CASE SUMMARY

In the Matter of the Accusation Against Pacifica Pharmacy; Thang Tran
Board of Pharmacy Case No. 3802; OAH No. 2011010644; Precedential Decision No. 2013-01
Made precedential by the Board of Pharmacy effective August 9, 2013

Available at http://www.pharmacy.ca.gov/enforcement/precedential.shtml

BRIEF SYNOPSIS: In a Decision and Order initially effective June 3, 2012 (after the lapse of a 30-day stay from its initial effective date of May 4, 2012), and made a precedential decision of the Board effective August 9, 2013, the Board of Pharmacy revoked the licenses issued by the Board to Pacifica Pharmacy, PHY 46715, a pharmacy licensee, and Thang Q. Tran, RPH 41172, a pharmacist licensee, based on allegations and proof that respondents engaged in unprofessional conduct including failures to exercise the "corresponding responsibility" a pharmacy/pharmacist owes under California law to determine the legitimate medical purpose of controlled substance prescriptions before dispensing, under Health and Safety Code section 11153, subdivision (a).

PROCEDURAL HISTORY: A Second Amended Accusation (operative pleading) was filed before the Board of Pharmacy on January 3, 2012. The case proceeded to a hearing conducted by Administrative Law Judge James Ahler of the Office of Administrative Hearings (OAH), San Diego, on January 23, 24, 25, and 31, and February 1, 2012. The Proposed Decision was issued on February 29, 2012. The Board adopted the Proposed Decision by Decision and Order issued April 4, 2012, made effective May 4, 2012. On April 10, 2012, the Board received a request for a 30-day stay to file a petition for reconsideration from respondents, and granted same, staying the effective date of the Decision and Order to June 3, 2012. On May 31, 2012, the Board issued an Order Denying Reconsideration, denying respondents' petition. That order confirmed that the Decision and Order of the Board would be effective and final as of June 3, 2012. On August 5, 2013, the Board designated the Decision as precedential, in its entirety, effective August 9, 2013.

DISCIPLINARY ORDER: On the basis of the factual findings and legal conclusions made in the 40-page Proposed Decision made the Decision and Order of the Board, the decision ordered:

- that Original Permit No. PHY 46715 issued to Pacifica Pharmacy Corp. is revoked;
- that Original Pharmacist License No. RPH 4117 issued to Thang Q. Tran is revoked; and
- that Pacifica Pharmacy Corp. and Thang Q. Tran shall pay to the Board of Pharmacy costs of investigation and enforcement in the total amount of $39,666.00.

FINDINGS AND CONCLUSIONS: The Second Amended Accusation filed January 3, 2012 included a total of eight causes for discipline, two alleged against both respondents, three alleged only against Pacifica Pharmacy, and three alleged only against Thang Q. Tran. All eight of the causes for discipline were sustained. Of these, the cause for discipline receiving the most legal analysis and argument in the decision was the first, for failure to comply with the "corresponding responsibility" placed on pharmacies and pharmacists by Health and Safety Code section 11153. The Decision and Order identifies a series of "red flags" surrounding prescriptions for controlled substances (OxyContin, Opana, Dilaudid, and Alprazolam) by Dr. T, an osteopath with an office located some distance from Pacific Pharmacy, and concludes that Pacifica Pharmacy and Thang Q. Tran failed to make the inquiries necessary to exercise their "corresponding responsibility."

CASE DETAILS: The investigation was prompted by a complaint from a neighbor of the pharmacy, who observed what he believed was unusual traffic in and out of the pharmacy by young patrons, who spread cash across the dashboard of a vehicle on one occasion, and appeared to be exchanging cash for prescriptions in the parking lot of the pharmacy. A CURES report for the pharmacy showed a high number of controlled substance prescriptions (1,844 from January 1, 2009 to January 5, 2010) written by Dr. T. and dispensed by Pacifica Pharmacy.

Inspections of the pharmacy revealed other issues, including expired drugs in active inventory, pre-filled containers with inadequate labels, and inventory discrepancies. But the primary focus of the investigation was controlled substance dispensing practices. During an interview, Thang Q. Tran revealed, among other things, that he had never spoken to Dr. T about the prescriptions received in the pharmacy, that he did not routinely verify prescriptions with prescribers or ask about their prescribing practices, that he considered his role in verifying the legitimacy of the prescription to be limited to verifying the prescription with the prescriber, where appropriate, that he did not ask his patients about their diagnosis or other medical information, that he did not know about the use of CURES reports for evaluating patient therapy, and that he did not have an issue with filling prescriptions for prescribers or patients located far away from the pharmacy.

Expert testimony established that a pharmacist must exercise professional judgment with regard to dispensing controlled substances, a duty that entails more than filling the prescription. After a pharmacist evaluates the prescription to make certain it is valid and legitimate on its face, there is also a duty to evaluate the patient, the prescriber, and the medication therapy. The Decision and Order includes a fairly detailed description of the pharmacist's standard of care / duty of inquiry.

The Decision and Order identified several "red flags" that should give a pharmacy / pharmacist the inkling of a potential problem with prescriptions, and invoke in them a duty of inquiry:

- Irregularities on the face of the prescription itself;
- Nervous patient demeanor;
- Age or presentation of patient (e.g., youthful patients seeking chronic pain medications);
- Multiple patients at the same address(es);
- Cash payments;
- Requests for early refills of prescriptions;
- Prescriptions written for an unusually large quantity of drugs;
- Prescriptions written for potentially duplicative drugs;
- The same combinations of drugs prescribed for multiple patients;
- Initial prescriptions written for stronger opiates (e.g., OxyContin 80mg);
- Long distances traveled from the patient's home to the prescriber's office or pharmacy;
- Irregularities in the prescriber's qualifications in relation to the medication(s) prescribed;
- Prescriptions that are written outside of the prescriber's medical specialty; and
- Prescriptions for medications with no logical connection to diagnosis or treatment;

The Decision and Order concluded that whenever a pharmacist believes that a prescription may not have been written for a legitimate medical purpose, the pharmacist must inquire; when the results of a reasonable inquiry do not overcome the pharmacist's concern about a prescription being written for a legitimate medical purpose, the pharmacist must not fill the prescription.

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

In the Matter of the Accusation Against**:** **PACIFICA PHARMACY CORP.;** **THANG TRAN** Respondents.	Case No. 3802 OAH No. 2011010644 PRECEDENTIAL DECISION NO. 2013-01

PRECEDENTIAL DECISION

(Government Code Section 11425.60(b))

The Board of Pharmacy, Department of Consumer Affairs, hereby designates as precedential the Decision, in its entirety, in the Matter of the Accusation Against Pacifica Pharmacy Corp. and Thang Tran (Board of Pharmacy Case No. 3802).

This precedential decision shall become effective on August 9, 2013.

DATED: August 5, 2013.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STANLEY C. WEISSER
Board President

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

In the Matter of the Accusation Against: **PACIFICA PHARMACY CORP** Original Pharmacy Permit PHY 46715 And **THANG Q. TRAN** Original Pharmacist License RPH 41172 Respondent.	Case No. 3802 OAH No. 2011010644

ORDER DENYING RECONSIDERATION

The Board of Pharmacy having read and considered respondent's petition for reconsideration of the board's decision effective June 3, 2012. NOW THEREFORE IT IS ORDERED that the petition for reconsideration is denied. The Board of Pharmacy's Decision and Order initially effective May 4, 2012 and thereafter stayed to June 3, 2012 is the Board of Pharmacy's final decision in this matter.

Date: May 31, 2012

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STANLEY C. WEISSER
Board President

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

In the Matter of the Accusation Against: **PACIFICA PHARMACY CORP** Original Pharmacy Permit PHY 46715 And **THANG Q. TRAN** Original Pharmacist License RPH 41172 Respondent.	Case No. 3802 OAH No. 2011010644 ORDER GRANTING 30-DAY STAY OF EFFECTIVE DATE OF DECISION AND ORDER

The Board of Pharmacy's Decision in the above-entitled matter was issued on April 4, 2012 to become effective on May 4, 2012. On April 10, 2012, the Board received Respondent's request for a 30-day stay to file a petition for reconsideration of the Board's Decision adopting the Proposed Decision issued by James Ahler, Administrative Law Judge.

In accordance with the provisions of Section 11521(a) of the Government Code, for the sole purpose of permitting the respondent to file a petition for reconsideration and good cause appearing therefor,

IT IS HEREBY ORDERED that the effective date of the Decision and Order in the above-entitled matter be stayed until June 3, 2012.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STANLEY C. WEISSER
Board President

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

In the Matter of the Accusation Against: **PACIFICA PHARMACY CORP** Original Pharmacy Permit PHY 46715 And **THANG Q. TRAN** Original Pharmacist License No. RPH 41172 Respondent.	Case No. 3802 OAH NO.: 2011010644

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on May 4, 2012.

It is so ORDERED on April 4, 2012.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

STANLEY C. WEISSER
Board President

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

In the Matter of the Accusation Against: **PACIFICA PHARMACY CORP** Original Pharmacy Permit PHY 46715 and **THANG Q. TRAN,** Original Pharmacist License No. RPH 41172, Respondents.	Case No. 3802 OAH No. 2011010644

PROPOSED DECISION

James Ahler, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter on January 23, 24, 25 and 31, and on February 1, 2012, in San Diego, California.

Marichelle S. Tahimic, Deputy Attorney General, Department of Justice, State of California, represented Complainant Virginia K. Herold, Executive Officer, Board of Pharmacy, Department of Consumer Affairs, State of California.

Armond Marcarian, Attorney at Law, represented Respondents Pacifica Pharmacy Corp and Thang Q. Tran. Respondent Tran was present each day of the disciplinary hearing.

PRELIMINARY STATEMENT

Thang Q. Tran has been licensed as a pharmacist in California since 1988. Since August 2004 Pharmacist Tran has owned and operated Pacifica Pharmacy, a community retail pharmacy in Huntington Beach.

Complainant asserted that the inspection of Pacifica Pharmacy disclosed expired drugs in its inventory, missing information on pre-filled medication containers, and a discrepancy in the inventory. Complainant also asserted that Respondents Pacifica Pharmacy

and Pharmacist Tran dispensed numerous prescriptions for controlled substances without determining whether any prescription was written for a legitimate medical purpose.

Pacifica Pharmacy and Pharmacist Tran denied the allegations. Pacifica Pharmacy asserted that a pharmacy cannot be liable under the corresponding responsibility statute because that statute applies only to a "pharmacist who fills the prescription." Pacifica Pharmacy claimed that the remaining allegations against are *de minimis* and unworthy of discipline. Respondents argued that the clear and convincing evidence did not establish that that Pharmacist Tran *knowingly* violated the corresponding responsibility statute, or that Pacifica Pharmacy dispensed any controlled substance for anything other than a legitimate medical purpose, or that Pharmacist Tran personally filled any of the prescriptions at issue. Furthermore, Respondents asserted that Pharmacist Tran and Pacifica Pharmacy stopped filling the prescriptions that Dr. T. wrote when notice was given that the prescriptions might not be for a legitimate medical purpose and promptly took other effective corrective action.

The many red flags surrounding the prescriptions written for OxyContin, Opana, Dilaudid, and Alprazolam by Dr. T., an osteopath whose medical office was located many miles away from Pacifica Pharmacy, required Pharmacist Tran and Pacifica Pharmacy to make some inquiry into whether the prescriptions had been written for legitimate medical purposes. The clear and convincing evidence established that Pharmacist Tran and Pacifica Pharmacy made no inquiry of Dr. T. or her patients before dispensing controlled substances. Respondents produced no compelling evidence in explanation, mitigation, or rehabilitation.

On this record, the only measure of discipline that will protect the public is the outright revocation of Pharmacist Tran's pharmacist license and Pacifica Pharmacy's pharmacy permit.

FACTUAL FINDINGS

Jurisdictional Matters

1. On January 3, 2012, Complainant Patricia F. Harris, the Board of Pharmacy's Executive Officer, signed the Second Amended Accusation in Case No. 3892, which was served thereafter on Respondent Pacifica Pharmacy Corp (Pacifica Pharmacy), Respondent Thang Q. Tran (Pharmacist Tran), and their attorney. New allegations were deemed controverted by Government Code section 11507.

The record in the disciplinary hearing was opened on January 23, 2012; the parties stipulated that the record in this disciplinary proceeding should be sealed; rulings were issued on several motions in limine; and an opening statement was given on Complainant's behalf. On January 23, 24, 25 and 31, 2012, official notice was taken; sworn testimony was received; and documentary evidence was produced. On February 1, 2012, closing arguments were given; the record was closed; and the matter was submitted.

The Parties' Contentions

2. The Second Amended Accusation alleged that Pacifica Pharmacy and Pharmacist Tran failed to comply with corresponding responsibility requirements (first cause for discipline); that Pacifica Pharmacy failed to maintain a current inventory (second cause for discipline); that Pacifica Pharmacy failed to provide a description of some medications as required by law (third cause for discipline); that Pacifica Pharmacy maintained expired drugs in its inventory (fourth cause for discipline); that Pacifica Pharmacy and Pharmacist Tran excessively furnished controlled substances from March 2008 through January 2010 (fifth cause for discipline); that Pharmacist Tran's dispensing practices involved gross negligence (sixth cause for discipline); that Pharmacist Tran's dispensing practices involved negligence (seventh cause for discipline); and that Pharmacist Tran engaged in general unprofessional conduct (eighth cause for discipline). Complainant sought the revocation of Pacifica Pharmacy's permit and Pharmacist Tran's license.

3. Respondents denied all allegations. Respondents asserted numerous factual and legal defenses, but at the heart of their argument was their assertion that Complainant had the obligation to establish that any prescription for any controlled substances at issue was not written for a legitimate medical purpose and failed to present one shred of evidence to establish that any prescription for a controlled substance was written for anything other than a legitimate medical purpose. Pacifica Pharmacy asserted the right to a dismissal. Pharmacist Tran argued that if discipline was imposed, nothing more than a letter of public reprimand should be issued.

Pacifica Pharmacy

4. On August 17, 2004, the Board of Pharmacy issued Original Permit No. PHY 46715 to Pacifica Pharmacy Corp. Thang Tran, RPH 41172, is Pacifica Pharmacy's President, Vice President, and Secretary. Pharmacist Tran has been Pacifica Pharmacy's Pharmacist-in-Charge since August 17, 2004.

There is no history of any prior discipline having been sought against Pacifica Pharmacy's permit.

5. Pacifica Pharmacy is a community pharmacy situated on Beach Boulevard in Huntington Beach. There are many other community pharmacies in Pacifica's trade area, some of which are small pharmacies, like Pacifica Pharmacy, and some of which are large chain drug stores. About 75 percent of Pacifica Pharmacy's customers are Vietnamese. Delivery service is provided to some of Pacifica Pharmacy's customers, and Pharmacist Tran personally provides delivery service after Pacifica Pharmacy's normal business hours.

Pacifica Pharmacy is approximately 500 square feet. It occupies a ground floor suite of a small office complex. A parking lot surrounds the complex where Pacifica Pharmacy is located, but only the parking lot area immediately in front of the pharmacy is visible from inside the pharmacy. Pacifica Pharmacy's interior includes a customer waiting area, which is

separated by a partition from a back area where prescriptions are processed and filled and where drugs and medications are stored.

Besides Pharmacist Tran, Pacifica Pharmacy employs four or five other persons, including a substitute pharmacist. Pacifica Pharmacy primarily sells directly to customers, but it also mails or ships some prescriptions to customers living outside Pacifica Pharmacy's immediate trade area.

Thang Q. Tran

6. On March 17, 1988, the Board issued Original Pharmacist License No. RPH 41172 to Thang Q. Tran.

There is no history of any prior discipline having been sought against Pharmacist Tran's license.

7. Pharmacist Tran has been licensed for more than 23 years. He has operated Pacifica Pharmacy for the past seven years. Pharmacist Tran is married to Khue Quan, D.D.S., a licensed dentist who is employed on a part-time basis by her mother, also a licensed dentist. Pharmacist Tran is a loving father to his 17-year-old stepdaughter (Ms. Quan's child from a previous relationship) and his and his wife's eight-year-old daughter.

8. Pharmacist Tran is well respected by his wife and employees. Dr. Quan described Pharmacist Tran as a generous, kind and loyal husband who is fair and honest. Dr. Quan mentioned that her husband does not understand others very well and does not express himself well. According to Dr. Quan, the disciplinary process has been very stressful on Pharmacist Tran and has resulted in many family problems.

A Pacifica Pharmacy employee, Dzung Cleary, described Pharmacist Tran as a good person who is very concerned about his staff and customers. Pharmacist Tran is well respected by his customers, some of whom travel many miles to trade at Pacifica Pharmacy. To show their gratitude and respect for the exemplary professional care they are given, many customers bring baked goods and desserts to the pharmacy during the holiday season.

The Citizen Complaint

9. BS is a concerned citizen who has no law enforcement experience. BS is a financial planner who maintains an upstairs office in the Beach Boulevard office complex where Pacifica Pharmacy is located. BS has a view of a portion of the building complex's parking lot from his office.

In November and December 2009, BS heard vehicles entering and leaving the parking lot and loud voices. On more than one occasion, BS looked out his window and observed cars parked randomly about the parking lot. He saw individuals going from the parking lot into and out of the area where Pacifica Pharmacy was located. The persons moving about

the parking lot were relatively young – in their 20s and 30s – and they walked between the cars that were parked there. On one occasion, he observed cash spread across the dashboard of a vehicle below his office; a man sitting inside that vehicle interacted with others who approached the vehicle from other areas of the parking lot. The abnormal activity in the parking lot continued for weeks. On at least one occasion, BS saw money and prescriptions changing hands in the parking lot.

BS maintained a computer log in which he documented his observations. BS contacted the building complex manager and the Huntington Beach Police Department concerning the abnormal activity in the parking lot, but he did not contact Pacifica Pharmacy. When BS's concerns were not satisfactorily addressed by the building manager or local law enforcement, BS filed a complaint with the Board of Pharmacy.

The January 13, 2010, Inspection

10. On January 13, 2010, Joseph Wong, Pharm.D. (Inspector Wong), a Pharmacy Board Inspector, conducted an inspection of Pacifica Pharmacy. The inspection was the result of BS's complaint. Inspector Wong was accompanied on the inspection by three other Pharmacy Board inspectors.

11. Investigator Wong received a doctor of pharmacy degree from the University of the Pacific School of Pharmacy in 2000. The Board of Pharmacy licensed Inspector Wong as a pharmacist in 2001. Inspector Wong worked as a pharmacist intern and then as a staff pharmacist and a pharmacist-in-charge at Walgreens outlets in Sacramento, Roseville, and Rockland before he began his employment with Board in 2006.

Inspector Wong is currently assigned to the Board's drug diversion and fraud team, an assignment he has held for the past four years. Investigator Wong estimated that he has participated in over 300 inspections, a few of which involved corresponding responsibility issues.

12. Before the inspection at Pacifica Pharmacy, Investigator Wong requested a report from Controlled Substance Utilization Review and Evaluation System (CURES)[1], a database maintained by the Department of Justice. Investigator Wong believed that improper dispensing practices might be occurring at Pacifica Pharmacy based on an inference he drew from BS's complaint and information made known to him by the Drug Enforcement Agency (DEA), which was investigating Dr. T. Inspector Wong requested a CURES report for prescriptions dispensed[2] by Pacifica Pharmacy that had been written by Dr. T. and another physician.

Pacifica Pharmacy submitted the data that was contained in the CURES report that Investigator Wong obtained and reviewed, and nothing established that Pacifica Pharmacy improperly submitted that data or that the CURES report that was provided to Inspector Wong contained any data that had not been provided by Pacifica Pharmacy.

Through the CURES report, Inspector Wong learned that Pacifica Pharmacy dispensed 1,844 prescriptions written by Dr. T. from January 1, 2009, through January 5,

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1 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.

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 sued 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.

2 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.

2010.[3] The prescriptions were written for a variety of drugs including, but not limited to, OxyContin[4], Opana[5], Hydromorphone (Dilaudid)[6], and Alprazolam.[7] According to Inspector

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[3] Notice is taken that Dr. T maintained medical offices in Rowland Heights, California, an unincorporated area in Los Angeles County. The distance from Dr. T's office in Rowland Heights to the Pacifica Pharmacy in Huntington Beach was about 24 miles, passing by or through the cities of Diamond Bar, La Habra, Fullerton, Anaheim, Orange, Santa Ana and Fountain Valley along the way.

[4] OxyContin is a brand name for oxycodone, a Schedule II controlled substance under Health and Safety Code section 11055 and a dangerous drug under Business and Professions Code section 4022. OxyContin is used to treat moderate to severe pain that is expected to last for an extended period of time. OxyContin is available in 10 mg, 20 mg, 40 mg, and 80 mg tablets. Some individuals abuse OxyContin for the euphoric effect it produces - an effect that is said to be similar to that associated with heroin use.

[5] Opana is a brand name for oxycodone, a Schedule II controlled substance and a dangerous drug. Opana is used to treat moderate to severe pain that is not expected to last for an extended period of time and to treat breakthrough pain. Opana is available as 5 mg and 10 mg tablets.

Opana ER is an extended-release form of oxycodone that is available in tablets in strengths of 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg. Opana ER is prescribed for pain that is expected to last for an extended period of time.

[6] Hydromorphone, sold under the brand name Dilaudid, is a Schedule II controlled substance under Health and Safety Code section 11055 and a dangerous drug under Business and Professions Code section 4022. Hydromorphone is used as an alternative to morphine to treat moderate to severe pain and as a second- or third-line narcotic cough suppressant. Dilaudid comes in 8 mg tablets.

[7] Alprazolam, sold under the brand name Xanax, is a Schedule IV controlled substance under Health and Safety Code section 11057 and a dangerous drug under Business and Professions Code section 4022. Alprazolam is used to treat anxiety disorders and panic disorder. Alprazolam is in a class of medications called benzodiazepines. Alprazolam comes as a tablet, an extended-release tablet, and an orally disintegrating tablet. The tablet and orally disintegrating table usually are taken two to four times a day. The extended-release tablet is taken once daily, usually in the morning. Alprazolam may heighten the euphoric effect resulting from the use of an oxycodone.

Wong, OxyContin 80 mg, Norco[8], and Alprazolam are popular in the drug culture and are diverted and abused. According to Investigator Wong, OxyContin has a value of $1 per mg on the black market, so that the cost of an OxyContin 80 mg tablet on the street is $80.

Before the January 13, 2010, inspection, Investigator Wong decided to investigate the OxyContin 80 mg prescriptions written by Dr. T. and that had been dispensed by Pacifica Pharmacy. Investigator Wong did not advise Pharmacist Tran about the focus of his investigation when he conducted the inspection on January 13, 2010.

13. On January 13, 2010, the Board of Pharmacy investigators arrived at Pacifica Pharmacy shortly after it opened. The investigators spent most of the day at the pharmacy. They reviewed pharmacy records, CURES data, examined the prescription drugs on back shelves, looked at medication containers, conducted a drug inventory, and evaluated security. Investigator Wong spoke with Pharmacist Tran, the pharmacist-in-charge.

At the conclusion of the inspection, Investigator Wong requested that Pacifica Pharmacy provide further documentation including the original prescriptions for brand and generic OxyContin 80 mg from March 25, 2008, through January 13, 2010; drug utilization review reports for OxyContin 80 mg; drug utilization reports for several prescribers including Dr. T; patient profiles for 18 patients that Investigator Wong selected not at random; various invoices; and a summary for all dangerous drugs/controlled substances that were dispensed by Pacifica Pharmacy from March 25, 2008, to January 13, 2010.

14. During the inspection, investigators determined that there were some expired drugs on inventory shelves. Pre-filled containers were found that did not include the drug name, lot number, expiration date, or the name of the drug manufacturer. Investigators believed these matters were in violation of Business and Professions Code section 4342 and Business and Professions Code section 4976. In addition, Pacifica Pharmacy failed to maintain a current inventory and the pharmacy could not account for an overage of approximately 782 dosage units of OxyContin 80 mg and 93 dosage units of Oxycodone 80 mg for the period extending from March 25, 2008, to January 13, 2010, in violation of Business and Professions Code section 4301, subdivision (j), in conjunction with Business and Professions Code section 4081, subdivision (a) and California Code of Regulations, title 16, section 17189.

15. Inspector Wong and Investigator Venegas spoke with Pharmacist Tran at the conclusion of the inspection. According to Investigator Wong, as he corroborated in his report of inspection, Pharmacist Tran represented that he obtained a driver's license of

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[8] Norco is a schedule II controlled substance under Health and Safety Code section 11055 and a dangerous drug under Business and Professions Code section 4022. Norco contains a combination of acetaminophen and hydrocodone, a narcotic pain reliever. Acetaminophen is a less potent pain reliever that increases the effects of hydrocodone. Norco is used to relieve moderate to severe pain.

individuals who dropped off prescriptions; that he sometimes checked doctor's licenses and National Provider Identifier numbers; that he sometimes contacted a prescriber to verify the prescription; that he evaluated pain patients by observing the diagnosis written on some of the prescriptions; that he documented early refills in patient profiles; that his "understanding of legitimate rxs was limited to verifying rx with md" and "no further evaluation of patient and history to determine legitimate"; that he stopped filling prescriptions written by Dr. F[ ] and Dr. G[ ] the month before the inspection because he believed that their prescriptions might not be written for legitimate medical purposes; that he "does not understand exactly what corresponding responsibility is"; that he "does not understand the prescribing practices of Dr. T[ ] (have not spoken personally with MD) or Dr F[ ], etc."; that he did not ask about patient diagnosis or other medical information unless that information was volunteered by the patient; that he felt that asking for additional information from patients infringed upon patient privacy; that he did not know about the use of CURES reports for the purpose of evaluating patient therapy and that he was aware only of his responsibility to transmit data; that he did not have issues filling prescriptions for patients who lived some distance from the pharmacy; that he did not have issues filling prescriptions written by physicians whose offices were located some distance from the pharmacy; that he did not have issues filling prescriptions for patients who lived some distance from the physician who prescribed controlled substances; that approximately 5 percent of the prescriptions Pacifica Pharmacy filled were written for OxyContin; and that Pacifica Pharmacy's primary source of record-keeping data was the computer.

During Inspector Wong and Inspector Venegas' interview with Pharmacist Tran, Pharmacist Tran did not claim that any other pharmacist at Pacifica Pharmacy filled Dr. T.'s prescriptions, or that Dr. T.'s patients did not pick up the prescriptions for controlled substances that were filled at Pacifica Pharmacy, or that the expired drugs found on the back shelves were being stored there and were not for sale, or that there was some good reason that auxiliary labels, known as backers, were not affixed to containers with medications.

16. Investigators took several photographs that depicted expired medications found on the back shelves where inventory was maintained and several photographs of unlabelled and/or improperly labeled containers of medications.

17. Inspector Wong prepared an Inspection Report that related to the January 13, 2010, inspection. That report contained the name and address of the pharmacy, the pharmacy permit number, the hours the pharmacy was open, and the date of the most recent DEA inventory. The report contained a summary of the conversation with Pharmacist Tran as set forth in Factual Finding 15. Investigator Wong provided Pharmacist Tran with a notice of non-compliance that directed Pacifica Pharmacy to take certain corrective action:

1. Required tablet descriptions were to be affixed to prescription labels, and auxiliary labels containing required information were to be affixed to prescription containers;

2. Pharmacist-in-charge Tran was directed to review and remove all outdated drug stock and dispose of expired drug stock in an appropriate manner.

Inspector Wong's Evaluation of Data

18. Inspector Wong evaluated the data contained in various CURES reports and the materials and data provided by Pacifica Pharmacy. His review of that data established:

A. Drug Usage Reports for OxyContin 80 from 2008 to January 2010 revealed that the majority of the prescriptions filled by Pacifica Pharmacy were for 80 mg strength and that several prescribers, including Dr. T., wrote those prescriptions.

B. From January 1, 2009, to January 6, 2010, Dr. T. wrote 11,486 controlled substance prescriptions, 917 of which were for OxyContin 80 mg, 654 of which were for Opana ER 40 mg, and 2,671 of which were for Alprazolam 2 mg.

C. Pacifica Pharmacy filled 1,844 of Dr. T.'s 11,486 controlled substance prescriptions, about three times more than the next highest number filled in Pacifica Pharmacy's trade area.

D. From March 25, 2008 to January 13, 2010, Pacifica Pharmacy dispensed more than 81,000 prescriptions. Controlled substances accounted for 14,063, or 17 percent of the prescriptions; OxyContin 80 mg accounted for 42 percent of all Schedule II controlled substance prescriptions. Pacifica Pharmacy filled more OxyContin 80 mg prescriptions than were filled by surrounding pharmacies – 803 OxyContin 80 mg prescriptions were filled by Pacifica Pharmacy; 389 were filled by Medical Towers Pharmacy; 281 were filled by Walgreens #5771; 129 were filled by CVS #8850; 38 were filled by CVS #6782, 21 were filled by Sav On #6124, and even fewer were filled by other pharmacies.

E. Of the 18 Pacifica Pharmacy patients that Inspector Wong selected for review because he observed that those patients presented OxyContin 80 mg prescriptions written by Dr. T., 15 patients had traveled 35 or more miles from

their home to see Dr. T. and 15 of them lived 20 miles or more from Pacifica Pharmacy.

F. Dr. T.'s prescribing practices, based on a review of some prescriptions filled by Pacifica Pharmacy, showed duplication in therapy (e.g., OxyContin 80 mg. and Opana ER were prescribed in combination and were to be taken at the same time) and a combination of several drugs was often prescribed (e.g., the combination of Alprazolam and Opana or the combination of Alprazolam, hydromorphone and OxyContin).

G. Many of Dr. T.'s patients to whom OxyContin was dispensed paid in cash.

Joseph Wong's Expert Testimony

19. Based upon his education, training, experience, investigations, conversation with Dr. Tran, and review of the CURES reports and other data, Investigator Wong expressed several expert opinions.

Standards of Care

20. The standard of care requires a pharmacist to use professional judgment when dispensing controlled substances, a duty that entails more than filling a prescription. A pharmacist must evaluate the prescription to make certain it is valid; once it is concluded that the prescription is legitimate on its face, the pharmacist must evaluate the patient, the prescriber, and the medication therapy. If the patient is unknown, the pharmacist may insist that the patient produce valid identification. The pharmacist should be cognizant of the patient's age, demeanor, and the distance from the patient's home to the prescriber's office and to the pharmacy. With respect to the prescriber, the pharmacist should determine whether the prescriber is licensed by the DEA and whether the prescriber holds a medical specialty. In evaluating the medication therapy, the pharmacist should determine whether the medications prescribed correlate to the patient's diagnosis, as well as observing the length of the therapy, whether there are any adverse drug combinations, and whether there are any contraindications for use.

In meeting the corresponding responsibility obligation, a pharmacist is to be alert for "warning signs" or "red flags" that indicate that the prescription may not have been issued for a legitimate medical purpose. These warning signs include irregularities on the face of the prescription itself, nervous patient demeanor, cash payments, traveling long distances from the patient's home to the prescriber's office or pharmacy, irregularities in the prescriber's qualifications in relation to the medication(s) prescribed, prescriptions that are written outside of the prescriber's medical specialty, and the prescribing of medications that have no logical connection to the patient's diagnosis or course of treatment.

Whenever a pharmacist believes that a prescription may not have been written for a legitimate medical purpose, the pharmacist must inquire; when the results of a reasonable inquiry do not overcome the pharmacist's concern about a prescription having been written for a legitimate medical purpose, the pharmacist must not fill the prescription.

Pacifica Pharmacy and Pharmacist Tran's Deviations from the Standard of Care

21. Pacifica Pharmacy and Pharmacist Tran failed to meet the standard of care in that Pharmacist Tran never once contacted Dr. T. to determine if her prescriptions were written for legitimate medical purposes. There were a sufficient number of red flags surrounding to Dr. T.'s prescribing practices, particularly related to OxyContin 80 mg, and a sufficient number of red flags related to the patients who presented the OxyContin 80 mg prescriptions written by Dr. T. (patient youth, cash payment, the distance they lived from Dr. T.'s office and the pharmacy, a number of patients lived at the same address, and the request for early refills) that it was unreasonable for Pacifica Pharmacy and Pharmacist Tran to fill all of the prescriptions that were presented. Pharmacist Tran did not make any inquiry on his own behalf or in his role as pharmacist-in-charge.

22. On cross-examination, Inspector Wong conceded that he had investigated only two or three other corresponding responsibility cases before this one; that this case was the first corresponding responsibility case in which he testified; that CURES did not provide pharmacists with real-time information during the period covered by the Second Amended Accusation; that he never spoke with Dr. T. to find out why she prescribed the medications that she had prescribed; that he did not make any effort to determine if Dr. T. had a medical specialty; that he had no idea whether Dr. T. was a pain management specialist; that he did not speak with the DEA agents who were investigating Dr. T.; that prescribing OxyContin and Dilaudid in combination was not against the law; that no community pharmacist ever sees the patient chart that is maintained by a prescriber; that prescribers may be difficult to contact; that he was not aware of any prescription Pacifica Pharmacy filled that was invalid on its face; that the overage of OxyContin 80 tablets discovered during the inventory was less than one-half of a one percent; that an interim suspension order was not issued against either Pacifica Pharmacy or Pharmacist Tran following his investigation; and that pharmacists are required to fill valid prescriptions.

The cross-examination established that Inspector Wong's investigation could have been more thorough, as is always the case. The cross-examination did not establish that Inspector Wong's testimony about the standard of care and the conclusions he reached was unclear or less than convincing.

Dr. Fujimoto's Expert Testimony

23. Darlene Fujimoto, Pharm.D., described herself as a regulatory/compliance pharmacist. She received her doctorate of pharmacy degree from the University of Southern California. She became licensed as a pharmacist in California in 1984. Dr. Fujimoto

subsequently completed a residency in Administrative/Ambulatory Care Pharmacy Practice at the University of California, Irvine.

Dr. Fujimoto was employed by PharMerica as a consultant from July 1986 through October 1998; as Director of Medical Liaisons from November 1998 through April 2000; by Purdue Pharma[9] from 1998 through 2003, where she worked and trained others in the areas of pain management, anesthesiology and the use of controlled substances; by Biogen Idec Pharmaceuticals from 2003 through 2008, where she managed a grant program and served on an Oncology Medical Product Review Committee; and as Assistant Chief, Pharmacy Regulatory/Compliance & Accreditation, Pharmacy Department, UCSD Health Systems, from 2009 to the present. Dr. Fujimoto has an interest in pain management and in the use of opioids. She serves on a safe medication practices committee. Dr. Fujimoto has provided professional education to dispensing pharmacists in the areas of appropriate pain medication and the use of opioids.

Dr. Fujimoto was a member of the California Board of Pharmacy from 1992 through 2001; she served as Board of Pharmacy President from 1996 through 1997. In her 25-plus year career in pharmacy, Dr. Fujimoto spent no more than seven years actually dispensing medications. Dr. Fujimoto had never worked as a pharmacist in a retail setting. Her interaction with patients has been very limited.

Dr. Fujimoto testified that as a result of her education, training, community rotation, and vocational experiences, she knew that commonly diverted prescription drugs included OxyContin, Opana, Dilaudid, benzodiazepines, and muscle relaxants.

Despite her relative inexperience as a dispensing pharmacist, Dr. Fujimoto's education, continuing education, training, employment history and service with the Board of Pharmacy established that she was qualified to provide expert testimony regarding various standards of care incumbent upon dispensing pharmacists in community pharmacies during the period referred to in the Second Amended Accusation.

24. Complainant contacted Dr. Fujimoto in early December 2011 to obtain expert opinion regarding whether Pharmacist Tran met applicable standards of care. Dr. Fujimoto defined the phrase "standard of care" as being what a reasonable and prudent pharmacist would do under the same or similar circumstances that existed at Pacifica Pharmacy during the period referred to in the Second Amended Accusation. In reaching her opinions, Dr. Fujimoto reviewed the Second Amended Accusation, Investigator Wong's reports, CURES data, patient drug history data, and copies of the prescriptions.

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[9] Purdue Pharma is a privately held pharmaceutical company that produces, among other medications, Dilaudid and OxyContin. According to Dr. Fujimoto, OxyContin is currently available in 10, 20, 40 and 80 mg tablets. A 160 mg OxyContin tablet was once available, but it was removed it from the market due to its potential for abuse.

25. With regard to the prescription of OxyContin 80 mg, Dr. Fujimoto testified that 80 mg was not "a startup dose" and that OxyContin 80 mg should not be prescribed for use by an opioid naïve patient. A patient who was prescribed OxyContin for the first time should not be prescribed more than one OxyContin 10 mg tablet every 12 hours. A patient who becomes tolerant of OxyContin may be prescribed much higher doses, and there is no upper limit. Dr. Fujimoto implied that when a new patient presents with a prescription for OxyContin 80mg, some inquiry should be made to determine if that is an appropriate dosage.

26. A prescription that calls for a patient to take a combination of OxyContin and Opana ER (extended release) at the same time is very concerning because each medication is a form of oxycodone whose effects are designed to last for an extended period of time; these are potentially dangerous, habit forming drug; these are drugs that are diverted and abused. A prescription that directs that both medications be taken at the same time may involve a duplication of medication therapy and there is a potential for diversion that requires inquiry.

Standards of Care

27. While the responsibility for the proper prescribing of a controlled substance is upon the prescriber, a corresponding responsibility rests with the pharmacist who dispenses a prescription; in other words, a pharmacist does not meet the standard of care simply by selecting the proper pharmaceutical product, accurately labeling that product for use, and counseling the patient. Reasonable inquiry is required.

When a pharmacist is presented with a prescription, the pharmacist must first look at the four corners of the prescription to determine whether the prescription is valid. The prescription must be on security paper; it must be complete; and it must be signed. Nothing should appear on the face of the prescription that makes it questionable. If something appears wrong with the prescription, a pharmacist must call the prescriber to verify that the prescriber has issued the prescription as set forth on the face of the prescription.

After the pharmacist determines that the prescription is valid on its face, the pharmacist should verify that the person presenting the prescription is the patient or the patient's legitimate representative. If the patient is new to the pharmacy, the standard of care requires that some evidence be produced to show that the person picking up the prescription is the patient or is entitled to do so on the patient's behalf. It is helpful for the pharmacist at this point to observe where the patient lives and where the prescriber's office is located, as these matters may be red flags that indicate that a prescription may not have been issued for a legitimate medical purpose. It is also helpful to determine the patient's age, because some medications may not be age appropriate and because a patient's relative youth may suggest the possibility of misuse or diversion.

Before dispensing the medication, a pharmacist or a staff member should find out whether the patient is taking other medications to ensure that there is no allergy to the new medication and that there will not be an adverse drug interaction. With an established patient, the relevant information is probably in the patient profile maintained by the

pharmacy. Direct inquiry may be required of a new patient. The contact with the patient or the patient's representative may be helpful in determining the patient's diagnosis and/or the condition for which the prescription was written.

The pharmacist should evaluate whether the drug therapy is appropriate. In some instances, especially where large amounts of narcotics are being prescribed, the pharmacist should know something about the prescriber's medical practice; the pharmacist should make inquiry about that if the prescriber is unknown. The pharmacist must look at the number and kinds of medications that have been prescribed to determine whether additional inquiry is required to make the determination that the prescription is for a legitimate medical purpose. There should be some logical relationship between the drugs that have been prescribed and the condition that is being treated.

There are a number of warning signs – red flags – that should put a reasonable and prudent dispensing pharmacist on notice that a prescription may not have been issued for a legitimate medical purpose. For example, there may be missing information on the script (e.g. a DEA number); the script may be written for an unusually large quantity of drugs; the script(s) may be written for medications that address the same medical problem and appear unreasonably duplicative; the same combination of drugs may be written by the same prescriber for a number of different patients; concern exists when a prescriber starts a patient on OxyContin 80 mg because that is not a usual starting dose; the prescriber's office or the pharmacy may be located a long distance from the patient's home; patients living at the same address who present prescriptions for the same drugs is a cause of concern; young patients presenting prescriptions for chronic pain medications without any explanation raises cause for concern; large cash payments is a red flag; and patients who requests early refills without any good reason is problematic.

The standard of care requires a pharmacist to consider these matters before dispensing a controlled substance. At some point, when reasonable concerns reach a critical mass, the pharmacist must not fill the prescription without making inquiry and resolving those matters.

28. A dispensing pharmacist must verify every suspicious prescription. A pharmacist meets this duty when he or she contacts the prescriber and confirms that the prescription has been written for a legitimate medical purpose; however, accomplishing that mission is often easier said than done. Physicians are busy; they can be difficult to locate; some prescribers do not regard pharmacist verifications as high priority tasks; and physicians can be defensive when confronted with questions about their prescribing practices. The duty of verification may be met in some instances by making inquiry of the patient, who may be able to explain the underlying medical history, the diagnosis, what the patient was told by the prescriber, and/or other relevant matters. The duty of verification in the face of numerous red flags is not met by doing nothing.

Pharmacist Tran's Violations from the Standard of Care

29. Dr. Fujimoto concluded that the evidence she reviewed established that Pharmacist Tran violated the corresponding responsibility statute and engaged in gross negligence during the period in question. She believed that Pharmacist Tran ignored many red flags including Dr. T.'s frequent prescription of OxyContin 80; Dr. T. prescribing OxyContin 80 and Opana ER in combination at the same time; Dr. T. prescribing the same combination of drugs for a number of different patients, including identical prescriptions written for two siblings who were two years apart and living at the same address (chronic pain patients have prescriptions that are usually unique); the relative youth of the patients who presented the OxyContin 80 and other opioid prescriptions; the cash payments for controlled substances in many instances; the distance the patients lived from Dr. T.'s office and from Pacifica Pharmacy; Pharmacist Tran's unfamiliarity with Dr. T.'s prescribing practices; and Pharmacist Tran's failure to contact Dr. T.

30. On cross-examination, Dr. Fujimoto conceded, among other matters, that a prescriber may deviate from a box warning related to a medication when the prescriber determines that doing so is appropriate; that high daily dosages of OxyContin may be required to control chronic pain, and there is no ceiling on such dosages; that it is not uncommon for a prescriber to issue a 30-day supply of sleeping pills; and that the standard of care does not require a pharmacist to contact a prescriber in every instance a controlled substance is prescribed. The cross-examination did not establish that Dr. Fujimoto's testimony concerning the standards of care and the deviations she found was unclear or less than convincing.

Pharmacist Bobby Ho's Testimony

31. Respondents called Bobby Ho, a registered pharmacist who works at a Walgreens pharmacy. Pharmacist Ho has been licensed as a pharmacist for 14 years. The Walgreens pharmacy where Pharmacist Ho works is located about one-quarter mile from Pacifica Pharmacy.

Pharmacist Ho responded to a letter written by Investigator Wong in May 2010 that inquired about Walgreens' prescribing practices and requested the production of certain records. The letter contained a hypothetical question that asked whether a prescription would be filled that was written for 60 tablets of OxyContin 80 mg by a doctor with offices in Los Angeles for a patient who lived in Orange County. Pharmacist Ho, with the assistance of Walgreens' general counsel, wrote:

> All prescriptions are filled in compliance with California and Federal regulations to ensure medications dispensed are pursuant to a valid prescription where in the professional judgment and good faith dispensing practices there is a true doctor-patient relationship. In addition, if the patient is "not known" to the pharmacy,

> the ID of the patient would be checked to help ensure there is no fraud – forgery – diversion.

The written answer Pharmacist Ho provided to the survey question focused on the existence of a "true doctor-patient relationship" as the touchstone for determining whether a prescription was written for a legitimate medical purpose.

Pharmacist Ho's testimony about what actually happened at Walgreens was far more enlightening. Pharmacist Ho testified that it was his practice and his outlet's practice to verify a prescription for OxyContin 80 mg by calling the prescriber's office, even if a patient diagnosis was set forth on the prescription itself. If a group of patients came in at the same time with prescriptions written for the same medications, Pharmacist Ho would call the prescriber's office to verify that each prescription was issued for a legitimate purpose.

With regard to Dr. T., Pharmacist Ho said that he became very wary of her prescribing practices and that he and his Walgreens pharmacy colleagues stopped filling prescriptions that Dr. T. wrote because of the relative youth of the patients who presented those prescriptions and because the prescriptions for OxyContin 80 were written in combination for other drugs that raised too many questions about whether the prescriptions were written for legitimate medical purposes.

Dr. Johnson's Expert Testimony

32. Shannon John Johnson, Pharm.D., received his doctor of pharmacy degree from the University of Pacific School of Pharmacy in 1998. He became licensed by the Board of Pharmacy in 1998. He became a certified geriatric pharmacist in 2005.

Dr. Johnson was called to testify by Respondents. He has been the recipient of many professional honors and awards. Dr. Johnson has been an expert witness in the area of pharmacy practices, and he has consulted in the area of pain management. Dr. Johnson is an active participant in multidisciplinary team/patient oriented care.

Dr. Johnson was a per diem staff pharmacist from 1997 through 1998; a clinical staff pharmacist at Sharp Chula Vista Medical Center from 1998-2000; a medication safety pharmacist and clinical staff pharmacist at Sharp Healthcare from 2000-2005; and has been the Director of Pharmacy, Sharp Healthcare, from 2005 to the present. Dr. Johnson does not dispense medications on a routine basis.

Dr. Johnson's education, continuing education, training, experience, employment history, and consulting service established that he was sufficiently qualified to provide expert opinion on some of the issues raised by the Second Amended Accusation.

Testimony Concerning the Standard of Care

33. Dr. Johnson testified that a dispensing pharmacist in a community pharmacy works in a busy environment that requires the pharmacist to have contact with many patients, to respond to numerous telephone calls from physicians, and to engage in constant interaction with technicians and other staff. The dispensing physician must resolve insurance concerns, obtain the right product for a patient, and provide appropriate patient consultation and counseling. Since a technician usually inputs patient data on a pharmacy label, the pharmacist may not know where the patient lives.

Dr. Johnson testified that a pharmacist must contact the prescriber whenever a prescription is illegible or incomplete. A pharmacist does not need to call a prescriber simply because multiple prescriptions are written and the same script, e.g., for OxyContin, Soma and Xanax. The only other time a pharmacist must contact a prescriber is when the pharmacist has reasonable cause to believe that a prescription may not be legitimate or has cause to believe that it may not have been written for a legitimate medical purpose.

Testimony Concerning Deviations from the Standard of Care

34. Dr. Johnson reviewed documentation that caused him to believe that Pharmacist Tran sometimes called a prescriber.[10] Real-time CURES reports were not available to Pacifica Pharmacy or to Pharmacist Tran during the period of time alleged in the Second Amended Accusation. Dr. Johnson testified that the Board of Pharmacy does not alert pharmacists concerning "red flags" or of the identity of dangerous prescribers through the Board's e-mail communications. Dr. Johnson conceded that while it might be argued that there were red flags in Dr. T.'s prescribing practices in hindsight, there was nothing that would have appeared out of the ordinary to a reasonable and prudent pharmacist when the prescriptions at issue were presented. The overage of OxyContin found during the audit was less than one-half of one percent, which was not a significant. Dr. Johnson was not provided with any Pacifica Pharmacy signature logs for review, and for that reason he was unable to determine who filled the prescriptions at issue or whether a patient actually picked up a prescription after it was filled.

35. Dr. Johnson could not reach any conclusions about whether Pharmacist Tran met his corresponding responsibility duty because he found no evidence that established that Pharmacist Tran actually dispensed any prescription and he found no evidence suggesting that any prescription for a controlled substance was provided for anything other than a legitimate medical purpose. Dr. Johnson testified that the evidence he reviewed did not establish that Pharmacist Tran filled the prescriptions at issue or that the prescriptions were picked up by patients.

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[10] Paragraph 22 of the Second Amended Accusation stated: "Occasionally, Respondent Tran would check the status of the prescribing physician's license or would contact the prescriber to verify the prescription. . . ." This allegation was supported by the evidence.

36. On cross-examination, Dr. Johnson conceded that certain matters - early refills, excessive quantities of narcotic medications, cash payments, excessive distances from the patient's home to the prescriber's office, and the filling prescriptions for several patients with the same address - could be "red flags" that might alert a pharmacist of the possibility that a prescription was not written for a legitimate purpose. He agreed that the corresponding responsibility duty required a pharmacist exercise reasonable professional judgment and to investigate questionable prescriptions.

Dr. Wallace's Expert Testimony

37. Mark S. Wallace, M.D., received his medical degree from Creighton University School of Medicine in 1987. He completed a one-year internship at the Washington Hospital Center in 1988, a two-year residency in Anesthesiology at the University of Maryland Hospital in 1991, and a two-year fellowship in Pain Medicine at the UCSD School of Medicine in 1994. Dr. Wallace has served as a Clinical Professor of Medicine at the University of Maryland Medical School and at the UCSD School of Medicine. Since 1996, Dr. Wallace has been the Program Director at the Center for Pain and Palliative Medicine at UCSD. Dr. Wallace holds board-certification in Anesthesiology, with added qualifications in Pain Management, and he is also board certified in Pain Medicine. Dr. Wallace has received numerous professional honors and awards, and he is a member of many professional organizations. He has published peer reviewed articles, primarily in the field of pain management.

38. Dr. Wallace provided many insights in the area of acute and chronic pain management.

Opioids have been used in the treatment of pain since the 1980s. There was an initial reluctance to treat pain with opioids, but the medical profession ultimately recognized that pain was undertreated, that opioids were effective in its treatment, that there was no justification for unnecessary pain, and that there were social and economic consequences related to untreated and undertreated pain. The pendulum swung from the under treatment of pain and a reluctance to prescribe opioids in the management of acute and chronic pain to the excessive prescribing of opioids - the result was that primary care physician and pharmacists "were caught in the middle." It was not until 2009 that national guidelines for the prescription and use of opioid medications were first adopted and published.

Because of problems associated with prescribing opioid medications and in caring for patients suffering from acute and chronic pain, many physicians do not undertake the care of these very difficult patients. These patients migrate to other physicians who will accept and care for them, even though a physician who ultimately provides pain management may not be formally educated or trained in that field. It is not uncommon for pain patients to travel some distance from their homes to obtain treatment.

The standard of care in treating acute and chronic pain permits a long-acting drug, such as OxyContin, to be prescribed in combination with a short-acting drug, such as Opana.

OxyContin is typically prescribed for a patient with acute or chronic pain within the 60 to 120 mg per day range; however, it was not established that was the starting dose. OxyContin may be prescribed as a PRN (as needed) medication in appropriate circumstances, and Dr. Wallace has prescribed it in that manner. About 40 percent of the patients diagnosed with acute or chronic pain take more medication than has been prescribed due to inadequate pain control, and early prescription refills are not necessarily a matter for concern or evidence of drug diversion.

Dr. Wallace rarely has had a dispensing pharmacist call him to inquire about the validity of a prescription he has written; this may be, in part, because he works in a pain clinic where staff pharmacists know his prescribing practices. Dr. Wallace has never shared a patient chart with a dispensing pharmacist.

Dr. Wallace looked at some of the prescriptions at issue; he could not state, without knowing more about the patient and the patient's medical situation, whether the prescriptions were written for a legitimate medical purpose; in order to reach that conclusion, he would need to review the patient's medical chart and records.

39. Dr. Wallace admitted that he holds no expertise concerning the standard of care that might be incumbent upon a dispensing pharmacist. He did not speak with Dr. T., and he did not consult with Pacifica Pharmacy or Pharmacist Tran.

Respondents' Evidence

40. Respondents cross-examined Complainant's witnesses and called Pharmacist Ho, Dr. Johnson, and Dr. Wallace to testify. In addition, Respondents called Dr. Quan and Ms. Cleary. The relevant testimony from these persons was outlined in the preceding Factual Findings. What Respondents did not produce was an explanation for the expired drugs being maintained in inventory with fresh drugs that were for sale, why there were many containers containing prescription medications that did not have a backer attached as required by law, whether the many prescriptions for OxyContin 80 mg were prescribed for experienced opioid users or whether the patients were opioid naïve, and why so many of Dr. T.'s patients selected Pacifica Pharmacy as the retail outlet to have prescriptions for controlled substances filled. No testimony was provided concerning any inquiry made of any prescriber to determine whether a prescription was written for a legitimate medical purpose. Respondents were in the best position to produce evidence that Pharmacist Tran did not fill the prescriptions at issue and/or that the patients for whom the prescriptions were filled did not pick up the prescriptions from Pacifica Pharmacy. Respondents were in the best position to produce evidence that the information Pacifica Pharmacy submitted to the Department of Justice was inaccurate, or to establish that the CURES reports on which the experts based their opinions were not reliable.

Assessment

41. Investigator Wong's testimony concerning the inspection of Pacifica Pharmacy was credible. Investigator Wong and Dr. Fujimoto's testimony concerning applicable standards of care was credible. Their expert testimony established that sometime between March 2008 and January 2010, sufficient suspicious circumstances surrounded Dr. T.'s prescriptions for OxyContin 80 mg and other controlled substances to the extent that a reasonable and prudent pharmacist would have made some inquiry to determine whether many of the prescriptions she wrote for OxyContin 80 and other controlled substances were issued for legitimate medical purposes. Pharmacist Tran admitted to Investigator Wong that he was unfamiliar with Dr. T., that he was unfamiliar with her prescribing practices, that he was unfamiliar with the corresponding responsibility concept and that he failed to make any inquiry of Dr. T. or her patients concerning the prescriptions she wrote. The totality of the circumstances required that Pharmacist Tran make some inquiry. He failed to do so. The clear and convincing evidence established that Pharmacist Tran, in his personal capacity as a pharmacist and in his designated capacity as pharmacist-in-charge at Pacifica Pharmacy, was negligent, grossly negligent, violated the corresponding responsibility law, and acted in an unprofessional manner.

Complainant's Costs

42. Complainant submitted a certification of costs which stated that 88 hours were expended in the investigation of this matter, and that investigative costs were $102 per hour. The investigation was thorough and was relatively well documented. It was not established that the time spent in the investigation or the hourly rate charged for investigation was unreasonable. The Board's costs of investigation totaled $8,976.

43. This matter was factually complicated and was vigorously defended by experienced, highly competent trial counsel who explored numerous factual and legal issues. The deputy who prosecuted this matter was well prepared and very professional.

The deputy who prosecuted this matter submitted a declaration to which a billing statement was attached. The billing statement detailed the legal services provided by the Attorney General's Office in the prosecution of this matter. Through January 19, 2012, the Office of the Attorney General billed the Board $28,650 for legal services. The deputy who prosecuted this matter estimated that she would bill another 12 hours before the hearing began, with her time billed at the rate of $170 per hour.

It is found that the Board's total costs of enforcement in this matter total $30,690.

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, protection of the public is 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 second amended accusation by clear and convincing evidence.

The Second Amended Accusation Provided Due Process

8. Due process involves the opportunity to be heard at a meaningful time and in a meaningful manner. Due process is not a technical conception with a fixed content unrelated to time, place and circumstance. Rather, due process is flexible and calls for such procedural protections as the particular situation demands. (*Southern Cal. Underground Contractors, Inc. v. City of San Diego* (2003) 108 Cal.App.4th 533, 543.) So long as a party is informed of the substance of the charge and is afforded the basic, appropriate elements of procedural due process, that party cannot complain of a variance between administrative pleadings and proof. (*Stearns v. Fair Employment Practice Com.* (1971) 6 Cal.3d 205, 213.)

9. The Second Amended Accusation sought the revocation of Pharmacist Tran's pharmacist license on several grounds including his alleged failure to comply with the corresponding responsibility law, the excessive furnishing of controlled substances, gross negligence, negligence, and unprofessional conduct. Paragraph 3 of the Second Amended Accusation specifically alleges that Pharmacist Tran was Pacifica Pharmacy's "Pharmacist-in-Charge." But, the Second Amended Accusation also conveyed the impression that Pharmacist Tran personally filled prescriptions and dispensed the controlled substance at issue. (See, for example, Second Amended Accusation, paragraphs 22 and 23).

Pharmacist Tran did not claim a due process violation based on evidence establishing that he was Pacifica Pharmacy's pharmacist-in-charge. Instead, Respondents objected to the Second Amended Accusation because three new causes for discipline (gross negligence, negligence, and unprofessional conduct) were filed less than three weeks before the disciplinary hearing commenced.[11]

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[11] Respondent Tran evidently believed that these new disciplinary theories were alleged because they required a lesser standard of proof to establish the charges. (See, Respondents Pacifica Pharmacy Corp. and Thang Tran's Opposition to the Second Amended Accusation and Motion to Strike, p. 1, lines 24-27.) If so, that was a mistaken belief. Clear and

During the hearing, Complainant stressed Pharmacist Tran's status as pharmacist-in-charge and his responsibility for Pacifica Pharmacy's compliance with all state and federal laws. Respondents did not object to the evidence or argument in that regard. Instead, Respondents presented evidence to show that the prescribing of the medications at issue might have been for a legitimate medical purpose (Dr. Wallace) and argued that Complainant failed to establish that the filling and dispensing of the prescriptions for controlled substances was unreasonable (Dr. Johnson). During closing argument, Respondents downplayed Pharmacist Tran's role as pharmacist-in-charge, suggesting it was a titular position. Respondents' defense throughout this disciplinary proceeding was inconsistent with the due process violation identified in *Smith v. Board of Pharmacy* (1995) 37 Cal.App.4th 229.[12]

Where, as here, a licensee is charged with specific violations, where the licensee does not object to the evidence produced to establish the charges, and where the licensee does not assert that he would have presented additional evidence to rebut the charges had he known about them, there is no due process violation. (*Margarito v. State Athletic Com.* (2010) 189 Cal.App.4th 159, 170-171.)

The Corresponding Responsibility Law

10. At the heart of this disciplinary matter is the allegation that Pharmacist Tran and Pacifica Pharmacy violated the corresponding responsibility law. The corresponding responsibility law is both a standard of care and a duty recognized by statute.

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 Wong and Pharmacist Fujimoto established the existence of this standard through their expert testimony. Pharmacist Ho confirmed the existence of this standard when he described his experience at Walgreens. Dr. Johnson

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convincing evidence was required to establish charges of gross negligence, negligence, and unprofessional conduct.

12 In *Smith v. Board of Pharmacy*, a pharmacist was informed that the Board was going to revoke his license for intentional acts of dispensing and furnishing controlled drugs. As it turned out, the evidence demonstrated, at most, the pharmacist's negligent supervision of others. The pharmacist advised the administrative law judge that the accusation did not allege that the Board was relying on a negligence theory and he complained that he would have called an expert witness to testify concerning the appropriate standard of care had he known the true charges. Following the disciplinary hearing, the Board of Pharmacy revoked the pharmacist's license. The revocation was upheld by the superior court. But on appeal it was determined that the pharmacist's due process rights had been violated at the disciplinary hearing because "it is clear that without adequate notice of the charge seeking to fix his responsibility for the acts of others on the basis of his capacity as pharmacist-in-charge, [the pharmacist] was left unprepared to contest this theory." (*Id.* at pp. 243-244.)

believed there was such a standard; he testified he was unable to reach any conclusion concerning Respondents' deviation from the corresponding responsibility standard without additional evidence; his testimony did not establish that a corresponding responsibility standard of care did not exist.

11. 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.[13] 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 a scheme 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 addicts or habitual 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. 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

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13 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.

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" on a prescribing practitioner and upon a 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 acts 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].)

The Parties' Arguments

Complainant asserted that a pharmacist has the duty to verify that a prescription written for controlled substances was issued for a legitimate medical purpose under existing standards of care and under the corresponding responsibility law as expressed in Health and Safety Code section 11153. To support this position, Complainant cited *Vermont & 110th Medial Arts Pharmacy v. Board of Pharmacy* (1981) 125 Cal.App.3d 19.[14] In *Vermont* the appellate court concluded:

> The statutory scheme plainly calls upon pharmacists to use their common sense and professional judgment. When their suspicions are aroused as reasonable professional persons by either ambiguities in the prescriptions, the sheer volume of controlled substances prescribed by a single practitioner for a small number of persons or, as in this case, when the control inherent in the prescription process is blatantly mocked by its obvious abuse as a means to dispense inordinate and incredible large amounts of drugs under the color and protection of law, pharmacists are called upon to obey the law and refuse to dispense. To fail to do so is either gross incompetence, gross negligence or moral turpitude. . .
>
> A profession is a vocation or occupation requiring special and advanced education and skill predominately of an intellectual nature. The practice of pharmacy, like the practice of medicine, is a profession.
>
> For this reason, society entrusts to persons in these professions the responsibility for control over a force

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[14] In *Vermont*, a pharmacy filled 10,000 prescriptions over a 45-day period which were written by a small group of doctors for four controlled substances that were popular in the illicit market. There were irregular circumstances surrounding the presentation of the prescriptions including 247 prescriptions being written on one day by an licensed practitioner, prescriptions written for patients with the same names but at different addresses, and prescriptions written for persons with such questionable names as "Henry Ford," "Wells Fargo," and "Pearl Harbor." All of the prescriptions were for controlled substances. In this situation, the Board of Pharmacy claimed that the pharmacists should have noticed the suspicious nature of the prescriptions being presented and should have concluded that the prescriptions could not have been made for legitimate medical purposes. In *Vermont* Respondents asserted that there were no guidelines setting forth their duties and which should have caused them to question the validity of a facially valid prescription.

> which, when properly used, has great benefit for mankind, but when abused is a force for evil and human destruction.
>
> It follows that society cannot tolerate the presence of individuals within these professions who abdicate their professional responsibility and permit themselves to be used as a conduit by which these controlled substances reach the illicit market and become that force of evil to which we allude.
>
> More importantly, for this case, such prostitutors of their profession will not be heard to explain their dereliction by the juvenile-like complaint "Nobody told me it was wrong." A true professional does not have to be told such things. (*Vermont & 100th Medical Arts Pharmacy v. Board of Pharmacy, supra*, pp. 25-26.)

Complainant observed that the decision in *Vermont & 100th Medical Arts Pharmacy v. Board of Pharmacy* specifically involved the Board's revocation of a permit to operate a pharmacy for, among other matters, the pharmacy's violations of Business and Professions Code section 11153. On this basis, Complainant argued that the statute has been interpreted to extend beyond a pharmacist who filled the prescriptions in a disciplinary proceeding.

Respondents made several assertions. First, the language of subdivision (a) does not extend by its very terms beyond "the pharmacist who fills the prescription." Second, Respondents asserted that no evidence was produced to establish that that Pharmacist Tran *knowingly* violated the corresponding responsibility statute. Third, Respondents claimed that no competent evidence established that Pharmacist Tran or Pacifica Pharmacy dispensed any controlled substance for anything other than a legitimate medical purpose, that Complainant failed to meet its burden of proof. Respondents asserted that the prescriptions at issue were valid on their face; there was a duty on Pacifica Pharmacy to dispense these prescriptions

under Business and Professions Code section 733.[15] Respondents asserted that the "red flags" mentioned by Investigator Wong and Dr. Fujimoto, as well as the arithmetic data, were "red herrings," nothing more than irrelevant items designed to distract the trier of fact from the real issue before the Board, i.e., whether the prescriptions at issue were written for legitimate medical purposes. Fourth, Respondents provided a variety of innocent explanations for the existence of the "red flags." Fifth, Respondents argued that the characterizing of innocent matters as "red flags" merely reflected Complainant's experts' inexperience in dispensing medications at the retail level. Sixth, while many other pharmacies and pharmacists in Pacifica Pharmacy's trade area also filled Dr. T.'s prescriptions for controlled substances, no other pharmacy or pharmacist doing so was charged with unprofessional conduct. They argued that Complainant's selective prosecution undermined the claim that there was a bright line, and that the Board's investigation was nothing more than a kneejerk response to a citizen's complaint.

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*. 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

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15 Business and Professions Code section 733 provides in part:

> (a) No licentiate shall obstruct a patient in obtaining a prescription drug . . . 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.
>
> (b) Notwithstanding any other provision of law, a licentiate shall dispense drugs . . . pursuant to a lawful order or prescription unless one of the following circumstances exists:
>
> (1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug . . . would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition. . . .

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* (1981) 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.

Unprofessional Conduct, Negligence, Gross Negligence

12. Unprofessional Conduct: Business and Professions Code section 4031 specifically provides that "Unprofessional conduct includes, but is not limited to" certain conduct.

Unprofessional conduct includes the conduct specifically enumerated by statute as well as other misconduct; however, this does not mean that an overly broad connotation should to be given to the term "unprofessional conduct;" it must relate to conduct which indicates an unfitness to practice a profession. Unprofessional conduct is that conduct which 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.)

13. Negligence and Gross Negligence: Professionals must exercise that degree of skill, knowledge, and care ordinarily possessed and exercised by members of their profession under similar circumstances. (*Powell v. Kleinman* (2007) 151 Cal.App.4th 112, 122.)

Expert testimony is required to prove or disprove that a professional performed in accordance with the standard of care unless negligence is obvious to a layperson. Expert testimony must be based on such matters as may be reasonably relied upon by an expert in forming an opinion on the subject. With regard to a standard of care derived from a professional practice, the induction of a rule from practice necessarily requires the production of evidence of an ascertainable practice. (*Johnson v. Superior Court* (2006) 143 Cal.App.4th 297, 305.)

Ordinary or simple negligence – an unintentional tort – consists of a failure to exercise the degree of care in a given situation that a reasonable person under similar

circumstances would employ to protect others from harm. "Gross negligence" long has been defined in California and other jurisdictions as either a "want of even scant care" or "an extreme departure from the ordinary standard of conduct." (*City of Santa Barbara v. Superior Court* (2007) 41 Cal.4th 747, 753-754.)

Relevant Disciplinary Statutes and Regulation

14. 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. . . .

15. Business and Professions Code section 4301 provides in part:

> 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:
>
> [¶] . . . [¶]
>
> (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.
>
> [¶] . . . [¶]

(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. . . .

16. Business and Professions Code section 4036.5 provides:

"Pharmacist-in-charge" means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.[16]

17. Business and Professions Code section 4076 provides in part:

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

[¶] . . . [¶]

(11)(A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules . . .

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container . . . .

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16 California Code of Regulations, title 16, section 10709.1 provides in part:

(a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.

(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy. . . .

18. Business and Professions Code section 4081 provides in part:

> (a) All records of . . . acquisition, or disposition of dangerous drugs . . . shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every . . . pharmacy . . . who maintains a stock of dangerous drugs or dangerous devices.[17]
>
> (b) The owner, officer, and partner of a pharmacy . . . shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.
>
> (c) The pharmacist-in-charge . . . shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

19. Business and Professions Code section 4342 provides in part:

> (a) 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,

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[17] California Administrative Code, title 16, section 1718 provides:

> "Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.
>
> The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

or that violate any provision of the Sherman Food, Drug and Cosmetic Law . . .

20. California Code of Regulations, title 16, section 17189 provides:

> "Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.
>
> The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

21. Health and Safety Code section 11153 was cited and discussed in Legal Conclusion 11.

Cause Exists to Impose Discipline Against Pacifica Pharmacy's Permit

22. First Cause for Discipline: The clear and convincing evidence established that the permit issued to Pacifica Pharmacy is subject to discipline under Business and Professions Code section 4031, subdivision (j), in conjunction with Health and Safety Code section 1153, subdivision (a). Pacifica Pharmacy failed to comply with the corresponding responsibility law. From March 8, 2008, through January 13, 2010, Pacifica Pharmacy, through its licensed personnel, had the duty to determine whether certain prescriptions for controlled substances were issued for legitimate medical purposes. The totality of suspicious circumstances surrounding Dr. T.'s prescriptions for OxyContin 80 mg and other controlled substances imposed a burden on Pacifica Pharmacy and its personnel to make reasonable inquiry into the purpose of one or more of the prescriptions for OxyContin 80 mg written by Dr. T. The Board was not required to establish that any particular prescription for a controlled substance was written for an illegitimate purpose given the nature and extent of the red flags that were established. Once Complainant produced sufficient evidence to support Pacifica Pharmacy's duty to make inquiry, the burden of producing evidence shifted to Pacifica Pharmacy to explain why no inquiry was made. Respondents' effort to explain away the "red flags" was insufficient to justify the failure to make any inquiry.

Pacifica Pharmacy's failure to meet its corresponding responsibility in the face of extensive and unmistakable evidence that required inquiry extended for nearly two years. In the absence any evidence in explanation or mitigation, and given the insignificant evidence of rehabilitation (all of which Pacifica Pharmacy had the burden to produce), it is concluded that only the outright revocation of Pacifica Pharmacy's permit will protect the public.

23. Second Cause for Discipline: The clear and convincing evidence established that the permit issued to Pacifica Pharmacy is subject to discipline under Business and Professions Code section 4301, subdivision (j), in conjunction with Business and Professions Code section 4081, subdivision (a) and California Code of Regulations, title 16, section 17189, in that Pacifica Pharmacy failed to maintain a current inventory and could not account for an overage of approximately 782 dosage units of OxyContin 80 mg and 93 dosage units of Oxycodone 80 mg for the period from March 25, 2008, to January 13, 2010. Pacifica Pharmacy did not offer any explanation for the overage, other than to establish that a discrepancy in the current inventory is not unusual and the amount of the overage at Pacifica Pharmacy was not extreme.

24. Third Cause for Discipline: The clear and convincing evidence established that the permit issued to Pacifica Pharmacy is subject to discipline under Business and Professions Code section 4301, subdivision (j), in conjunction with Business and Professions Code section 4076, subdivision (a)(11), in that Pacifica Pharmacy failed to have a physical description of the dispensed medication from the auxiliary label affixed to the prescription container on dispensed prescriptions. Respondents had the burden of establishing that an exemption or exception to this general rule existed, and they failed establish any exemption or exception to the rule.

25. Fourth Cause for Discipline: The clear and convincing evidence established that the permit issued to Pacifica Pharmacy is subject to discipline under Business and Professions Code section 4342, which prohibits the sale of pharmaceutical drugs lacking quality and strength, in that on January 13, 2010, Pacifica Pharmacy had in its inventory expired drugs and repacked drugs that lacked appropriate labeling. Respondent offered no explanation for the reason expired medications were comingled with medications in inventory that were for sale, or why some containers that were filled with medications did not have appropriate labels.

26. Fifth Cause for Discipline: The clear and convincing evidence established that the permit issued to Pacifica Pharmacy is subject to discipline under Business and Professions Code section 4301, subdivision (d), which provides that clearly excessive furnishing of controlled substances constitutes unprofessional conduct. Pacifica Pharmacy failed to comply with the corresponding responsibility law. The arithmetic data produced by Investigator Wong from his review of CURES data and the records produced by Pacifica Pharmacy established that Pacifica Pharmacy was the pharmacy of choice in Huntington Beach for the filling of controlled substance prescriptions written by Dr. T. Pacifica Pharmacy filled far more prescriptions for Schedule II controlled substances than any nearby pharmacy, including chain pharmacies. The patients' selection of Pacifica Pharmacy was not by accident. No questions were asked at Pacifica Pharmacy, and Dr. T.'s prescriptions for controlled substances were always filled so long as there was nothing unusual about the face of the prescription. To paraphrase *Vermont & 110th Medial Arts Pharmacy v. Board of Pharmacy* (1981) 125 Cal.App.3d 19, society cannot tolerate pharmacies which abdicate their professional responsibility and permit themselves to be used as a conduit by which controlled substances reach the illicit market and become a force of evil.

Pacifica Pharmacy clearly furnished excessive quantities of controlled substances without substantial justification for doing so. Public respect and confidence is merited by eliminating irresponsible and incompetent pharmacies. The outright revocation of Pacifica Pharmacy's permit will protect the public.

Cause Exists to Impose Discipline Against Pharmacist Tran's License

27. First Cause for Discipline: The clear and convincing evidence established that the license issued to Pharmacist Tran is subject to discipline under Business and Professions Code section 4031, subdivision (j), in conjunction with Health and Safety Code section 1153, subdivision (a). Pharmacist Tran, a licensed professional who was responsible for Pacifica Pharmacy's compliance with the law, was unfamiliar with the concept of corresponding responsibility. He made no inquiry of Dr. T. regarding her prescribing practices, which included numerous prescriptions for OxyContin 80 mg and other Schedule II controlled substances. He did not ask her patients why those drugs had been prescribed, erroneously claiming that a patient's right to privacy trumped any other consideration. From March 8, 2008, through January 13, 2010, Pharmacist Tran owned and operated Pacifica Pharmacy; he was the pharmacist-in-charge; given the size of the pharmacy, it is far more likely than not that he was the primary dispensing pharmacist. Complainant presented evidence sufficient to establish a requisite degree of belief that Pharmacist Tran filled most of the controlled substance prescriptions at issue, and that he was the pharmacist-in-charge when all of those prescriptions were filled; the burden of producing evidence to the contrary shifted to Pharmacist Tran to refute Complainant's prima facie case. No evidence to the contrary was provided.

In his defense, Pharmacist Tran could have produced testimony from those who actually filled the prescriptions at issue; or he could have produced testimony from others who observed pharmacists other than Pharmacist Tran fill the prescriptions at issue; or Pharmacist Tran could have established through documentary evidence that someone else filled the prescriptions at issue. Pharmacist Tran failed to produce that kind of evidence when it was within his power to do so.

The totality of circumstances surrounding Dr. T.'s prescription for OxyContin 80 mg and other controlled substances imposed a burden on Pharmacist Tran – personally and in his capacity as pharmacist-in-charge - to make reasonable inquiry into one or more of the prescriptions for controlled substances written by Dr. T. The effort to explain away the red flags and arithmetic data, which went to the issue of notice, was insufficient to justify Pharmacist Tran's lack of inquiry.

Very little evidence was offered in explanation or mitigation. Slightly more evidence was offered in rehabilitation, but experiencing a difficult family life as a result of stress imposed by disciplinary proceedings, being a good husband and parent, being a good employer, and producing some forms to document contact with a prescriber is not compelling evidence of rehabilitation.

On this record, it is concluded that the only measure of discipline that will protect the public is the outright revocation of Pharmacist Tran's license.

28. Fifth Cause for Discipline: The clear and convincing evidence established that the license issued to Pharmacist Tran is subject to discipline under Business and Professions Code section 4301, subdivision (d), which provides that the clearly excessive furnishing of controlled substances constitutes unprofessional conduct. Pharmacist Tran failed to comply with the corresponding responsibility law. The arithmetic data produced by Investigator Wong from his review of CURES data and the records produced by Pacifica Pharmacy established that Pacifica Pharmacy was the pharmacy of choice in Huntington Beach for the filling of controlled substance prescriptions written by Dr. T. Pacifica Pharmacy filled far more prescriptions for Schedule II controlled substances than any nearby pharmacy, including chain pharmacies. The patients' selection of Pacifica Pharmacy was not by accident. No questions were asked at Pacifica Pharmacy, and Dr. T.'s prescriptions for controlled substances were always filled so long as there was nothing unusual about the face of the prescription. Pharmacist Tran was the pharmacist-in-charge and was responsible for Pacifica Pharmacy's compliance with federal and state law. He likely filled a majority of the prescriptions written by Dr. T.

Pharmacist Tran clearly furnished excessive quantities of controlled substances without substantial justification for doing so. Public respect and confidence is merited by eliminating irresponsible and incompetent pharmacists. The outright revocation of Pharmacist Tran's license will protect the public.

29. Sixth Cause and Eighth Cause for Discipline: The clear and convincing evidence established that the license issued to Pharmacist Tran is subject to discipline under Business and Professions Code section 4031. The expert testimony established the existence of a corresponding responsibility – a pharmacist's professional duty to determine whether a prescription for a controlled substance has been issued for a legitimate medical purpose when the circumstances require that inquiry. The expert testimony established that suspicious circumstances existed at Pacifica Pharmacy from March 2008 through January 2010 that required Pharmacist Tran to make such an inquiry. Pharmacist Tran was negligent and engaged in unprofessional conduct in carrying out his responsibilities as a licensed pharmacist, both personally and in his capacity as a pharmacist-in-charge. Pharmacist Tran was unfamiliar with the concept of corresponding responsibility. He caused prescriptions to be filled and he permitted prescriptions to be filled for controlled substances under suspicious circumstances without making required inquiry of the prescriber or the patient about the medical purpose for the medication he was responsible for dispensing.

On this record, it is concluded that the only measure of discipline that will protect the public is the outright revocation of Pharmacist Tran's license.

30. Seventh Cause for Discipline: The clear and convincing evidence established that the license issued to Pharmacist Tran is subject to discipline under Business and Professions Code section 4031, subdivision (c). Pharmacist Tran was grossly negligent in

meeting his responsibilities as a licensed pharmacist personally and in his capacity as a pharmacist-in-charge. He was unfamiliar with the concept of corresponding responsibility. He exercised scant care. His conduct in causing and permitting prescriptions to be filled for controlled substances under suspicious circumstances without making any inquiry was an extreme departure from the standard of care.

On this record, it is concluded that the only measure of discipline that will protect the public is the outright revocation of Pharmacist Tran's license.

Complainant's Costs

31. Business and Professions Code section 125.3 provides in part:

> (a) Except as otherwise provided by law, in any order issued in resolution of a disciplinary proceeding before any board within the department [of Consumer Affairs] . . . upon request of the entity bringing the proceeding, the administrative law judge may direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.
>
> (b) In the case of a disciplined licentiate that is a corporation or a partnership, the order may be made against the licensed corporate entity or licensed partnership.
>
> (c) A certified copy of the actual costs, or a good faith estimate of costs where actual costs are not available, signed by the entity bringing the proceeding or its designated representative shall be prima facie evidence of reasonable costs of investigation and prosecution of the case.

32. The Board must exercise its discretion to reduce or eliminate cost awards in a manner that will ensure the award does not deter licensees with potentially meritorious claims or defenses from exercising their right to a hearing. (*Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.App.4th 32, 45.)

It was not established that any of the Zukerman criteria applied in this matter.

33. It is concluded that the Board of Pharmacy's reasonable costs of investigation and enforcement total $39,666.

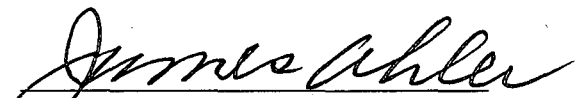
ORDERS

Original Permit No. PHY 46715 issued to Pacifica Pharmacy Corp is revoked.

Original Pharmacist License No. RPH 41172 issued to Thang Q. Tran is revoked.

Pacifica Pharmacy Corp and Thang Q. Tran shall pay to the Board of Pharmacy costs of investigation and enforcement in the total amount of $39,666.00.

DATED: February 29, 2012



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

In the Matter of the Second Amended Accusation Against: **PACIFICA PHARMACY CORP** 18682 Beach Blvd., #115 Huntington Beach, CA 92648 **Original Permit No. PHY 46715** and **THANG Q. TRAN** 18682 Beach Blvd., #115 Huntington Beach, CA 92648 **Original Pharmacist License No. RPH 41172** Respondents.	Case No. 3802 **SECOND AMENDED** **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about August 17, 2004, the Board of Pharmacy issued Original Permit Number PHY 46715 to Respondent Pacifica Pharmacy Corp, Thang Tran, President, Vice President and

Secretary. The Original Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2012, unless renewed.

3. On March 17, 1988, the Board of Pharmacy issued Original Pharmacist License No. RPH 41172 to Respondent Thang Q. Tran, Pharmacist-In-Charge. The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2013, unless renewed.

JURISDICTION

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

5. Section 4300 of the Code states:

> (a) Every license issued may be suspended or revoked.
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> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
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> (1) Suspending judgment.
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> (2) Placing him or her upon probation.
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> (3) Suspending his or her right to practice for a period not exceeding one year.
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> (4) Revoking his or her license.
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> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
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> . . .
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> (e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

6. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender, cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

STATUTORY AND REGULATORY PROVISIONS

7. Section 4076 of the Code states:

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

...

(11)(A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.
(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.
(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph....

8. Section 4081 of the Code states:

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

9. Section 4301 of the Code states:

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

. . .

(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.

. . .

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

10. Section 4342 provides:

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

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321.

11. Section 1718 of title 16, California Code of Regulations provides:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

12. Section 11153 of the Healthy and Safety Code 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....

COST RECOVERY

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

DRUGS

14. Alprazolam, sold under the brand name Xanax, is a Schedule IV controlled substance as designated by Health and Safety Code section 11057(d)(1), and is a dangerous drug pursuant to Business and Professions Code section 4022. Alprazolam tablets are indicated for the management of anxiety disorder or the short-term relief of symptoms of anxiety.

15. Hydromorphone, sold under the brand name Dilaudid, is a Schedule II controlled substance as designated by Health and Safety Code Section 11055(b)(1)(K) and is a dangerous drug pursuant to Business and Professions Code section 4022. Dilaudid is a narcotic analgesic prescribed for the relief of moderate to severe pain.

16. Opana, a brand name for oxymorphone, is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (b)(1)(O), and is a dangerous drug pursuant to Business and Professions Code section 4022.

17. Oxycontin, a brand name for oxycodone, is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (b)(1)(N), and is a dangerous drug pursuant to Business and Professions Code section 4022.

FACTS

18. In or about December, 2009, the Board received a consumer complaint from B.S. regarding alleged suspicious activity at Pacifica Pharmacy Corp (hereinafter "Pacifica"). B.S. complained of abnormal activity in the parking lot of Pacifica over the course of several days,

including several occasions when groups of people entered and exited Pacifica at one time, or were dropped off by a vehicle in Pacifica's parking lot.

19. On January 13, 2010, Board inspectors conducted an inspection of Pacifica. Drug Usage Reports were requested from Pacifica and were reviewed, together with the pharmacy's drug inventory, DEA inventories, patient prescription profiles, acquisition records, and enrollment in the on-line Prescription Drug Monitoring Program, among other documents.

20. During the inspection, expired drug stock was found on inventory shelves. Pre-filled containers with medication lacked the drug name, lot number, expiration date and name of manufacturer. In addition, the dosage form descriptions on the prescription labels were auxiliary labels and were not affixed to the prescription container when the medication was dispensed.

21. During the inspection, Respondent Tran stated that he does not evaluate a patient's information with regard to drug diversion or addiction issues. He does not request CURES[1] reports to evaluate a patient's therapy. Respondent Tran stated that he was only aware of his responsibility to transmit controlled substance information and does not use any reports to determine drug diversion or addiction issues.

22. When filling a prescription for a controlled substance, Respondent Tran stated that Pacifica obtains and photocopies the driver's license of the individual presenting the prescription for their records. Occasionally, Respondent Tran would check the status of the prescribing physician's license or would contact the prescriber to verify the prescription. He evaluated patients' prescribed pain medication by review of the diagnosis written on some of the prescriptions. For those patients who were prescribed other controlled substances, he would document early refill authorizations or lost script issues on the patient's profile.

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[1] Controlled Substance Utilization Review and Evaluation System, C.U.R.E.S, is a database that contains over 100 million entries of controlled substance drugs that were dispensed in California. CURES is part of a program developed by the California Department of Justice, Bureau of Narcotic Enforcement, which allows access to the Prescription Drug Monitoring Program (PDMP) system. The PDMP allows pre-registered users including licensed healthcare prescribers eligible to prescribe controlled substances, pharmacists authorized to dispense controlled substances, law enforcement, and regulatory boards to access patient controlled substance history information. (http://ag.ca.gov/bne/cures.php)

23. In the days following the inspection, the Board continued to receive complaints from B.S. about suspicious activity in Pacifica's parking lot. On February 1, 2010, Board inspectors requested records from Pacifica showing controlled substances furnished after the Board's inspection on January 13, 2010. Those records showed the continued filling of controlled substance prescriptions from several of the physicians in question, including Dr. T. Specifically, Respondent Tran continued to dispense Oxycontin 80 mg to Dr. T's patients. When asked whether the prescribing pattern written by the same physician for the same drug for many of Pacifica's patients seemed reasonable, Respondent Tran stated that the majority of prescriptions for Dr. T were for controlled substances and that about 5 percent of Pacifica's prescriptions were for Oxycontin.

24. Drug Usage Reports of Oxycontin from 2008 to January 2010 revealed that the majority of Oxycontin prescriptions filled by Pacifica were for the 80 mg strength during the last two years and that these prescriptions were written by several recurring physicians, in particular, Dr. T.

25. From January 1, 2009 to January 6, 2010, Dr. T. prescribed about 11,486 controlled substance prescriptions. Of these 11,486 controlled substance prescriptions, the number of prescriptions written by Dr. T. for Oxycontin, Opana and Alprazolam are shown below:

Drug	No. of Prescriptions	No. of dosage units
Oxycontin 80 mg	917	46,727
Opana ER 40 mg	654	25,005
Alprazolam 2 mg	2,671	175,584

26. Of these 11,486 controlled substance prescriptions, Pacifica filled 1,844 prescriptions, about three times more than what was filled by the pharmacy with the next highest volume: Bolsa Medical Arts Pharmacy filled 101 prescriptions, Dial Drug filled 566, White Front Drug and Discount filled 663. Other pharmacies accounted for less than 100 prescriptions.

27. An overall review of the dispensing practice of Pacifica showed that it dispensed 81,066 prescriptions for dangerous drugs and controlled substances from March 25, 2008 to January 13, 2010. Controlled substance prescriptions accounted for 14,063 or 17% of all prescriptions. Oxycontin 80 mg prescriptions accounted for 42% of all Schedule II controlled substances. There were 5318 prescriptions for Schedule II controlled substances during this period of time. In comparison to other surrounding pharmacies, Pacifica filled an inordinately disproportionate number of Oxycontin 80 mg prescriptions: 803 prescriptions filled by Pacifica, 389 by Medical Towers Pharmacy, 281 by Walgreens No. 5771, 129 by CVS # 8850, 38 by CVS #6782, 21 by Sav On #6124, and even less by others.

28. Further investigation of Drug History Reports revealed questionable dispensing practices by Pacifica, such as early refills of controlled substance prescriptions, filling prescriptions for patients outside the normal trade area and prescriptions by prescribers whose offices were outside Pacifica's normal trade area. For example, Patient Drug History reports of 18 of Dr. T.'s patients showed that almost all had a home address outside of Pacifica's normal trade area and that nearly all of them traveled approximately 40 miles to see Dr. T. A comparison of other pharmacies surrounding Pacifica showed very few prescriptions filled for patients outside their normal trade area.

29. A review of information from sources available to Respondents, such as the Patient Drug History reports, would have revealed that several of these 18 patients had multiple prescribers for controlled substances, had multiple dispensing pharmacies and had early refilling of controlled substance prescriptions.

30. Furthermore, a review of Dr. T.'s prescribing practices for prescriptions filled by Pacifica showed duplication of therapy (e.g. Opana and Oxycontin were both prescribed or hydromorphone and Oxycontin were both prescribed) as well as combinations of drugs commonly prescribed together by Dr. T. (e.g. the combination of alprazolam and Opana or the combination of alprazolam, hydromorphone and Oxycontin).

31. Further review of Oxycontin prescription documents from the period March 28, 2008 to January 13, 2010 show a disproportionate number of Oxycontin prescriptions from Dr. T.,

whose patients also showed a disproportionate number of cash payments in relation to private insurance, a government payor or other form of payment. Many of the prescriptions filled were to addresses with multiple patients at the same address. In addition, there were discrepancies with the addresses on the prescription backer label, the prescription and/or the patient's driver's license/ID.

FIRST CAUSE FOR DISCIPLINE

AS TO PACIFICA PHARMACY AND THANG Q. TRAN

(Failure to Comply with Corresponding Responsibility for Legitimate Controlled Substance Prescriptions)

32. Respondents Pacifica Pharmacy and Thang Q. Tran are subject to discipline pursuant to Code section 4301, subdivision (j), in conjunction with Health and Safety Code section 11153(a) for unprofessional conduct in that Respondents failed to comply with their corresponding responsibility to ensure that controlled substances are dispensed for a legitimate medical purpose when Respondents failed to evaluate the totality of the circumstances (information from the patient, physician and other sources) to determine the prescription's legitimate medical purpose in light of information showing that prescriptions for controlled substances were filled early, there was duplication of therapy, the same drug combinations were repeatedly prescribed for multiple patients by the same prescriber, numerous patients had addresses outside of Pacifica's normal trade area, and certain prescribers wrote a disproportionate number of prescriptions for Oxycontin, among other things, as more fully set forth in paragraphs 18-31 above, and incorporated by this reference as though set forth in full herein.

SECOND CAUSE FOR DISCIPLINE

AS TO PACIFICA PHARMACY ONLY

(Failure to Maintain Current Inventory)

33. Respondent Pacifica Pharmacy is subject to discipline pursuant to Code section 4301, subdivision (j), in conjunction with Code section 4081(a) and title 16, California Code of Regulations section 1718, for unprofessional conduct in that Respondent Pacifica Pharmacy failed to maintain a current inventory in that it could not account for an overage of approximately

782 dosage units of Oxycontin 80 mg and 93 dosage units of Oxycodone 80 mg for the period March 25, 2008 to January 13, 2010.

THIRD CAUSE FOR DISCIPLINE

AS TO PACIFICA PHARMACY ONLY

(Incomplete Labeling)

34. Respondent Pacifica Pharmacy is subject to discipline pursuant to Code section 4301, subdivision (j), in conjunction with Code section 4076(a)(11) for unprofessional conduct in that on January 13, 2010, Respondent Pacifica Pharmacy failed to have the physical description of the dispensed medication from the auxiliary label affixed to the prescription container on dispensed prescriptions.

FOURTH CAUSE FOR DISCIPLINE

AS TO PACIFICA PHARMACY ONLY

(Expired Drugs)

35. Respondent Pacifica Pharmacy is subject to discipline pursuant to Code section 4342, which prohibits the sale of pharmaceutical drugs lacking quality and strength, in that on January 13, 2010, Respondent Pacifica Pharmacy maintained expired dangerous drugs and controlled substances as part of its drug stock on its inventory shelves. Additionally, repackaged (pre-counted or poured) drugs lacked appropriate labeling of name of drug, strength, dosage form, manufacturer's name and lot number, expiration date, and quantity per repackaged unit.

FIFTH CAUSE FOR DISCIPLINE

AS TO PACIFICA PHARMACY AND THANG Q. TRAN

(Excessive Furnishing of Controlled Substances)

36. Respondents Pacifica Pharmacy and Thang Q. Tran are subject to discipline pursuant to Code section 4301, subdivision (d), for unprofessional conduct in that Respondents clearly excessively furnished controlled substances during the period March 25, 2008 to January 13, 2010, as more fully set forth in paragraphs 18-31 above, and incorporated by this reference as though set forth in full herein.

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SIXTH CAUSE FOR DISCIPLINE

AS TO THANG Q. TRAN

(Unprofessional Conduct – Gross Negligence)

37. Respondent Thang Q. Tran is subject to discipline pursuant to Code section 4301, subdivision (c), for unprofessional conduct in that Respondent was grossly negligent in dispensing controlled substances during the period March 25, 2008 to January 13, 2010, in that Respondent knew or should have known that the controlled substances prescribed by Dr. T. were likely to be diverted or used for other than a legitimate medical purpose and that Respondent failed to take appropriate steps upon being presented with numerous prescriptions for the same controlled substances, including Oxycontin 80 mg, from a small group of prescribers, including but not limited to, contacting the prescribers, interviewing the patients and performing additional investigation to determine whether the prescriptions were issued for a legitimate medical purpose, as more fully set forth in paragraphs 18-31 above, and incorporated by this reference as though set forth in full herein.

SEVENTH CAUSE FOR DISCIPLINE

AS TO THANG Q. TRAN

(Unprofessional Conduct – Negligence)

38. Respondent Thang Q. Tran is subject to discipline pursuant to Code section 4301, for unprofessional conduct in that Respondent was negligent in dispensing controlled substances during the period March 25, 2008 to January 13, 2010, in that Respondent knew or should have known that the controlled substances prescribed by Dr. T. were likely to be diverted or used for other than a legitimate medical purpose and that Respondent failed to take appropriate steps upon being presented with numerous prescriptions for the same controlled substances, including Oxycontin 80 mg, from a small group of prescribers, including but not limited to, contacting the prescribers, interviewing the patients and performing additional investigation to determine whether the prescriptions were issued for a legitimate medical purpose, as more fully set forth in paragraphs 18-31 above, and incorporated by this reference as though set forth in full herein.

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EIGHTH CAUSE FOR DISCIPLINE

AS TO THANG Q. TRAN

(Unprofessional Conduct)

39. Respondent Thang Q. Tran is subject to discipline pursuant to Code section 4301 for unprofessional conduct in that Respondent engaged in the activity described in paragraphs 18-31 above, and incorporated by this reference as though set forth in full herein.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Original Permit Number PHY 46715, issued to Pacifica Pharmacy Corp;

2. Revoking or suspending Original Pharmacist License Number RPH 41172, issued to Thang Q. Tran;

3. Ordering Pacifica Pharmacy Corp and Thang Tran, jointly and severally, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

DATED: 1/3/12

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

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