complicated case, which includes her allergies to various substances. She observes that respondent Chan has "always watched out" for her particular needs with regard to her acquiring controlled substances.

As recently as the day prior to her testimony, Dr. Bittner had heard from her treating rheumatologist that that medical doctor receives telephone inquiries from respondent Chan regarding the prescriptions presented to Dr. Bittner through respondent Jefferson Plaza Pharmacy. According to Dr. Bittner, her treating medical doctor has reported being impressed with respondent Chan, and the physician views respondent Chan as being "a very good pharmacist," who works with Dr. Bittner's treating physician so as to solve problems with prescriptions.

Dr. Bittner is impressed with the physical plant that makes up the premises of respondent Jefferson Plaza Pharmacy. She understands respondents have a good system to assure that expired drugs are not distributed to the public.

Should respondent Jefferson Plaza Pharmacy close because of license revocations, Dr. Bittner does not know what she will do to readily fill her prescription for pain relief medications. She fears that the "big box" pharmacies may not expeditiously fill the level of prescriptions for controlled substances that she requires to comfortably live with her various disease processes.

31. Notwithstanding the poignant, heart-felt statements from Dr. Bittner, some aspects of her testimony were not plausible. She did not state, for example, that on any occasion when a corporate pharmacy has denied the filling of a prescription for her to acquire a controlled substance that she has filed a complaint with the board based on the large pharmacy's violation of Business and Professions Code section 733.¹⁵ And even

¹⁵ Businesss and Professions Code section 733 sets out, in part:

(a) A licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that

though it might be inconvenient for a family member of Dr. Bittner to drive one or two miles to a large, corporate-oriented pharmacy, Dr. Bittner was not believable that the revocation of respondents' licensure status would result in a grave hardship to her or other consumers who have procured narcotics from respondent.

Respondent Johnny Pinghon Chan

RESPONDENT CHAN'S BACKGROUND AND MATTERS IN MITIGATION

32. In 1978, respondent Chan graduated from University of the Pacific in Stockton, California with a doctorate degree in Pharmacy. Earlier in his advanced formal education years in the United States, he spent one year (1975) in studies at the University of Wisconsin School of Medicine; but, he did not earn a degree from that university.

33. Respondent Chan has been a licensed pharmacist for 35 years. He was first employed by Thrifty Drugs before working as the pharmacist-in-charge at Jefferson Plaza Pharmacy.

Respondent Chan views respondent Jefferson Plaza Pharmacy as a family-owned pharmacy, which for 30 years has been owned, in part, by his wife.

34. Jefferson Plaza Pharmacy employs five individuals, including respondent Chan and his wife. As a local, community pharmacy, respondent Jefferson Plaza Pharmacy serves several retirement homes and elderly people. And, the pharmacy provides services to local hospice facilities and other medical treatment institutions in proximity to the premises of the pharmacy.

Unlike the large corporate pharmacy enterprises, respondent Jefferson Plaza Pharmacy makes home delivery of narcotics and controlled substances used by patients to treat disabling pain and grave physical discomfort.

35. Respondent Chan asserts that respondent Jefferson Plaza Pharmacy is very consumer oriented and that consumers pay relatively lower prices for drugs when compared to large corporate-owned pharmacies. Cash paying consumers receive price discounts under the policy established by respondent Chan. And, respondent Jefferson Plaza Pharmacy operates as a "fast and efficient" pharmacy.

Respondent Chan claims that respondent Jefferson Plaza Pharmacy receives very good reviews in various rating guides for consumers. He produced pages from the Yelp internet site's set of glowing and very complimentary consumer reviews for respondents, especially of Jefferson Plaza Pharmacy as compared with large corporate pharmacies.

patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

RESPONDENTS' PROGRESS TOWARDS REHABILITATION

36. Respondent Chan has the respect of individual health care providers. At the hearing, respondent offered five letters.¹⁶ Those letters, which supplement and explain¹⁷ other evidence, especially respondent's testimony, include remarks such as:

As a member of [San Mateo County Pharmacists Association, respondent Chan] has been serving as treasurer for over 10 years. As . . . treasurer, he has displayed stellar professionalism, great motivational skills and accuracy. In addition . . .; he volunteered his time to help lobby for the passage of several pharmacy bills, at senior health care centers, sponsor[ed] pharmacy students for various events . . . (letter by Sagee Thirucote)

[Respondents] have been uniformly responsive and helpful to my patients, as well as to my staff and me. [¶] . . . [Respondents] give excellent service . . . (letter by David A. Jacoby, M.D.)

[Respondent Chan] is one of the oldest and most trusted member in the [San Mateo county Pharmacists Association] . . . Throughout the years, I have not had any reasons to doubt [respondent Chan's] integrity as a person or as our fellow member who handles our finances . . . (letter by Chau Phan, M.S., Pharm. D.)

Since I moved to private practice, I have had many patients who have filled their medications regularly at Jefferson Plaza Pharmacy and have interacted with [respondent Chan]. I have had numerous conversations with [respondent Chan] regarding patients of mine who fill medications, as well as he has initiated calls to me when he had concerns about

¹⁶ A letter, dated October 2, 2014, by Sagee Thirucote, president-elect, San Mateo County Pharmacists Association; a letter, dated October 1, 2014, by David A. Jacoby, M.D.; a letter, dated October 1, 2014, by Chau Phan, M.S., Pharm.D., president, San Mateo County Pharmacists Association; a letter, dated June 1, 2015, by R. Elaine Lambert, M.D., Adjunct Clinical Professor of Medicine (Rheumatology) Stanford School of Medicine; and, a letter, dated September 20, 2014, by Jeff Wasel, Ph.D.

¹⁷ Government Code section 11513, subdivision (d).

patients' usage of their opioids. I have never been aware of any instances when [respondent Chan] did not fill any prescription accurately or provide the medication to my patients in a timely manner.

[¶ . . . ¶] It is very important that independent pharmacists, who have a special interest in dealing with chronic pain patients, such as [respondent Chan], be allowed to remain in independent pharmacy practice. [¶ . . . ¶] I give [respondent Chan] my full support as a qualified and compassionate pharmacist in my area
(letter by R. Elaine Lambert, M.D.)

After several months of frustration at getting my prescriptions needs met, my pain management physician recommended I see [respondent Chan] at Jefferson Plaza Pharmacy [¶ . . . ¶] What a relief from all the nonsense and negativity I experienced at [three named national pharmacy chains]! [Respondent Chan] and his team were a breath of fresh air, always ready with a smile and a pleasant, 'can do' attitude to even the most complex script requests. [¶] . . . I've gone nowhere else since discovering this hidden gem and I always recommend Jefferson Plaza Pharmacy whenever I get the chance (letter by Jeff Wasel, Ph.D.)

37. Since the date that respondent Chan became aware of Inspector Shafir's Investigative Report, which described the clutter, disorganization, and dirty, unhealthy appearance of the pharmacy's premises and compounding work area, the pharmacist-in-charge has caused respondent Jefferson Plaza Pharmacy's premises to be thoroughly cleaned. Respondent Chan directed that the work areas within the pharmacy, including the compounding space, to be remodeled. The remodeling has included adding shelves and removing many previously unsightly features at Jefferson Plaza Pharmacy. (At the hearing of this matter, respondents presented recent photographs (taken in approximately June 2015) of the interior of Jefferson Plaza Pharmacy that show images of the conditions that are dramatically improved relative to the July 2013 images, which are included in complainant's Investigative Report as prepared by Inspector Shafir.)

38. Currently, respondent Chan is actively using a "Compounding Self-Assessment" questionnaire to meet the requirements of the board's regulations (Cal. Code Regs., tit. 16, §§ 1735 & 1735.1.) for a community pharmacy engaged in crafting compounds for prescriptions. Also, respondent Chan has created for respondent Jefferson Plaza Pharmacy a two-page document titled "Compounding Policies and Procedures."

39. Respondent Chan has developed, for use in assessing personnel of Jefferson Plaza Pharmacy a form titled, "Pharmacist/ Pharmacy Technician Performance Evaluation." The evaluation form has been used, according to respondent Chan, every three months so as to assure the professionalism of board licensees working at Jefferson Plaza Pharmacy.

40. Since the Investigative Report by Inspector Shafir, respondent Chan has authored a document titled, "Standard Operating Procedure Manual" for Jefferson Plaza Pharmacy. The manual's pages set out impressive goals and performance standards that are to be executed by personnel working for respondent Jefferson Plaza Pharmacy.

41. Both respondent Chan and Ms. Esmabe, who is working as a pharmacist trainee, have taken several continuing professional education courses in subjects pertaining to: (i) "compounding" as well as (ii) handling and dispensing controlled substances. Respondent Chan's recent continuing education courses, which have been amassed in the immediately-aforestated two critical areas, include:

| <i>Course Name</i> | <i>Date</i> |
|---|------------------|
| "Drugs, Drugs and More Drugs" | August 18, 2013 |
| "California Board of Pharmacy Update" | August 18, 2013 |
| "Combating Pharmacy Diversion" | August 18, 2013 |
| "Drug Theft Prevention" | August 18, 2013 |
| "Management of Common Pain Conditions Encountered by Osteoarthritis" | August 26, 2013 |
| "Regulatory and Ethical Issues in Pain Management" | August 26, 2013 |
| "Drug Rescheduling and Controlled Substances" | October 29, 2013 |
| "Compounding Update: Regulatory Guidelines and Standards of Practice" | July 31, 2014 |

42. Since the findings and conclusion as set out in complainant's Investigative Report regarding the custom within Jefferson Plaza Pharmacy for the compounding of suspected medications within the pharmacy's premises, respondent Chan has implemented a practice of sending, every three months, various drugs for independent analysis. At the hearing, respondent produced sample Certificate(s) of Analysis by Analytical Research Laboratories that have tested drugs compounded at Jefferson Plaza Pharmacy. Respondent Chan proclaims that the independent testing results have consistently shown the high quality of the products compounded by, or under the direction of, respondent Chan.

43. With regard to respondents having used respondent Maricon Payte Esmabe (Ms. Esmabe) as an unlicensed pharmacy technician, respondent Chan provided a poignant account of the young woman's struggles and the aid given her by respondent Chan.

Ms. Esmabe graduated from a pharmacy college in the Philippines. Respondents hired her as a pharmacy technician and potential intern. Ms. Esmabe experienced difficulty

in passing the board's pharmacist licensing examination, which she failed on two attempts. When she did not pass the pharmacist examination, respondent Chan encouraged Ms. Esmabe to apply to gain registration as a pharmacy technician. Before she acquired the pharmacy technician registration, respondent Chan hired Ms. Esmabe as "an intern" because of her abilities in working with "retirement home" customers. In addition to working with the pharmacy's durable equipment and other supplies for the elderly, Ms. Esmabe did aid respondent Chan in compounding under his strict supervision. Respondent Chan noted that Ms. Esmabe's problem with passing the board's pharmacist's examination was her weakness in executing calculations for compounding, which is not an area of study in the pharmacist education regime in the Philippines. In order to gain strength with calculations, respondent Chan oversaw Ms. Esmabe's calculations for compounding. Ms. Esmabe signed the "compounding log" as directed by respondent Chan; but according to the uncorroborated testimony, respondent Chan was the only worker at Jefferson Plaza Pharmacy who actually engaged in compounding prescriptions. In time, Ms. Esmabe passed the board's examination for her registration as pharmacy technician, but due to a board requirement that she present a high school diploma from the Philippines a delay occurred for her to acquire actual registration. The delay in the registration for Ms. Esmabe occurred at the time of the on-site inspection (July 2013) by Inspector Sharif, which happened at a time before the board granted Ms. Esmabe's pharmacy technician registration on August 23, 2013. As of the date of the hearing (June 2015), Ms. Esmabe continued to work at Jefferson Plaza Pharmacy. (Respondent Chan observed that Ms. Esmabe has passed the board's examination for licensure as a pharmacist; but the actual licensure had been "held up" by the board due to the Accusation in this matter.)

Respondents did not call Ms. Esmabe to testify on matters advanced by respondent Chan. (Hence, the after-the-fact rationalizations offered at the hearing cannot be given much weight as being credible and reliable.)

44. Respondent Chan vividly asserts that he is a dedicated professional. He has been, and continues, to be an active member in the San Mateo Pharmacist Association. Respondent Chan promotes high professional standards for pharmacists, including traveling with a delegation of other licensees to Sacramento to meet with legislators on laws important to the pharmacy profession. Respondent Chan has been an organizer of such programs as "Talk to a Pharmacist Day" as held in Hillsdale Mall, where he offers free services to the public. Respondent Chan asserts that he has not misused his education in that he has sought to promote the role of a pharmacist.

45. Respondent Chan claims that he and respondent Jefferson Plaza Pharmacy are currently very diligent with the use of the CURES program. And, respondent Chan has devoted himself to daily use of the program's system to check the dispensing of controlled substances to all patients. He has not been "locked out" of the system for any measurable amount of time since the occurrence of the inspection by Inspector Shafir.

MATTERS THAT CAST NEGATIVE LIGHT UPON RESPONDENT CHAN

46. Respondent Chan was not credible when he described the inspection performed in July 2013 as “pretty confrontational.” He was not persuasive when he testified that upon being confronted by Inspector Shafir he became nervous. Uncompellingly, respondent Chan asserted at the hearing that when he is confronted with conflicts he tends to “withdraw,” and he cannot think very well. Hence, he wishes to imply that the supposed disagreeable, or purported hostile disposition of the inspector resulted in respondent Chan’s poor performance during the inspection so that he made inexact statements that resulted in the adverse findings and conclusions as to unprofessionalism by respondents.

Respondent Chan’s unbelievable, after-the-fact rationalization for respondents’ unprofessional acts and omissions, as revealed during Inspector Shafir’s inspection, cannot be attributed, to the inspector’s supposed mean disposition or confrontational attitude, even if accurate, which is doubtful. Respondent Chan’s testimony on this matter must be wholly discounted and deemed to be without merit.

Complainant’s inspector made findings and reached determinations that were based upon close scrutiny of the objectively discernible poor conditions and disorganization of respondents’ physical plants, which comprised of respondents’ pharmacy and compounding areas; the compilation and analysis of records and documents furnished by respondent Chan; and, extensive study of the facts gathered over many hours following July 12, 2013. The bulk of the findings and determinations by Inspector Shafir were made well after the date, time and place of the actual inspection.

47. Respondent Chan was not accurate with his testimony that during the past year’s board inspection, another inspector made no adverse findings against respondents. On cross-examination, complainant established that the immediate past inspection was actually deferred to a future date. And, the immediate past year’s inspection did not necessarily give complimentary findings to respondents.

49. Respondent Chan’s explanation at the hearing was wholly unbelievable regarding respondents’ past limited use or reliance upon the CURES program’s data to verify whether a patient was engaged in “pharmacy shopping,” or otherwise improperly seeking to acquire narcotics. Despite his education and experience, respondent Chan unpersuasively claimed at the hearing that the use of the CURES)¹⁸, computerized system was very complex

¹⁸ Notice is taken that California doctors and pharmacies must report to the California Department of Justice every schedule II, III and IV drug prescription that is written or dispensed within seven days. Pharmacies are required to do so under Health and Safety Code section 11165, subdivision (d). The information provided establishes the CURES database, which includes information about the drug dispensed, drug quantity and strength, patient name, address, prescriber name, and prescriber authorization number including DEA number and prescription number.

and that the program was not very reliable. Respondent Chan gave no evidence that the CURES system was "not very good" with the process of uploading data and that the CURES software program's requirement for frequent changes of passwords was a barrier for him to use that program.

50. During his direct testimony, respondent Chan falsely testified that expired medications were not used for the compounding of prescriptions at the licensed facility of respondent Jefferson Plaza Pharmacy. But, on cross-examination, respondent made an admission that, at least, on February 26, 2013, an ingredient number 2 (Gapapentin), used in compounding prescriptions, was an expired medication because it had an expiration date of May 30, 2011.

51. Respondent Chan unpersuasively sought to refute the determination by Inspector Sharif that an industry wholesale drug vendor, which sells controlled substances, had suspended its business with Jefferson Plaza Pharmacy in the way of delivering controlled substances to respondent because of the supposed excessive ordering of narcotics for dispensing through respondents. Respondent Chan produced at the hearing an invoice, dated June 8, 2015, issued by AmerisourceBergen that shows delivery to Jefferson Plaza Pharmacy of controlled substances including: Fentanyl; Methadone HCL; Oxycodone 30 mg. Respondent Chan proclaimed that Inspector Shafir misunderstood his comments regarding the relationship between the drug whole sellers and Jefferson Plaza Pharmacy on the matter of a suspension of the narcotics supply due to respondents' inordinate volume of purchases of controlled substances.

Respondent Chan declared that respondents have never suffered an interruption or delay in delivery of controlled substances from any supplier. During the months of April 2015 and May 2015, respondent Jefferson Plaza Pharmacy received each month approximately 20 separate deliveries of controlled substances from the AmerisourceBergen company.

But, respondent Chan did not produce either a witness from, or a declaration under oath by, a representative of AmerisourceBergen company to correct or refute that the matter of the diminished supply of drugs to respondent, which was set out in the Investigative Report.

52. At the hearing of this matter, respondent was not credible when he attempted to retract a prior inconsistent statement made to Inspector Shafir on the date of the July 2013

The Attorney General's Office provides authorized persons and agencies with Patient Activity Reports that reflect all controlled substances dispensed to an individual. These reports may be used by doctors and pharmacies to identify persons attempting to collect multiple narcotics prescriptions from many different doctors. There was no real-time retrieval system before 2011, and pharmacies and others seeking information maintained by CURES before 2011 received data that was usually one to two weeks old.

inspection. Respondent Chan's statement is included in the Investigative Report. As noted above, the statement was that AmerisourceBergen had diminished or limited the shipment by that drug wholesale company of controlled substances to respondent Jefferson Plaza Pharmacy. On cross-examination, respondent Chan was shown to have either engaged in making false statements to the board inspector or to a physician specializing in pain management medicine about respondents experiencing a diminution of a supply of narcotics from a drug supplier due to limits placed on respondents because of the past large orders for controlled substances by respondent Jefferson Plaza Pharmacy.

53. At the hearing of this matter, respondent Chan failed, or refused, to acknowledge the potential harm to the public through the array of unprofessional acts and omissions detected by the board Inspector Shafir's investigation. Respondent Chan's attitude suggests an ethical lapse on his part.

54. The number and variety of recently detected violations of the Pharmacy Law by respondent were significant as established by the findings and determinations in complainant's Investigative Report and the testimony of Inspector Shafir.

55. Respondents' acts and omissions must be viewed as serious violations of the Pharmacy Law.

56. Respondents' violations as detected in the investigation by Inspector Shafir are very recent in time. The recency of the violations suggests that respondents may not have had adequate time to completely implement contemplated corrective measures, practices and policies designed to address respondents' array of violations of the Pharmacy Law.

57. Due to the large volume of controlled substances sold by, or through, respondents, it is not difficult to infer that there were substantial financial benefits received by respondents from the collective misconduct and unprofessional acts and omissions as revealed by the weight of the evidence in this matter. Respondents' sale of tens of thousands of doses of controlled substances, more likely than not, translated into great profits for respondents.

Complainant's Request for Recovery of Costs of Investigation and Prosecution and Respondent's Objection to Imposition of Costs

58 Complainant requests that respondents be ordered to pay the board the costs of prosecution under Business and Professions Code section 125.3. In support of the request for cost recovery, complainant offers a declaration, dated June 2, 2015, by Inspector Manisha Shafir of the board, as well as complainant's personal declaration, also dated June 2, 2015, which supported the Certification of Investigative Costs. Also, the declaration, dated June 3, 2015, by Deputy Attorney General Settles was filed in support of the Certification of Prosecution Costs. The declarations state that the board has incurred the following costs in connection with the investigation and enforcement of complainant's accusation as follows:

| | |
|--|--------------------|
| California Department of Justice, Office of Attorney General | |
| Costs of Prosecution | \$15,940 |
| Complainant's Inspector's | |
| Investigative Costs | <u>\$13,846.30</u> |
| Total Costs of Investigation and Prosecution | \$29,786.30 |

59. The declarations by Inspector Shafir, complainant, and Deputy Attorney General Settles fairly present requisite information by which the reasonableness of the costs may be determined and weighed for the board's recovery for the investigation and prosecution activities before June 8, 2015, which was the commencement date for the hearing in this matter. The declarations and their attachments set forth general, yet clear, descriptions of the tasks performed during the investigation and prosecution of this matter, as well as the time spent in attending to such tasks, and the methods of tabulating the hours involved in calculating the costs, as required by California Code of Regulations, title 1, section 1042.

The comprehensive nature of the declarations, and the supporting documents, for the certifications of costs establish that the board is entitled to the total measure of its costs of investigation and enforcement. The time expended by personnel of the Department of Justice is well within reason and was justified and necessary to establish the extent of respondent's negligence, incompetence, and unprofessional conduct. The facts developed at the hearing indicate that the deputy attorney general devoted a reasonable amount of time, which is found to have been of a prudent nature, for the prosecution of this matter.

Complainant's investigative costs, as incurred through the indepth analysis, data gathering, requisite travel, and thorough report writing, support the expenses incurred. First, Inspector Shafir exerted time in nine distinct areas relating to the investigation, including: reviewing and prioritizing her assignments upon receipt of the investigative file; communicating with complainant, namely the board's executive officer; contacting and interviewing witnesses as well as the licensees; preparing correspondence; collecting, organizing and evaluating documentation; performing audits of documents created or possessed by respondents; researching various topics of a complex and specialized nature; and conferring with agency supervisors. Such investigation entailed recording 48.50 hours, which is approximately six to eight full days of work. She then spent 48.75 hours, or approximately another six to eight full days, in preparing the detailed investigative report and its attachments. (The investigative report covers 42 pages, and when the attachments are added the entire investigative work product is made up of more than 500 pages.) It is not unreasonable for Inspector Sharfir to have billed 36 hours, or four and one-half days to six days, in "hearing preparation," which necessarily means detailed study of the investigative report and its attachments so as to intelligently and collaboratively interact with the deputy attorney general, and then to refocus in order to come into the administrative hearing.

Importantly, at the hearing Inspector Sharif demonstrated her thorough, erudite knowledge of all aspects of the investigation. The board's inspector rendered unhesitating responses to all inquiries directed at her during the hearing. And, she offered reliable, trustworthy and persuasive testimonial evidence, which must be credited to the energy and time expended by her before the hearing date.

60 In this matter, respondent Chan and respondent Jefferson Plaza Pharmacy did not advance a meritorious defense in the exercise of respondents' right to a hearing in this matter insofar as to justify any reduction of the total amount of the costs sought for recovery. And, neither respondent Chan nor respondent Jefferson Plaza Pharmacy can be seen, under the facts set out above, to have committed slight or inconsequential misconduct in the context of the Accusation. Also, respondents did not raise a "colorable challenge" to the Accusation's paramount causes for discipline, namely respondent's unprofessional conduct, as manifested through breaching professional standards, such as the corresponding responsibilities doctrine, the requirement that pharmacies not expose consumers to the risk of receiving expired medications, and respondents' disregard of the Pharmacy Law's requirements regarding unlicensed persons being prohibited from the process of compounding prescriptions. Further, respondent Chan failed to acknowledge the seriousness of the violations of law as set out in the Accusation, which highlights several acts and omissions constituting unprofessional conduct on the part of respondents.

At the hearing of this matter, respondent Chan did not offer evidence that, at the time of the hearing, either he or Jefferson Plaza Pharmacy can be considered desperately impaired financially, or fiscally destitute, so that the imposition of an order for cost recovery will operate as a grave hardship. Respondent Chan provided no financial records or certification under oath from a certified public accountant that establishes respondents' financial liabilities are greater than their collective total assets. No balance sheets, statements of assets and liabilities or past tax returns were offered into evidence to show respondents' limited financial means.

The immediate foregoing factors indicate that the imposition upon respondents of the full costs of investigation and prosecution will not unfairly penalize either respondent. A substantial basis does not exist to warrant a reduction of the assessment against respondents for the costs of prosecution and investigation incurred by complainant.

Respondents did not provide adequate, competent evidence to establish that complainant's certifications for recovery of costs of investigation and prosecution are inappropriate.

61. Accordingly the reasonable and appropriate amount of costs owed by respondents to the Department of Consumer Affairs, on behalf of the board, is set at \$29,786.30

LEGAL CONCLUSIONS

The Regulation of Pharmacy

1. The Pharmacy Law governs the practice of pharmacy. Pharmacies must be licensed by the Board of Pharmacy, which has as its highest priority the protection of the public. Every pharmacy must have a “pharmacist-in-charge,” an individual licensed by the board who is responsible for a pharmacy’s compliance with all state and federal laws. A pharmacist may be assisted by a pharmacy technician as specified in Business and Professions Code section 4115. (*Golden Drugs Co., Inc. v. Maxwell-Jolly* (2009) 179 Cal.App.4th 1455, 1458-1459.)

2. The Board of Pharmacy is guided by a statute that mandates that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public must be paramount. (Bus. & Prof. Code, § 4001.1.)

The Purpose of Administrative Disciplinary Proceedings

3. A license revocation proceeding is civil in nature. Neither a criminal prosecution nor a malpractice action serves the purpose of a license revocation proceeding, which is not intended to punish the licensee, but to afford protection to the public upon the rationale that public respect and confidence is merited by eliminating dishonest, immoral, disreputable or incompetent persons from the ranks of practitioners. (*Fahmy v. Medical Bd. of California* (1995) 38 Cal.App.4th 810, 817.)

The Burden and Standard of Proof

4. An individual who holds a license to practice a particular profession has a fundamental vested right to continue in that licensed activity. Procedural due process requires a regulatory board or agency seeking to suspend or revoke a professional license to prove the allegations of an accusation by clear and convincing evidence, rather than proof by a preponderance of the evidence. (*Owen v. Sands* (2009) 176 Cal.App.4th 985, 991-992.)

5. Clear and convincing evidence requires a finding of high probability; the evidence must be so clear as to leave no substantial doubt; it must be sufficiently strong to command the unhesitating assent of every reasonable mind. This requirement presents a heavy burden, far in excess of the preponderance of evidence standard that is sufficient for most civil litigation. (*Christian Research Institute v. Alnor* (2007) 148 Cal.App.4th 71, 84.)

6. The terms “burden of proof” and “burden of persuasion” are synonymous. A party has the burden of proof as to each fact the existence or nonexistence of which is essential to the claim for relief or defense that he is asserting except as otherwise provided by law. To prevail, the party bearing the burden of proof must present evidence sufficient to establish in the mind of the trier of fact a requisite degree of belief. The burden of proof does

not shift during trial - it remains with the party who originally bears it. Unlike the burden of proof, the burden of producing evidence may shift throughout the trial. Initially, the burden of producing evidence as to a particular fact rests on the party with the burden of proof. When that party fails to produce sufficient evidence to make a prima facie case, that party risks an unfavorable determination. But, once that party produces evidence sufficient to make its prima facie case, the burden of producing evidence shifts to the other party to refute the prima facie case. Even though the burden of producing evidence shifts, a party need not offer evidence in reply, but the failure to do so risks an adverse outcome. Once a prima facie showing is made, it is for the trier of fact to say whether or not the crucial and necessary facts have been established. (*Sargent Fletcher, Inc. v. Able Corp.* (2003) 110 Cal.App.4th 1658, 1667-1668.)

7. The burden of proof in this matter - the burden of persuasion - was on complainant to establish the allegations in the Accusation by clear and convincing evidence.

Relevant Disciplinary Statutes and Regulations

8. Business and Professions Code section 4300 provides, in 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 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. . . .

9. Business and Professions Code section 4301, subdivision (o), provides:

The board shall take action against any holder of a license who is guilty of unprofessional conduct . . .

Unprofessional conduct shall include, but is not limited to, any of the following:

[¶] . . . [¶]

(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.

10. Business and Professions Code section 4342, subdivision (a), sets forth:

The board may institute any action . . . as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law . . .

11. Business and Professions Code section 4115, provides, in part:

(a) 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. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty.

(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(e) No person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

[¶] . . . [¶]

(h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

(Emphasis added.)

12. Business and Professions Code section 4051, subdivision (a), sets forth:

Except as otherwise provided in [Chapter 9-Pharmacy, Business and Professions Code], it is unlawful for any person to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription pursuant to Section 4040 [the meaning of "prescription" and "electronic transmission prescription"] of a prescriber unless he or she is a pharmacist under this chapter.

13. Business and Professions Code section 4328 provides:

Except as otherwise provided in [Chapter 9-Pharmacy, Business and Professions Code], any person who permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs in his or her pharmacy, except by a pharmacist, is guilty of a misdemeanor.

14. Business and Professions Code section 4301, subdivision (j), establishes:

The board shall take action against any holder of a license who is guilty of unprofessional conduct . . .
Unprofessional conduct shall include, but is not limited to, any of the following:

[¶] . . . [¶]

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. . . .

15. Business and Professions Code section 4301, subdivision (d), provides :

The board shall take action against any holder of a license who is guilty of unprofessional conduct . . .
Unprofessional conduct shall include, but is not limited to, any of the following:

[¶] . . . [¶]

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

16. Business and Professions Code section 4306.5, subdivision (a), states:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

17. Business and Professions Code section 4306.5, subdivision (b), states:

Unprofessional conduct for a pharmacist may include any of the following:

[¶] . . . [¶]

Acts or omissions that involve, in whole or in part, the failure to exercise or implement his . . . best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

18. California Code of Regulations, title 16, section 1714, subdivision (b), provides:

Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

19. California Code of Regulations, title 16, section 1714, subdivision (c), provides:

The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

20. California Code of Regulations, title 16, section 1735.5, sets out, in part:

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

(c) The policy and procedure manual shall include the following

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

21. California Code of Regulations, title 16, section 1735.7, subdivisions (a), and (b), establishes:

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

22. California Code of Regulations, title 16, section 1735.8, subdivision (a), sets forth:

Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

Cause Exists to Impose Discipline Against Medical Plaza Pharmacies, Inc., Inc., doing business as respondent Jefferson Plaza Pharmacy

FIRST CAUSE FOR DISCIPLINE - DRUGS LACKING QUALITY OR STRENGTH

23. The clear and convincing evidence established that the permit issued to respondent Jefferson Plaza Pharmacy is subject to discipline under Business and Professions Code section 4031, subdivision (o), in conjunction with Business and Professions Code section 4342, subdivision (a), by reason of Factual Findings 10, 11, and 12, along with Legal Conclusions 8, 9 and 10.

SECOND CAUSE FOR DISCIPLINE – OPERATIONAL STANDARDS AND SECURITY

24. The clear and convincing evidence established that the permit issued to respondent Jefferson Plaza Pharmacy is subject to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1714, subdivisions (b) and (c), by reason of Factual Findings 10, 11, and 13, along with Legal Conclusions 8, 9, 18 and 19.

THIRD CAUSE FOR DISCIPLINE - NO WRITTEN COMPOUNDING PROCEDURE AND MANUAL

25. The clear and convincing evidence established that the permit issued to respondent Jefferson Plaza Pharmacy is subject to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.5, subdivision (a) and (b), by reason of Factual Findings 10, 11, and 14, along with Legal Conclusions 8, 9, and 20.

FOURTH CAUSE FOR DISCIPLINE - TRAINING RECORDS AND COMPETENCY EVALUATION PROCESS

26. The clear and convincing evidence established that the permit issued to respondent Jefferson Plaza Pharmacy is subject to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.7, subdivision (a) and (b), by reason of Factual Findings 10, 11, and 15, along with Legal Conclusions 8, 9, and 21.

FIFTH CAUSE FOR DISCIPLINE - FAILURE TO PROVIDE COMPOUNDING QUALITY ASSURANCE

27. The clear and convincing evidence established that the permit issued to respondent Jefferson Plaza Pharmacy is subject to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.8, subdivision (a), by reason of Factual Findings 10, 11, and 16, along with Legal Conclusions 8, 9, and 22.

SEVENTH CAUSE FOR DISCIPLINE - PERMITTING AN UNLICENSED PERSON TO ENGAGE IN ACTS REQUIRING A VALID PHARMACY TECHNICIAN REGISTRATION

28. The clear and convincing evidence established that the permit issued to respondent Jefferson Plaza Pharmacy is subject to discipline under Business and Professions Code section 4031, subdivision (o), in conjunction with Business and Professions Code section 4115, subdivision (e), section 4051, subdivision (a) and section 4328, by reason of Factual Findings 10, 11, and 17, along with Legal Conclusions 8, 9, 11, 12 and 13.

EIGHTH CAUSE FOR DISCIPLINE - FAILURE TO EXERCISE CORRESPONDING
RESPONSIBILITY IN DISPENSING CONTROLLED SUBSTANCES

THE CORRESPONDING RESPONSIBILITY LAW

29. An issue of central importance is the Accusation's allegation that respondents violated the corresponding responsibility law. The corresponding responsibility law is both a standard of care and a duty recognized by statute. It is a critical doctrine in the Pharmacy Law.

The standard of care requires pharmacists and pharmacies to determine whether a prescription was issued for a legitimate medical purpose whenever the surrounding circumstances require such an inquiry. Inspector Sharif provided clear and convincing evidence establishing the existence of this standard, as shown by her clear and compelling testimony, and respondents' deviation from the corresponding responsibility standard.

Health and Safety Code section 11153 expresses a corresponding responsibility standard of care. That statute provides in part:

(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

(b) Any person who knowingly violates this section shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or in a county jail not exceeding one year, or by a fine not exceeding twenty thousand dollars (\$20,000), or by both that fine and imprisonment. . . .

LEGISLATIVE HISTORY

The previous version of Health and Safety Code section 11153 was repealed and a new version was enacted in 1982. The new version mirrored Federal Regulations.¹⁹ Supporters of the 1982 assembly bill (AB 3376) sought to bring Health and Safety Code section 11153 in line with parallel federal regulations to facilitate state prosecutions. The change was also prompted by concerns about the growing numbers of "prescription mills" through which medical practitioners issued prescriptions for large amounts of high abuse drugs that were filled at pharmacies willing to participate in schemes that served to divert those drugs into the illegal street market. The newly enacted version of Health and Safety Code section 11153 clarified and strengthened the statute not only to reach practitioners who prescribed drugs for known drug addicts or habitual, unethical users, but also to target physicians and pharmacists who issued and filled high volume prescriptions for controlled substances with no legitimate medical purpose.

Health and Safety Code section 11153, subdivision (a), sets forth the statutory corresponding responsibility standard. And, Health and Safety Code section 115132, subdivision (b), sets forth the punishment that may be imposed upon "any person" who "knowingly" violates subdivision (a).

APPELLATE INTERPRETATION

Health and Safety Code section 11153, subdivision (b), uses the unambiguous and all-inclusive term "any person." The term includes everyone, regardless of whether the person

¹⁹ Code of Federal Regulations, title 21, section 1306.04, subdivision (a), provides:

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

is licensed or unlicensed. The term is specific, free from ambiguity, and therefore is not subject to any construction other than a literal one. (*People v. Gandotra* (1992) 11 Cal.App.4th 1355, 1363-1365 (holding that a licensed physician could not rely on medical appropriateness of unlicensed assistant's illegal prescription to escape liability for aiding and abetting unlawful furnishing of controlled substance; the statute does not require evidence establishing the medical inappropriateness of a drug to support a charge based upon unlicensed person's furnishing of controlled substance.))

In reviewing Health and Safety Code section 11153, several matters are obvious.

First, Health and Safety Code section 11153 sets forth a "corresponding responsibility" upon both the prescribing practitioner and upon the pharmacist who fills a prescription for a controlled substance. (Clear and convincing evidence is required in an administrative disciplinary proceeding alleging a violation of the statute, but proof beyond a reasonable doubt is not required. A disciplinary proceeding may be maintained even though the accused has been acquitted on criminal charges covering the same facts or has obtained a dismissal of such charges. (*Wong v. State Bar* (1975) 15 Cal.3d 528, 531.))

Second, subdivision (a) uses the term "corresponding responsibility," and not the term "identical responsibility." A pharmacist's role in filling a prescription corresponds to the prescriber's role in issuing a prescription, but it is not identical. The pharmacist's burden is to be alert, to make reasonable inquiry when circumstances require, and to refuse to fill a questionable prescription for a controlled substance when nothing establishes that the prescription at issue was issued for a legitimate medical purpose after engaging in due diligence. To paraphrase the decision in *Vermont & 100th Medical Arts Pharmacy v. Board of Pharmacy* (1981) 125 Cal.App.3d 19, 25, pharmacists, as reasonable professional persons, should obey the law, and they must refuse to dispense drugs when their suspicions are aroused by unexplained ambiguities in the prescriptions or the sheer volume of controlled substances prescribed by a single practitioner for a small number of persons.

Third, subdivision (b) imposes a "knowingly" requirement for criminal prosecution. But, the "knowingly" requirement does require a showing that a pharmacist actually knew that the prescription was not issued for a legitimate medical purpose. This is the case because a section 11153 is a general intent crime. To constitute general criminal intent, it is not necessary to prove the intent to violate the law. When a person intentionally does that which the law declares to be a crime, he is acting with general criminal intent, even though he may not know that his act is unlawful. The requirement of acting "knowingly" is satisfied when the person committing the act has knowledge of the facts. "Knowingly" does not require knowledge of the unlawfulness of the act itself. The word "knowing" imports only an awareness of the facts that bring the act within the terms of the statute. (*People v. Lonergan* (1990) 219 Cal.App.3d 82, 95 [defining "knowingly" within the context of Health and Safety Code section 11153, subdivision (b), as indicated].)

CONCLUSIONS REGARDING CORRESPONDING RESPONSIBILITY

The corresponding responsibility law is both a standard of care and a duty imposed by statute. In both cases, pharmacists and pharmacies must determine whether a prescription for a controlled substance was issued for a legitimate medical purpose whenever the surrounding circumstances require such an inquiry. The misconduct that gives rise to this professional duty need not be as egregious as that described in *Vermont & 100th Medical Arts Pharmacy v. Board of Pharmacy, supra*, 125 Cal.App.3d 19. Reasonable judgment is all that is expected, but professional judgment must be exercised when required. Within the administrative disciplinary context, Health and Safety Code section 11153 applies to pharmacists, pharmacists-in-charge, and pharmacies. This interpretation promotes the statute's beneficial purpose and is consistent with the outcome reached in *Vermont & 100th Medical Arts Pharmacy v. Board of Pharmacy, supra*, 125 Cal.App.3d 19.

To establish a violation of the corresponding responsibility standard, complainant was not required to establish that a prescription for a controlled substance was in fact written by a prescriber for an illegitimate purpose; rather to establish a violation of the standard of care and a violation of the statute, complainant was merely required to establish that circumstances were present that would cause a reasonable and prudent pharmacist to question whether a prescription for a controlled substance was issued for a legitimate medical purpose and to show that the pharmacist failed to make the required inquiry. It is concluded that requiring such an inquiry to be made before dispensing a controlled substance does not violate the language or the spirit of Business and Professions Code section 733. But, when a pharmacist does nothing in the face of circumstances that require that some positive action be taken, the pharmacist is guilty of negligence, unprofessional conduct, and violates the corresponding responsibility law when he does nothing.

30. The clear and convincing evidence established that the permit issued to respondent Jefferson Plaza Pharmacy is subject to discipline under Business and Professions Code section 4301, subdivision (j), in conjunction with Health and Safety Code section 11153, subdivision (a), by reason of Factual Findings 10, 11 and 18, along with Legal Conclusions 8, 14 and 29.

NINTH CAUSE FOR DISCIPLINE - EXCESSIVE FURNISHING OF CONTROLLED SUBSTANCES

31. The clear and convincing evidence established that the permit issued to respondent Jefferson Plaza Pharmacy is subject to discipline under Business and Professions Code section 4301, subdivision (d), in conjunction with Health and Safety Code section 11153, subdivision (a), by reason of Factual Findings 10, 11 and 19, along with Legal Conclusions 8, 15 and 29.

Cause Exists to Impose Discipline Against Pharmacist Chan's License

FIRST CAUSE FOR DISCIPLINE - DRUGS LACKING QUALITY OR STRENGTH

32. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4031, subdivision (o), in conjunction with Business and Professions Code section 4342, subdivision (a), by reason of Factual Findings 10, 11, and 12, along with Legal Conclusions 8, 9 and 10.

SECOND CAUSE FOR DISCIPLINE - OPERATIONAL STANDARDS AND SECURITY

33. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1714, subdivisions (b) and (c), by reason of by reason of Factual Findings 10, 11, and 13, along with Legal Conclusions 8, 9, 18 and 19.

THIRD CAUSE FOR DISCIPLINE - NO WRITTEN COMPOUNDING PROCEDURE AND MANUAL

34. The clear and convincing evidence established the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.5, subdivision (a) and (b), by reason of Factual Findings 10, 11, and 14, along with Legal Conclusions 8, 9, and 20.

FOURTH CAUSE FOR DISCIPLINE - TRAINING RECORDS AND COMPETENCY EVALUATION PROCESS

35. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.7, subdivision (a) and (b), by reason of Factual Findings 10, 11, and 15, along with Legal Conclusions 8, 9, and 21.

FIFTH CAUSE FOR DISCIPLINE - FAILURE TO PROVIDE COMPOUNDING QUALITY ASSURANCE

36. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.8, subdivision (a), by reason of Factual Findings 10, 11, and 16, along with Legal Conclusions 8, 9, and 22.

SEVENTH CAUSE FOR DISCIPLINE - PERMITTING AN UNLICENSED PERSON TO ENGAGE
IN ACTS REQUIRING A VALID PHARMACY TECHNICIAN REGISTRATION

37. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4031, subdivision (o), in conjunction with Business and Professions Code section 4115, subdivision (e), section 4051, subdivision (a) and section 4328, by reason of Factual Findings 10, 11, and 17, along with Legal Conclusions 8, 9, 11, 12 and 13.

EIGHTH CAUSE FOR DISCIPLINE - FAILURE TO EXERCISE CORRESPONDING
RESPONSIBILITY IN DISPENSING CONTROLLED SUBSTANCES

40. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4301, subdivision (j), in conjunction with Health and Safety Code section 11153, subdivision (a), by reason of Factual Findings 10, 11 and 18, along with Legal Conclusions 8, 14 and 29.

NINTH CAUSE FOR DISCIPLINE - EXCESSIVE FURNISHING OF CONTROLLED
SUBSTANCES

41. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4301, subdivision (d), in conjunction with Health and Safety Code section 11153, subdivision (a), by reason of Factual Findings 10, 11 and 19, along with Legal Conclusions 8, 15 and 29..

TENTH CAUSE FOR DISCIPLINE - MISUSE OF EDUCATION

42. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4306.5, subdivision (a), by reason of Factual Findings 10, 11, and 19, along with Legal Conclusion 16.

ELEVENTH CAUSE FOR DISCIPLINE -- FAILURE TO EXERCISE OR IMPLEMENT BEST
PROFESSIONAL JUDGMENT OR CORRESPONDING RESPONSIBILITY

43. The clear and convincing evidence established that the license issued to Pharmacist Chan is subject to discipline under Business and Professions Code section 4306.5, subdivision (b), by reason of Factual Findings 10, 11 and 21, along with Legal Conclusion 17.

Inexact Allegation against Respondent Jefferson Plaza Pharmacy and Respondent Chan Under the Accusation's Twelfth Cause for Discipline

44. Business and Professions Code section 4301 specifically provides that unprofessional conduct includes the conduct specifically enumerated by statute as well as other misconduct. But, this does not mean that an overly broad connotation should be given to the term "unprofessional conduct." The acts or omissions must relate to conduct that indicates an unfitness to practice a profession. Unprofessional conduct is that conduct that breaches the rules or ethical code of a profession, or conduct which is unbecoming a member in good standing of a profession. (*Shea v. Board of Medical Examiners* (1978) 81 Cal.App.3d 564, 575.)

45. Business and Professions Code section 4301, establishes, in its entirety:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

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

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

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.

(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.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the

time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(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.

(p) Actions or conduct that would have warranted denial of a license.

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

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall

include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, 'long-term care facility' shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

46. Complainant's Twelfth Cause for Discipline in the Accusation, which is directed against both respondents, is overbroad and "it is so indefinite or uncertain that [respondents] cannot identify the transaction or prepare a defense" (Gov. Code, § 11506). The Twelfth Cause for Discipline's allegation seeks to impose disciplinary action against respondents for "unprofessional conduct" under the full scope of Business and Professions Code section 4301. But, in order to establish clear and convincing proof, several of the subdivisions of Code section 4301 require proof by way of an independent expert witness's determinations and opinion testimony, namely subdivisions (b) (incompetence) and (c) (gross negligence). And, no evidence was offered to show a violation of subdivision (a) (gross immorality). Further, complainant's Twelfth Cause for Discipline suggests respondents' commission of acts involving moral turpitude, dishonesty, fraud, deceit, or corruption; however, there is no clear and convincing evidence of respondents' violation of subdivision (f). Also, complainant did not offer evidence to establish that respondents' knowingly made or signed a certificate or other document that falsely represented the existence or nonexistence of a state of facts as proscribed by Code section 4301, subdivision (g). Additionally, complainant did not offer proof that respondent Chan engaged in administering to himself of any controlled substance, or used any dangerous drug or alcoholic beverages to the extent or in a manner as to be dangerous or injurious to himself, or to any other person or to the public contrary to the subject section's subdivision (h). Also, respondents have not been convicted of any crime so as to have violated the section's subdivisions (k) or (l). And, other subdivisions under Code section 4301 are clearly not applicable to either respondent.

By reason of Factual Finding 22, dismissal is required as to the Accusation's Twelfth Cause for Discipline

Complainant's Cost Recovery Petition

47. Business and Professions Code section 125.3 prescribes that a "licentiate found to have committed a violation or violations of the licensing act" may be directed to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

California Code of Regulations, title 1, section 1042, subdivision (2), sets forth "a certificate or affidavit in support of costs incurred by the agency for services provided by regular agency employees should include sufficient information by which the ALJ can determine the costs incurred in connection with the matter and the reasonableness of such costs, for example, a general description of tasks performed, the time spent on such tasks, and the method of calculation the cost for such services."

The California Supreme Court's reasoning as to the obligation of a licensing agency to fairly and conscientiously impose costs in administrative adjudication as articulated in *Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, 45-46, is persuasive and should be considered in this matter. Scrutiny of certain factors, which pertain to the board's exercise of discretion to analyze or examine factors that might mitigate or reduce costs of prosecution upon a licensee found to have engaged in unprofessional conduct, are set forth in Factual Finding 60.

48. By reason of Factual Findings 58, 59, and 61, the reasonable and appropriate costs of investigation and prosecution is set at \$29,786.30.

Established Guidelines for Imposition of License Disciplinary Action

49. The board has promulgated a booklet titled "Disciplinary Guidelines," which serves as a manual of disciplinary guidelines and a set of model disciplinary orders.

The guidelines, which are authorized by California Code of Regulations, title 16, section 1760, suggest factors in mitigation, witnesses in mitigation, matters in rehabilitation, and as well as matters in aggravation should be weighed in the imposition of license disciplinary action. Accordingly, the matters set out in Factual Findings 24 through 56 have been considered in making the Orders below.

Among many topics in the board's Guidelines is the board's formulation for categories of violations of provisions under the Pharmacy Law (Bus. & Prof. Code, § 4000 et seq.). The categories correlate to recommended penalties upon finding a licensee's violations of law. The categories for violations of the law range from Category I to Category IV, that is for minor violations to the egregious violations that must result in absolute revocation without the possibility of a term of probation.

Under the factual findings, above, respondents committed numerous Category II violations. Those categories focus upon violations that pertain to: acts having greater

disregard for pharmacy law; reflect poorly on the licensees' ethics; or poor care being exercised or simple incompetence being shown by respondents, their agents or employees. Such violations have as a minimum level of discipline as a stay of licensure revocation with a three-year term of probation. In this matter, respondents' Category II violations include: unprofessional conduct as defined at Business and Professions Code section 4301, subdivision (j)²⁰; violations of a pharmacist's duty of effecting vigorous supervision of a pharmacy technician under Business and Professions Code section 4115; a pharmacist's dereliction with regard to permitting impermissible compounding, dispensing or furnishing by a non-pharmacist contrary to Business and Professions Code section 4328; acts of excessive furnishing of controlled substances that constitutes unprofessional conduct under Business and Professions Code section 4301, subdivision (d); and, the misuse of a pharmacist's education as proscribed by Business and Professions Code section 4306.5, subdivision (a).

In addition in this matter, clear and convincing evidence established respondents' commission of Category III violations. Such violations involve such conduct as: knowingly or willfully violating laws or regulations pertaining to dispensing or distributing dangerous drugs or controlled substances; as well as, violations of a licensee's corresponding responsibility. Such violations have a minimum level of discipline to be: a stay of licensure revocation, a 90-day period of actual suspension of licensure (with corresponding cessation of practice activity and business dealings), a three to five year term of probation, along with a pharmacist taking courses of study. In this matter, respondents' Category III violations include: unprofessional conduct as defined at Business and Professions Code section 4301, subdivision (o); allowing an individual to engage in compounding prescriptions when that person does not possess either a pharmacist license or a valid pharmacy technician registration in violation of Business and Professions Code section 4051, subdivision (a); violation of a licensee's corresponding responsibility contrary to Business and Professions Code section 4301, subdivision (j).

50. It is determined that complainant established that the nature and extent of respondents' violations, which fall into Category III offenses, warrant the discipline prescribed in the Guidelines. But, due to factors regarding matters in mitigation and matters in rehabilitation, respondent Chan's professional background, his participation in civic and professional endeavors, and the lack of past record of license disciplinary action against respondents' licenses, the minimum discipline for Category III violations is set out below.

²⁰ Under the Guidelines, a violation of Business and Professions Code section 4301, subdivision (j), (violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs) may be either a Category II or a Category III violation.

ORDERS

Respondent Jefferson Plaza Pharmacy

Original Permit No. PHY 11062 issued to Medical Center Pharmacies, Inc. (respondent owner), with Ruth Fung Chan²¹ as president, doing business as Jefferson Plaza Pharmacy (respondent pharmacy), and with Johnny Pinghon "John" Chan, as Pharmacist-in-Charge, is revoked. However, the revocation of the pharmacy permit is stayed and respondent owner, doing business as respondent pharmacy, is placed on probation for four years upon the following terms and conditions:

1. Suspension

Original Permit No. PHY 11062 issued to respondent owner, to conduct business as respondent pharmacy, is suspended for a period of 90 days beginning the effective date of this Decision.

Respondent owner shall cease all pharmacy operations during the period of suspension. Failure to comply with this suspension term and condition shall be considered a violation of probation.

2. 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 contendere 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 owner's PHY 11062 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.

²¹ The board has issued to Ruth Fung Chan Pharmacist License Number RPH 32217.

3. 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, by the corporation's president or an agent acceptable to the board, 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.

4. 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.

5. 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 probation. Failure to cooperate shall be considered a violation of probation.

6. Reimbursement of Board Costs

Medical Center Pharmacies, Inc., doing business as respondent Jefferson Plaza Pharmacy, or its successor-in-interest or assignee (respondent owner), is jointly and severally liable with respondent Johnny Pinghon Chan, for the costs incurred by complainant, and both or either person shall pay to the Department of Consumer Affairs, on behalf of the Board of Pharmacy, the costs of investigation and enforcement in the total amount of \$29,786.30.

As a condition precedent to successful completion of probation, respondent owner shall pay the costs of investigation and prosecution in the above stated amount of \$29,786.30. Respondent owner shall make said payments of the full measure of the costs within 60 days of the effective date of this Decision. 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 as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent owner, or the liquidation of the corporation, shall not relieve respondent owner, or its principal shareholders, of the responsibility to reimburse the board its costs of investigation and prosecution.

7. Probation Monitoring Costs

Respondent owner shall pay any costs associated with probation monitoring as determined by the board for 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 probation monitoring costs by the deadline(s) as directed shall be considered a violation of probation.

8. 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 owner's permit to do business as respondent pharmacy, 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 owner's permit shall be subject to all terms and conditions of this probation not previously satisfied.

9. License Surrender While on Probation/Suspension

Following the effective date of this Decision, should respondent owner discontinue business, respondent owner may tender the premises 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 owner will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender of the permit, 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 of the permit. 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 the corporation shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender of the permit.

10. 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.

11. 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 corporate president and corporate secretary, including any owner or holder of ten percent (10%) or more of the interest in respondent pharmacy or respondent owner's stock, and any corporation director, 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.

12. 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.

13. Violation of Probation

If a respondent owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent pharmacy's permit, 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 permit will be fully restored.

15. Separate File of Records

Respondent owner shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

16. Report of Controlled Substances

Respondent owner shall submit quarterly reports to the board detailing the total acquisition and disposition of such controlled substances as the board may direct. Respondent owner shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent owner shall report on a quarterly basis or as directed by the board. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

17. Posted Notice of Suspension

Respondent owner shall prominently post a suspension notice provided by the board in a place conspicuous and readable to the public. The suspension notice shall remain posted during the entire period of suspension ordered by this Decision.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement, orally, electronically or in writing, 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 closure of the licensed entity.

Respondent Johnny Pinghon Chan

Original Pharmacist License RPH 32261 issued to respondent Johnny Pinghon Chan is revoked; however, the revocation of the pharmacist license is stayed, and respondent Chan's license is placed on probation for four years upon the following terms and conditions:

1. Obey All Laws

Respondent Chan shall obey all state and federal laws and regulations.

Respondent Chan 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 contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment; or,
- a conviction of any crime, discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's Original Pharmacist License RPH 32261 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 Chan 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 Chan 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 Chan 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 Chan shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent Chan'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 Chan 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 Chan shall notify all present and prospective employers of this Decision and the terms, conditions and restrictions imposed on respondent Chan by the Decision, as follows:

Within thirty (30) days of the effective date of this Decision, and within fifteen (15) days of respondent Chan undertaking any new employment, Respondent Chan shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent Chan's tenure of employment) or business owner to report to the board in writing acknowledging that the listed individual(s) has/have read the Decision in case number 5113, and terms and conditions imposed thereby. It shall be Respondent Chan's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent Chan works for or is employed by or through a pharmacy employment service, respondent Chan must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of this Decision in advance of respondent Chan 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 Chan undertaking any new employment by or through a pharmacy employment service, respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the Decision and the terms and conditions imposed thereby. It shall be respondent Chan's responsibility to ensure that his employer(s), or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/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 Chan is an employee, independent contractor or volunteer.

7. Reimbursement of Board Costs

Respondent Johnny Pinghon Chan is jointly and severally liable with respondent Jefferson Plaza Pharmacy, through its respondent owner, for the costs incurred by complainant, and both or either person shall pay to the Board of Pharmacy costs of investigation and enforcement in the total amount of \$29,786.30.

As a condition precedent to successful completion of probation, respondent Chan shall pay to the board its costs of investigation and prosecution in the amount of \$29,786.30. Respondent Chan shall make full payment of the costs within 60 days of the effective date of this Decision.

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 Chan shall not relieve him of the responsibility to reimburse the board its costs of investigation and prosecution.

8. Probation Monitoring Costs

Respondent Chan 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.

9. Status of License

Respondent Chan 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 Chan'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.

10. License Surrender While on Probation/Suspension

Following the effective date of this Decision, should respondent Chan cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent Chan may tender his 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 Chan 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 respondent's license history with the board.

Upon acceptance of the surrender, respondent Chan shall relinquish his pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent Chan may not reapply for any license from the board until, at least, the passage of three (3) years from the effective date of the surrender. Respondent Chan 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.

11. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent Chan 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 Chan 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.

12. Tolling of Probation

Except during periods of suspension, respondent Chan shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 100 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 Chan must nonetheless comply with all terms and conditions of probation.

Should respondent Chan, regardless of residency, for any reason (including vacation) cease practicing in California as a pharmacist for a minimum of 100 hours per calendar month, 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 Chan'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 16 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 100 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

13. Violation of Probation

If respondent Chan has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent Chan, 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 Chan 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.

14. Completion of Probation

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

15. Remedial Education

Within sixty (60) days of the effective date of this Decision, respondent Chan shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to: (1) standard practices for compounding prescriptions, and (2) the corresponding responsibility law and doctrine. The program of remedial education shall consist of at least 40 hours, which shall be completed within nine months of the effective date of this Decision at respondent Chan's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent Chan, at his own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent Chan does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent Chan to take another course approved by the board in the same subject area.

16. Pharmacy Self-Assessment Mechanism

Within the first 18 months of probation, respondent Chan shall complete the Pharmacist Self-Assessment Mechanism (PSAM) examination provided by the National Association of Boards of Pharmacy (NABP). Respondent Chan shall submit a record of completion to the board demonstrating he/she has completed this examination. Respondent Chan shall bear all costs for the

examination. Continuing education hours received for this examination shall not be used as part of the required continuing education hours for renewal purposes.

Failure to timely complete the PSAM or submit documentation thereof shall be considered a violation of probation.

Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee. Based on the results of the examination, the board shall determine which courses are appropriate for remedial education.

17. Separate File of Records

Respondent Chan shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

18. Report of Controlled Substances

Respondent Chan shall submit quarterly reports to the board detailing the total acquisition and disposition of such controlled substances as the board may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the board. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

19. Consultant for Owner or Pharmacist-In-Charge

During the period of probation, respondent Chan shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge. However, if during the period of probation respondent serves as a pharmacist-in-charge, respondent shall retain an independent consultant at his or her own expense who shall be responsible for reviewing pharmacy operations on a [monthly/quarterly] basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a 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. Respondent shall not be a

pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

20. Tolling of Suspension

During the period of suspension, respondent Chan shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of the (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent Chan must nonetheless comply with all terms and conditions of probation.

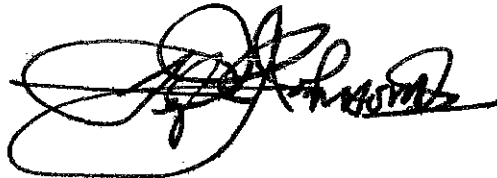
Respondent Chan must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent Chan shall not resume the practice of pharmacy until notified by the board that the period of suspension has been satisfactorily completed.

21. Ethics Course

Within forty-five (45) calendar days of the effective date of this Decision, respondent Chan 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 Chan shall submit a certificate of completion to the board or its designee within five days after completing the course.

DATED: July 16, 2015

A handwritten signature in black ink, appearing to read "Perry O. Johnson", written over a horizontal line.

PERRY O. JOHNSON
Administrative Law Judge
Office of Administrative Hearing

1 KAMALA D. HARRIS
Attorney General of California
2 DIANN SOKOLOFF
Supervising Deputy Attorney General
3 SUSANA A. GONZALES
Deputy Attorney General
4 State Bar No. 253027
1515 Clay Street, 20th Floor
5 P.O. Box 70550
Oakland, CA 94612-0550
6 Telephone: (510) 622-2221
Facsimile: (510) 622-2270
7 *Attorneys for Complainant*

8 **BEFORE THE**
9 **BOARD OF PHARMACY**
10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

12 In the Matter of the Accusation Against:

Case No. 5113

13 **JEFFERSON PLAZA PHARMACY**
3137 Jefferson Avenue
14 Redwood City, CA 94061

ACCUSATION

15 Pharmacy Permit No. PHY 11062

16 **JOHNNY PINGHON CHAN**
260 Sierra Drive
17 Hillsborough, CA 94010

18 Pharmacist License No. RPH 32261

19 **MARICON PAYTE ESMABE**
3561 Farmhill Blvd., #10
20 Redwood City, CA 94061

21 Pharmacy Technician Registration No. TCH
124483

22 Respondents.

23
24 Complainant alleges:

25 **PARTIES**

26 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
27 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
28

1 2. On or about October 1, 1981, the Board of Pharmacy issued Pharmacy Permit
2 Number PHY 11062 to Medical Plaza Pharmacies, doing business as Jefferson Plaza Pharmacy
3 ("Respondent Jefferson Plaza Pharmacy"). The Pharmacy Permit was in full force and effect at
4 all times relevant to the charges brought in this Accusation and will expire on October 1, 2014,
5 unless renewed.

6 3. On or about August 8, 1978, the Board of Pharmacy issued Pharmacist License
7 Number RPH 32261 to Johnny Pinghon Chan ("Respondent Chan"). The Pharmacist License was
8 in full force and effect at all times relevant to the charges brought in this Accusation and will
9 expire on May 31, 2016, unless renewed.

10 4. On or about August 23, 2013, the Board of Pharmacy issued Original Pharmacy
11 Technician Registration Number TCH 124483 to Maricon Payte Esmabe ("Respondent Esmabe").
12 The Pharmacy Technician Registration will expire on May 31, 2016, unless renewed.

13 JURISDICTION

14 5. This Accusation is brought before the Board of Pharmacy ("Board"), Department of
15 Consumer Affairs, under the authority of the following laws. All section references are to the
16 Business and Professions Code unless otherwise indicated.

17 6. Section 4011 of the Code provides that the Board shall administer and enforce both
18 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances
19 Act [Health & Safety Code, § 11000 et seq.].

20 7. Section 4300, subdivision (a), of the Code provides that every license issued by the
21 Board may be suspended or revoked.

22 8. Section 4300.1 of the Code states:

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

28 ///

1
2
3
4
5
6
7
8
9
0
1
2
3
4
5
6
7
8
9
0
1
2
3
4
5
6
7
8

2
3
4
5
6
7
8
9
0
1
2
3
4
5
6
7
8
9
0
1
2
3
4
5
6
7
8

3
4
5
6
7
8
9
0
1
2
3
4
5
6
7
8
9
0
1
2
3
4
5
6
7
8

6
7
8
9
0
1
2
3
4
5
6
7
8
9
0
1
2
3
4
5
6
7
8

7
8
9
0
1
2
3
4
5
6
7
8
9
0
1
2
3
4
5
6
7
8

9
0
1
2
3
4
5
6
7
8
9
0
1
2
3
4
5
6
7
8

5
6
7
8
9
0
1
2
3
4
5
6
7
8

6
7
8
9
0
1
2
3
4
5
6
7
8

8
9
0
1
2
3
4
5
6
7
8

9
0
1
2
3
4
5
6
7
8

3
4
5
6
7
8

6
7
8

7
8

8

1 11. Section 4306.5 of the Code states, in pertinent part:

2 "Unprofessional conduct for a pharmacist may include any of the following:

3 "(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or
4 her education, training, or experience as a pharmacist, whether or not the act or omission arises in
5 the course of the practice of pharmacy or the ownership, management, administration, or
6 operation of a pharmacy or other entity licensed by the board.

7 "(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement
8 his or her best professional judgment or corresponding responsibility with regard to the
9 dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with
10 regard to the provision of services.

11 "(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate
12 patient, prescription, and other records pertaining to the performance of any pharmacy function."

13 12. Code section 4342, subdivision (a), states:

14 "The board may institute any action or actions as may be provided by law and that, in its
15 discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not
16 conform to the standard and tests as to quality and strength, provided in the latest edition of the
17 United States Pharmacopoeia or the National Formulary, or that violate any provision of the
18 Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division
19 104 of the Health and Safety Code)."

20 13. Code section 4115, subdivision (c)(1), states:

21 "No person shall act as a pharmacy technician without first being licensed by the board as a
22 pharmacy technician."

23 14. Code section 4051, subdivision (a), states:

24 "Except as otherwise provided in this chapter, it is unlawful for any person to manufacture,
25 compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or
26 compound a prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist
27 under this chapter."

28 ///

1 15. Code section 4328 provides, "[e]xcept as otherwise provided in this chapter, any
2 person who permits the compounding or dispensing of prescriptions, or the furnishing of
3 dangerous drugs in his or her pharmacy, except by a pharmacist, is guilty of a misdemeanor."

4 16. Health and Safety Code section 11153, subdivision (a) states:

5 "A prescription for a controlled substance shall only be issued for a legitimate medical
6 purpose by an individual practitioner acting in the usual course of his or her professional practice.
7 The responsibility for the proper prescribing and dispensing of controlled substances is upon the
8 prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the
9 prescription. Except as authorized by this division, the following are not legal prescriptions: (1)
10 an order purporting to be a prescription which is issued not in the usual course of professional
11 treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of
12 controlled substances, which is issued not in the course of professional treatment or as part of an
13 authorized narcotic treatment program, for the purpose of providing the user with controlled
14 substances, sufficient to keep him or her comfortable by maintaining customary use."

15 17. California Code of Regulations, title 16, section 1714, states, in pertinent part:

16 ...

17 "(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and
18 equipment so that drugs are safely and properly prepared, maintained, secured and distributed.
19 The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice
20 of pharmacy.

21 "(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly
22 condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly
23 lighted. The pharmacy shall be equipped with a sink with hot and cold running water for
24 pharmaceutical purposes."

25 18. California Code of Regulations, title 16, section 1735.5, states, in pertinent part:

26 "(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure
27 manual for compounding that establishes procurement procedures, methodologies for the
28

1 formulation and compounding of drugs, facilities and equipment cleaning, maintenance,
2 operation, and other standard operating procedures related to compounding.

3 “(b) The policy and procedure manual shall be reviewed on an annual basis by the
4 pharmacist-in-charge and shall be updated whenever changes in processes are implemented.”

5 19. California Code of Regulations, title 16, section 1735.7, states, in pertinent part:

6 “(a) Any pharmacy engaged in compounding shall maintain written documentation
7 sufficient to demonstrate that pharmacy personnel have the skills and training required to properly
8 and accurately perform their assigned responsibilities relating to compounding.

9 “(b) The pharmacy shall develop and maintain an on-going competency evaluation process
10 for pharmacy personnel involved in compounding, and shall maintain documentation of any and
11 all training related to compounding undertaken by pharmacy personnel.”

12 20. California Code of Regulations, title 16, section 1735.8, subdivision (a), states:

13 “Any pharmacy engaged in compounding shall maintain, as part of its written policies and
14 procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency,
15 quality, and labeled strength of compounded drug products.”

16 21. California Code of Regulations, title 16, section 1793 states:

17 “‘Pharmacy technician’ means an individual who, under the direct supervision and control
18 of a pharmacist, performs packaging, manipulative, repetitive, or other nondiscretionary tasks
19 related to the processing of a prescription in a pharmacy, but who does not perform duties
20 restricted to a pharmacist under section 1793.1.”

21 22. California Code of Regulations, title 16, section 1793.2 addresses the duties of a
22 pharmacy technician and states:

23 “‘Nondiscretionary tasks’ as used in Business and Professions Code section 4115, include:

24 “(a) removing the drug or drugs from stock;

25 “(b) counting, pouring, or mixing pharmaceuticals;

26 “(c) placing the product into a container;

27 “(d) affixing the label or labels to the container;

28 “(e) packaging and repackaging.”

1 CONTROLLED SUBSTANCES AND DANGEROUS DRUGS

2 23. Code section 4021 states:

3 “‘Controlled substance’ means any substance listed in Chapter 2 (commencing with Section
4 11053) of Division 10 of the Health and Safety Code.”

5 24. Code section 4022 provides:

6 “‘Dangerous drug’ or ‘dangerous device’ means any drug or device unsafe for self-use in
7 humans or animals, and includes the following:

8 “(a) Any drug that bears the legend: ‘Caution: federal law prohibits dispensing without
9 prescription,’ ‘Rx only’ or words of similar import.

10 “(b) Any device that bears the statement: ‘Caution: federal law restricts this device to sale
11 by or on the order of a _____,’ ‘Rx only,’ or words of similar import. . .

12 “(c) Any other drug or device that by federal or state law can be lawfully dispensed only on
13 prescription or furnished pursuant to Section 4006.”

14 25. Oxycodone is a semi-synthetic narcotic analgesic with multiple actions qualitatively
15 similar to those of Morphine. It is schedule II controlled substance and narcotic as designated by
16 Health and Safety Code section 11055, subdivision (b)(1), and a dangerous drug under Code
17 section 4022. Oxycodone can produce drug dependence and has the potential for being abused.

18 26. Hydrocodone with APAP is also known by the brand names Lortab and Vicodin.
19 Hydrocodone is a Schedule III controlled substance under California Health and Safety Code
20 section 11056, subdivision (e), and a dangerous drug under Code section 4022.

21 COST RECOVERY

22 27. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
23 administrative law judge to direct a licensee found to have committed a violation or violations of
24 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
25 enforcement of the case.

26 ///

27 ///

28 ///

FACTUAL ALLEGATIONS

28. From March 1, 1986, through the present, Respondent Chan has been the Pharmacist-in-Charge ("PIC") of Respondent Jefferson Plaza Pharmacy.

29. On or about January 30, 2012, the Board received a complaint from Dr. N.A. stating that Respondent Jefferson Plaza Pharmacy dispensed five different narcotics in a ten day period to a patient he was treating for opioid dependence. On July 12, 2013, a Board inspector went to Respondent Jefferson Plaza Pharmacy and conducted an inspection. Respondent Chan, the PIC, was present and assisted with the inspection. Patient profiles, prescription records, and other documents were obtained and reviewed during and after the inspection.

30. During the inspection on July 12, 2013, Respondent Jefferson Plaza Pharmacy and Respondent Chan were unable to provide a written policy and procedure manual for compounding. They were also unable to provide written documentation sufficient to demonstrate that the pharmacy personnel had the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding. Additionally, Respondents were unable to provide any training records for compounding staff or any written quality assurance plans for compounded prescriptions.

31. The inspection revealed that pharmacy clerk and Respondent Esmabe compounded prescriptions at the pharmacy from January 19, 2013, through July 9, 2013. Respondent Esmabe had applied for a pharmacy technician's license, but had not yet been granted one. Respondent Esmabe's intern pharmacist license had expired on January 31, 2012.

32. During the inspection conducted on July 12, 2013, the inspector observed that Respondent Jefferson Plaza Pharmacy and Respondent Chan maintained numerous outdated drugs in the pharmacy's current inventory of the compounding bulk ingredients and in the general inventory of the pharmacy. The inspector also observed that the pharmacy was extremely disorganized, dirty, and cluttered, especially in the compounding area of the pharmacy.

33. An overall review of the dispensing practice of Respondent Jefferson Plaza Pharmacy revealed that between July 12, 2010, and July 12, 2013, Respondent Jefferson Plaza Pharmacy and Respondent Chan dispensed 25,261 prescriptions for controlled substances, 4,178 of which

1 were for Dr. B.W., who prescribed excessive quantities of "drug cocktails" of controlled
2 substances, and provided early re-fills for patients as revealed by the Controlled Substance
3 Utilization Review and Evaluation System ("CURES") data for some of his patients.

4 34. The CURES program started in 1998, and required mandatory pharmacy reporting of
5 dispensed Schedule II controlled substances. The CURES program was amended in January
6 2005, to require mandatory pharmacy reporting of Schedule II, III, and IV controlled substances.
7 The data is collected statewide and can be used by healthcare professionals such as pharmacists
8 and prescribers to evaluate and determine whether their patients are utilizing their prescriptions
9 for controlled substances correctly. The data may be used to aid in the determination of whether a
10 patient has been to multiple prescribers and multiple pharmacies to fill controlled substance
11 prescriptions through the CURES Prescription Drug Monitoring Program ("PDMP"). The
12 CURES program currently requires mandatory weekly pharmacy reporting of Schedule II, III, and
13 IV controlled substances.

14 35. During the July 12, 2013, inspection, Respondent Chan stated that Dr. B.W. was a
15 local doctor who typically prescribed high doses of controlled substances. Respondent Chan did
16 not question the quantities because Dr. B.W. was a local "pain specialist." After initially calling
17 Dr. B.W. a few times to verify prescriptions, Respondent Chan no longer called Dr. B.W.
18 regarding the prescriptions he wrote. Respondent Chan was unfamiliar with the PDMP, and was
19 unable to articulate a clear understanding of the meaning of corresponding responsibility.

20 36. Further investigation of the records obtained during the inspection revealed
21 questionable dispensing by Respondent Jefferson Plaza Pharmacy. Between the period of July 12,
22 2010, and July 12, 2013, Respondent Jefferson Plaza Pharmacy and Respondent Chan dispensed
23 controlled substance prescriptions for prescribers and patients who were outside of the
24 pharmacy's normal service area. Respondents did not verify whether the prescriptions were
25 issued for a legitimate medical purpose. Respondents failed to use industry tools, such as the
26 PDMP, to verify early or duplicate dispensing for patients who were "doctor shopping" or
27 "pharmacy shopping," or both, as demonstrated by the activities of at least ten different patients.
28 Respondents failed to recognize "red flags," which should have given them the inkling of a

1 potential problem with the prescriptions, and invoked a duty of inquiry. These "red flags"
2 included filling prescriptions for patients outside the pharmacy service area and prescribers
3 outside of the pharmacy service area, the payment method of cash was far greater than third party
4 insurance, and early dispensing of controlled substances for various patients as determined by
5 CURES data.

6 37. Between July 12, 2010, and July 12, 2013, Respondent Jefferson Plaza Pharmacy and
7 Respondent Chan dispensed 25,261 prescriptions for various controlled substances. Respondent
8 Jefferson Plaza Pharmacy and Respondent Chan dispensed 204,195 doses of Hydrocodone/APAP
9 10/325 milligrams, and 528,718 tablets of Oxycodone 30 milligrams, far exceeding the volumes
10 of the same drugs dispensed by other pharmacies in the area with longer operating hours.

11 FIRST CAUSE FOR DISCIPLINE

12 (Drugs Lacking Quality or Strength)

13 (Bus. & Prof Code, §§ 4301, subd. (o), 4342, subd. (a))

14 38. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their
15 licenses to disciplinary action in that Respondents possessed pharmaceutical preparations and
16 drugs that did not conform to the standards and tests for quality and strength, as provided in the
17 latest edition of the United States Pharmacopeia or the National formulary, or that violate any
18 provision of the Sherman Food, Drug, and Cosmetic Law. (Bus. & Prof. Code, §§ 4301, subd.
19 (o), 4342, subd. (a).) The circumstances are set forth in paragraphs 28 through 35, above.

20 SECOND CAUSE FOR DISCIPLINE

21 (Operational Standards and Security)

22 (Bus. & Prof. Code, § 4301, subd. (o), Cal. Code Regs., tit. 15, § 1714, subds. (b), (c))

23 39. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their
24 licenses to disciplinary action in that they failed to maintain Jefferson Plaza Pharmacy's facility,
25 space, fixtures, and equipment so that drugs could be safely and properly prepared, maintained,
26 secured and distributed. (Bus. & Prof. Code, § 4301, subd. (o), Cal. Code of Regs., tit. 16, §
27 1714, subd. (b).) Respondent Jefferson Plaza Pharmacy and Respondent Chan also failed to
28 maintain Jefferson Plaza Pharmacy's fixtures and equipment in a clean and orderly condition.

1 (Bus. & Prof. Code, § 4301, subd. (o), Cal. Code of Regs., tit. 16, § 1714, subd. (c).) The
2 circumstances are set forth in paragraphs 28 through 37, above.

3 THIRD CAUSE FOR DISCIPLINE

(No Written Compounding Procedure and Manual)

4 (Bus. & Prof. Code, § 4301, subd. (o), Cal. Code Regs., tit. 16, § 1735.5, subds. (a),(b))

5 40. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their
6 licenses to disciplinary action in that they failed to maintain a written policy and procedure
7 manual for compounding and failed to maintain clearly defined compounding policy and
8 procedures to reflect the compounding activities of the pharmacy. (Bus. & Prof. Code, § 4301,
9 subd. (o), Cal. Code Regs., tit. 16, § 1735.5, subds. (a), (b).) The circumstances are set forth in
10 paragraphs 28 through 37, above.

11 FOURTH CAUSE FOR DISCIPLINE

(Training Records and Competency Evaluation Process)

12 (Bus. & Prof. Code, § 4301, subd. (o), Cal. Code Regs., tit. 16, § 1735.7, subd. (a), (b))

13 41. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their
14 licenses to disciplinary action in that they failed to maintain written documentation sufficient to
15 demonstrate that their pharmacy personnel had the skills and training to perform compounding
16 activities and they failed to develop and maintain an on-going competency evaluation process.
17 (Bus. & Prof. Code, § 4301, subd. (o), Cal. Code Regs., tit. 16, § 1735.7, subd. (a), (b).) The
18 circumstances are set forth in paragraphs 28 through 37, above.

19 FIFTH CAUSE FOR DISCIPLINE

(Failure to Provide Compounding Quality Assurance)

20 (Bus. & Prof. Code, § 4301, subd. (o), Cal. Code of Regs., tit. 16, § 1735.8, subd. (a))

21 42. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their
22 licenses to disciplinary action in that they failed to maintain a written policy and procedure
23 designed to monitor and ensure the integrity, potency, quality, and labeled strength of
24 compounded drug products. (Bus. & Prof. Code, § 4301, subd. (o), Cal. Code of Regs., tit. 16, §
25 1735.8, subd. (a).) The circumstances are set forth in paragraphs 28 through 37, above.

26 ///

27 ///

28

1 SIXTH CAUSE FOR DISCIPLINE

2 (Bus. & Prof. Code, §§ 4301, subd. (o), 4115, subd. (e), 4051, subd. (a))
3 (Engaging in Acts of Pharmacy Technician or Pharmacist Without a License)

4 43. Respondent Esmabe has subjected her pharmacy technician registration to
5 disciplinary action in that she engaged in compounding activities without a pharmacy technician
6 registration or pharmacist license. (Bus. & Prof. Code, §§ 4301, subd. (o), 4115, subd. (e), 4051,
7 subd. (a).) The circumstances are set forth in paragraphs 28 through 37, above.

8 SEVENTH CAUSE FOR DISCIPLINE

9 (Bus. & Prof. Code, §§ 4301, subd. (o), 4115, subd. (e), 4051, subd. (a), 4328)
10 (Engaging in Acts of Pharmacy Technician Without a License)

11 44. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their
12 licenses to disciplinary action in that they allowed Respondent Esmabe to compound prescriptions
13 without a pharmacist license or pharmacy technician registration. (Bus. & Prof. Code, §§ 4301,
14 subd. (o), 4115, subd. (e), 4051, subd. (a), 4328.) The circumstances are set forth in paragraphs
15 28 through 37, above.

16 EIGHTH CAUSE FOR DISCIPLINE

17 (Bus. & Prof. Code, § 4301, subd. (j))
18 (Failure To Exercise Corresponding Responsibility In Dispensing Controlled Substances)

19 45. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their
20 licenses to disciplinary action in that they failed to comply with their corresponding responsibility
21 to ensure that controlled substances are dispensed for a legitimate medical purpose when they
22 furnished prescriptions for controlled substances despite the presence of numerous "red flags."
23 (Bus. & Prof. Code, § 4307, subd. (j), Health and Saf. Code, § 11153, subd. (a).) The
24 circumstances are set forth in paragraphs 28 through 37, above.

25 NINTH CAUSE FOR DISCIPLINE

26 (Bus. & Prof. Code, § 4301, subd. (d))
27 (Excessive Furnishing of Controlled Substances)

28 46. Respondent Jefferson Plaza Pharmacy and Respondent Chan have subjected their
29 licenses to disciplinary action in that from July 11, 2010, through July 11, 2013, Respondents
30 furnished clearly excessive amounts of controlled substances in violation of Health and Safety
31 Code section 11153, subdivision (a). (Bus. & Prof. Code, § 4301, subd. (d).) Specifically, from

1 July 11, 2010, through July 11, 2013, Respondents dispensed 25,261 prescriptions for various
2 controlled substances. Respondents dispensed 204,195 doses of Hydrocodone/APAP 10/325
3 milligrams, and 528,718 tablets of Oxycodone 30 milligrams. These amounts far exceeded the
4 volumes of the same drugs dispensed by other pharmacies in the area with longer operating hours.
5 The circumstances are set forth in paragraphs 28 through 37, above.

6 TENTH CAUSE FOR DISCIPLINE
7 (Bus. & Prof. Code, § 4306.5, subd. (a))
8 (Misuse of Education by Pharmacist)

9 47. Respondent Chan has subjected his Pharmacist License to disciplinary action in that
10 from July 11, 2010, through July 11, 2013, he failed to use his education, training, and experience
11 as a pharmacist when he filled prescriptions for large quantities of narcotics for patients who used
12 multiple prescribers and obtained early refills at Respondent Jefferson Plaza Pharmacy, as set
13 forth above in paragraphs 28 through 37. (Bus. & Prof. Code, § 4301, subd. (c), Bus. & Prof.
14 Code, § 4306.5, subd. (a).)

15 ELEVENTH CAUSE FOR DISCIPLINE
16 (Bus. & Prof. Code, § 4306.5, subd. (b))
17 (Failure to Exercise or Implement Best Professional Judgment or Corresponding Responsibility)

18 48. Respondent Chan has subjected his Pharmacist License to disciplinary action in that
19 he failed to exercise or implement his best professional judgment or corresponding responsibility
20 with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or
21 dangerous devices, or with regard to the provision of services. (Bus. & Prof. Code, § 4306.5,
22 subd. (b).) Specifically, from July 11, 2010, through July 11, 2013, Respondent Chan filled
23 prescriptions for large quantities of narcotics for patients who used multiple prescribers, paid
24 cash, and obtained early refills at Respondent Jefferson Plaza Pharmacy without taking measures
25 to confirm the prescriptions and that the large quantities of narcotics were prescribed for a
26 legitimate medical purpose. The circumstances are set forth in paragraphs 28 through 37, above.

27 ///

28 ///

///

1 TWELFTH CAUSE FOR DISCIPLINE

2 (Bus. & Prof. Code, § 4301)

3 (Unprofessional Conduct)

4 49. Respondents have subjected their licenses to disciplinary action in that they engaged
5 in unprofessional conduct as set forth in paragraphs 28 through 37, above. (Bus. & Prof. Code, §
6 4301.)

7 PRAYER

8 WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this
9 Accusation, and that following the hearing, the Board of Pharmacy issue a decision:

10 1. Revoking or suspending Pharmacy Permit Number PHY 11062, issued to Jefferson
11 Plaza Pharmacy;

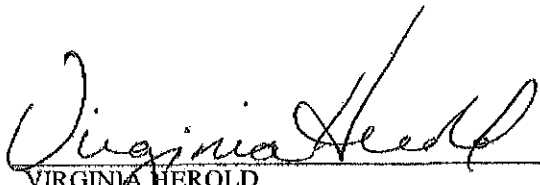
12 2. Revoking or suspending Pharmacist License Number RPH 32261, issued to Johnny
13 Pinghon Chan;

14 3. Revoking or suspending Original Pharmacy Technician Registration Number TCH
15 124483, issued to Maricon Payte Esmabe;

16 4. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the
17 investigation and enforcement of this case, pursuant to Business and Professions Code section
18 125.3;

19 5. Taking such other and further action as deemed necessary and proper.

20
21
22 DATED: 7/27/14


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

23
24
25
26 SF2014902162
27 90390995.doc
28