DATE: November 14, 2013

RE: Agenda Item V – Presentation on a Pharmacist’s Corresponding Responsibility Under California Law By Board Staff

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.