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

11 In the Matter of the Second Amended
Accusation Against:

Case No. 3802

12 **PACIFICA PHARMACY CORP**
13 18682 Beach Blvd., #115
Huntington Beach, CA 92648

SECOND AMENDED

14 **Original Permit No. PHY 46715**

A C C U S A T I O N

15 and

16 **THANG Q. TRAN**
17 18682 Beach Blvd., #115
Huntington Beach, CA 92648

18 **Original Pharmacist License No. RPH 41172**

19 Respondents.
20

21 Complainant alleges:

22 **PARTIES**

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

25 2. On or about August 17, 2004, the Board of Pharmacy issued Original Permit Number
26 PHY 46715 to Respondent Pacifica Pharmacy Corp, Thang Tran, President, Vice President and
27

28

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

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

7 **JURISDICTION**

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

11 5. Section 4300 of the Code states:

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

13 (b) The board shall discipline the holder of any license issued by the board,
14 whose default has been entered or whose case has been heard by the board and
found guilty, by any of the following methods:

15 (1) Suspending judgment.

16 (2) Placing him or her upon probation.

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

19 (4) Revoking his or her license.

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

21 . . .

22 (e) The proceedings under this article shall be conducted in accordance with
23 Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the
24 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.

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

STATUTORY AND REGULATORY PROVISIONS

1
2 7. Section 4076 of the Code states:

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

6 ...

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

10 (i) Prescriptions dispensed by a veterinarian.

11 (ii) An exemption from the requirements of this paragraph shall be granted
12 to a new drug for the first 120 days that the drug is on the market and for the 90
13 days during which the national reference file has no description on file.

14 (iii) Dispensed medications for which no physical description exists in any
15 commercially available database.

16 (B) This paragraph applies to outpatient pharmacies only.

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

19 (D) This paragraph shall not become operative if the board, prior to January
20 1, 2006, adopts regulations that mandate the same labeling requirements set forth in
21 this paragraph....

22 8. Section 4081 of the Code states:

23 (a) All records of manufacture and of sale, acquisition, or disposition of
24 dangerous drugs or dangerous devices shall be at all times during business hours
25 open to inspection by authorized officers of the law, and shall be preserved for at
26 least three years from the date of making. A current inventory shall be kept by
27 every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer,
28 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.

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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

1 professional treatment or in legitimate and authorized research; or (2) an order for
2 an addict or habitual user of controlled substances, which is issued not in the course
3 of professional treatment or as part of an authorized narcotic treatment program, for
4 the purpose of providing the user with controlled substances, sufficient to keep him
5 or her comfortable by maintaining customary use....

4 **COST RECOVERY**

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

9 **DRUGS**

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

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

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

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

24 **FACTS**

25 18. In or about December, 2009, the Board received a consumer complaint from B.S.
26 regarding alleged suspicious activity at Pacifica Pharmacy Corp (hereinafter "Pacifica"). B.S.
27 complained of abnormal activity in the parking lot of Pacifica over the course of several days,
28

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

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

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

11 21. During the inspection, Respondent Tran stated that he does not evaluate a patient's
12 information with regard to drug diversion or addiction issues. He does not request CURES¹
13 reports to evaluate a patient's therapy. Respondent Tran stated that he was only aware of his
14 responsibility to transmit controlled substance information and does not use any reports to
15 determine drug diversion or addiction issues.

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

23
24 _____
25 ¹ Controlled Substance Utilization Review and Evaluation System, C.U.R.E.S, is a
26 database that contains over 100 million entries of controlled substance drugs that were dispensed
27 in California. CURES is part of a program developed by the California Department of Justice,
28 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>)

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

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

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

18

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

23

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

28

1 27. An overall review of the dispensing practice of Pacifica showed that it dispensed
2 81,066 prescriptions for dangerous drugs and controlled substances from March 25, 2008 to
3 January 13, 2010. Controlled substance prescriptions accounted for 14,063 or 17% of all
4 prescriptions. Oxycontin 80 mg prescriptions accounted for 42% of all Schedule II controlled
5 substances. There were 5318 prescriptions for Schedule II controlled substances during this
6 period of time. In comparison to other surrounding pharmacies, Pacifica filled an inordinately
7 disproportionate number of Oxycontin 80 mg prescriptions: 803 prescriptions filled by Pacifica,
8 389 by Medical Towers Pharmacy, 281 by Walgreens No. 5771, 129 by CVS # 8850, 38 by CVS
9 #6782, 21 by Sav On #6124, and even less by others.

10 28. Further investigation of Drug History Reports revealed questionable dispensing
11 practices by Pacifica, such as early refills of controlled substance prescriptions, filling
12 prescriptions for patients outside the normal trade area and prescriptions by prescribers whose
13 offices were outside Pacifica's normal trade area. For example, Patient Drug History reports of
14 18 of Dr. T.'s patients showed that almost all had a home address outside of Pacifica's normal
15 trade area and that nearly all of them traveled approximately 40 miles to see Dr. T. A comparison
16 of other pharmacies surrounding Pacifica showed very few prescriptions filled for patients outside
17 their normal trade area.

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

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

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

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

6 **FIRST CAUSE FOR DISCIPLINE**

7 **AS TO PACIFICA PHARMACY AND THANG Q. TRAN**

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

10 32. Respondents Pacifica Pharmacy and Thang Q. Tran are subject to discipline pursuant
11 to Code section 4301, subdivision (j), in conjunction with Health and Safety Code section
12 11153(a) for unprofessional conduct in that Respondents failed to comply with their
13 corresponding responsibility to ensure that controlled substances are dispensed for a legitimate
14 medical purpose when Respondents failed to evaluate the totality of the circumstances
15 (information from the patient, physician and other sources) to determine the prescription's
16 legitimate medical purpose in light of information showing that prescriptions for controlled
17 substances were filled early, there was duplication of therapy, the same drug combinations were
18 repeatedly prescribed for multiple patients by the same prescriber, numerous patients had
19 addresses outside of Pacifica's normal trade area, and certain prescribers wrote a disproportionate
20 number of prescriptions for Oxycontin, among other things, as more fully set forth in paragraphs
21 18-31 above, and incorporated by this reference as though set forth in full herein.

22 **SECOND CAUSE FOR DISCIPLINE**

23 **AS TO PACIFICA PHARMACY ONLY**

24 **(Failure to Maintain Current Inventory)**

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

1 782 dosage units of Oxycontin 80 mg and 93 dosage units of Oxycodone 80 mg for the period
2 March 25, 2008 to January 13, 2010.

3 **THIRD CAUSE FOR DISCIPLINE**

4 **AS TO PACIFICA PHARMACY ONLY**

5 **(Incomplete Labeling)**

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

11 **FOURTH CAUSE FOR DISCIPLINE**

12 **AS TO PACIFICA PHARMACY ONLY**

13 **(Expired Drugs)**

14 35. Respondent Pacifica Pharmacy is subject to discipline pursuant to Code section 4342,
15 which prohibits the sale of pharmaceutical drugs lacking quality and strength, in that on January
16 13, 2010, Respondent Pacifica Pharmacy maintained expired dangerous drugs and controlled
17 substances as part of its drug stock on its inventory shelves. Additionally, repackaged (pre-
18 counted or poured) drugs lacked appropriate labeling of name of drug, strength, dosage form,
19 manufacturer's name and lot number, expiration date, and quantity per repackaged unit.

20 **FIFTH CAUSE FOR DISCIPLINE**

21 **AS TO PACIFICA PHARMACY AND THANG Q. TRAN**

22 **(Excessive Furnishing of Controlled Substances)**

23 36. Respondents Pacifica Pharmacy and Thang Q. Tran are subject to discipline pursuant
24 to Code section 4301, subdivision (d), for unprofessional conduct in that Respondents clearly
25 excessively furnished controlled substances during the period March 25, 2008 to January 13,
26 2010, as more fully set forth in paragraphs 18-31 above, and incorporated by this reference as
27 though set forth in full herein.

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1 **SIXTH CAUSE FOR DISCIPLINE**

2 **AS TO THANG Q. TRAN**

3 **(Unprofessional Conduct – Gross Negligence)**

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

15 **SEVENTH CAUSE FOR DISCIPLINE**

16 **AS TO THANG Q. TRAN**

17 **(Unprofessional Conduct – Negligence)**

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

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1 **EIGHTH CAUSE FOR DISCIPLINE**

2 **AS TO THANG Q. TRAN**

3 **(Unprofessional Conduct)**

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

7 **PRAYER**

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

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

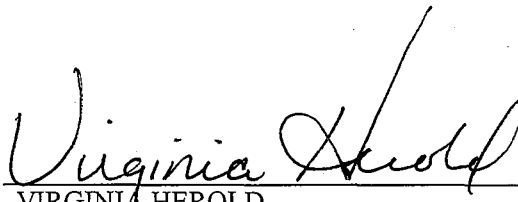
12 2. Revoking or suspending Original Pharmacist License Number RPH 41172, issued to
13 Thang Q. Tran;

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

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

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21 DATED: _____

1/3/12



22 VIRGINIA HEROLD
23 Executive Officer
24 Board of Pharmacy
25 Department of Consumer Affairs
26 State of California
27 Complainant

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