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

In the Matter of the Accusation Against:

MODERN DRUG, INC.
Pharmacy Permit No. PHY 53920;

and

QUOC CHAN LUONG,
Pharmacist License No. RPH 65421,

Respondents

Agency Case No. 6677

OAH No. 2020010490

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 at 5:00 p.m. on December 1, 2021.

It is so ORDERED on November 1, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Seung W. Oh, Pharm.D.
Board President

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PROPOSED DECISION

Adam L. Berg, Administrative Law Judge (ALJ), Office of Administrative Hearings, State of California, heard this matter on April 26 through 30, 2021. The hearing was conducted by telephone/videoconference due to the ongoing public health emergency.

Daniel J. Cross, Deputy Attorney General, Department of Justice, State of California, represented complainant, Anne Sodergren, Executive Officer, Board of Pharmacy (board), Department of Consumer Affairs, State of California.

Armand Markarian, Attorney at Law, represented respondents Modern Drug, Inc. and Quon Chan Luong (collectively "respondents").

Oral and documentary evidence was received, and the record was held open for the parties to submit written closing arguments. After several extensions were granted, the parties' closing arguments were received, and the matter submitted for decision on August 27, 2021.

FACTUAL FINDINGS

Background

1. On April 25, 2011, the board issued Pharmacist License No. RPH 65421 to respondent Quoc Chan Luong.[1] The license will expire on February 28, 2023, unless renewed.

2. On February 17, 2016, the board issued Pharmacy Permit No. PHY 53920 to respondent Modern Drug, Inc., doing business as Modern Drug, located in Garden Grove, California. The permit expired on February 1, 2021, and has not been renewed. Since the permit was issued, respondent has been the pharmacist-in-charge. He is also the corporate secretary and 25 percent owner of Modern Drug, Inc.

[1] All future references to "respondent" are to Quoc Chan Luong.

3. There is no history of discipline imposed against the permit or license.

4. On August 1, 2019, complainant signed the accusation alleging eight causes for discipline against both Modern Drug and respondent for: 1) failing to ensure the legitimacy of controlled substance prescriptions; 2) the clearly excessive furnishing of controlled substances;[2] 3) dispensing prescriptions with errors or irregularities; 4) dispensing non-complying controlled substance prescriptions; and 5) unprofessional conduct. The accusation alleges additional causes for discipline against respondent for: 6) gross negligence; 7) failing to exercise best professional judgment and corresponding responsibility; and 8) allowing unlicensed clerks to perform licensed tasks. Complainant seeks to revoke Modern Drug's permit and respondent's license; to prohibit respondent from serving in a managerial capacity; and to recover investigation and enforcement costs.

5. Respondents timely filed a notice of defense; this hearing followed.

Testimony and Report by Inspector Connie Tang

6. Connie Tang is a board inspector who testified at hearing and prepared an inspection report dated November 1, 2018, and an investigation report dated November 21, 2018. Tang obtained a Bachelor of Science in Pharmacology from the University of California (UC) Santa Barbara in 2006 and a Doctor of Pharmacy from the University of Southern California (USC) in 2010. She worked at a national-chain retail pharmacy for six years, until she was hired by the board as an inspector in 2016.

[2] At the conclusion of hearing, complainant withdrew the second cause for discipline, the clearly excessive furnishing of controlled substances. Evidence received on this issue is not discussed in this decision.

During her initial training with the board, she completed national certified investigator and inspector basic training and gained experience with different teams before joining the Prescription Drug Abuse team. In that capacity, she is responsible for investigations related to diversion of controlled substances and pharmacist corresponding responsibility. She has conducted over 160 inspections of licensed locations to date. However, at the time of the inspection in this case, she had only conducted approximately 60 to 70 inspections, only three or four of which related to "corresponding responsibility."

7. Tang discussed in general the legal responsibility of pharmacists in combatting prescription drug abuse. Health and Safety Code section 11153 requires that a prescription for a controlled substance shall only be issued for a legitimate medical purpose; while the responsibility for the proper prescribing and dispensing of controlled substances rests on the prescriber, a corresponding responsibility rests with the pharmacist filling the prescriptions. On August 9, 2013, the board made precedential the decision in *In re Pacifica Pharmacy; Thang Tran* (2013) Precedential Decision No. 2013-01 (*Pacifica*). The *Pacifica* decision identified a series of "red flags" surrounding prescriptions for controlled substances and held that a pharmacist must make reasonable inquiries when he or she believes that a prescription is not written for a legitimate medical purpose. Furthermore, a pharmacist must not fill a prescription when the results of a reasonable inquiry do not overcome the pharmacist's concern. In the Spring of 2014, the board published in its newsletter, the "Script," a summary of the *Pacifica* decision and the red flags that should place a pharmacist on notice that there is a potential problem with the prescription so as to require further inquiry. In addition, the Drug Enforcement Administration (DEA) provides information on its website addressing frequently abused drugs.

8. There are four controlled substances at issue in this case. Oxycodone (brand name Roxycodone) is an opioid prescribed for pain and is a Schedule II controlled substance. (Health & Saf., Code, § 11055, subd. (b)(1)(M).) Promethazine with codeine (brand name Phenergan with codeine), is a cough syrup containing an antihistamine and opioid and is a Schedule V controlled substance. (*Id.* at § 11058, subd. (c)(1).) Alprazolam (brand name Xanax) is a benzodiazepine prescribed for anxiety and is a Schedule IV controlled substance. (*Id.* at § 11057, subd. (d)(1).) Carisoprodol (brand name Soma) is a muscle relaxant, and while not scheduled in California, is a Schedule IV controlled substance pursuant to 21 Code of Federal Regulations section 1308.14(c)(6). All of the above are dangerous drugs within the meaning of Business and Professions Code section 4022. The "holy trinity" of drugs refers to a combination of muscle relaxants, benzodiazepines and opioids that has a very high abuse potential. All of the above are common drugs of abuse and are frequently found on the black market.

9. The board initiated an investigation into Modern Drug's dispensing practices of controlled substances based on a review of the Controlled Substance Utilization Review and Evaluation System (CURES). At the time relevant to these proceedings, Health and Safety Code section 11165, subdivision (d), required all pharmacies in California to report to CURES all filled prescriptions for Schedule II through IV controlled substances within seven days of being dispensed. Certain information contained in the CURES database is accessible to pharmacists and includes information about the drug dispensed, drug quantity and strength, patient name and address, prescriber name, and prescriber authorization numbers. Based on a review of CURES reports for Modern Drug, the board determined a need to further review the pharmacy's dispensing practices of controlled substances prescribed by Dr. B. Previous board inspections identified controlled substance prescriptions purportedly issued by

Dr. B. that did not conform to the requirements of Health and Safety Code section 11162.1, which requires certain security features for controlled substance prescriptions.

10. Tang conducted an inspection of Modern Drug on August 1, 2018. Respondent and two pharmacy clerks were present. During the inspection, Tang observed pre-filled vials of what respondent told her were fast-moving medications. A logbook contained the initials of an unlicensed clerk who filled the vials. Respondent confirmed that the vials had been filled by an unlicensed clerk. The counting of medications must be performed by either a pharmacist or licensed pharmacy technician.

11. Tang collected approximately 40 original prescriptions for controlled substances written by Dr. B., along with computer notes maintained by Modern Drug regarding these prescriptions. Respondent reported that Modern Drug was an independent pharmacy processing an average of 20 to 30 prescriptions per day. The pharmacy was located in a medical office building containing a doctor's office, chiropractic office, and laboratory. Tang interviewed respondent regarding the procedures he used for satisfying his corresponding responsibility to verify the medical legitimacy of controlled substance prescriptions. Respondent referenced utilizing a "Cash Price Code Flowchart," which was posted in the pharmacy. The steps in the flowchart, which was received as evidence, were to verify CURES, scan the patient's driver's license, not accept postal boxes, verify "ICD-10" diagnosis codes for all new clinics, and ensure the patient either pick up the prescription, or designate a person, who must also have photo identification. Respondent also told Tang that he reviewed CURES reports and documented information in the patient profile within the pharmacy's computer system. When asked about any policies for dispensing controlled substances for out-of-area doctors and patients, respondent said during the

first year of business, he considered 50 to 60 miles (or one hour in traffic) to be out-of-area. In the summer of 2017, once he became more familiar with the area, he reduced this to a 30-mile radius. Respondent provided what he believed to be the appropriate starting dosages for oxycodone (15 mg 2 to 3 times daily) and alprazolam (0.5 mg 1 to 2 times daily). When asked what steps he took to determine if a patient was naïve as to a certain medication (i.e., had not previously been on the medication in order to build tolerance justifying a higher dose), respondent said that in the case of opiates, he called the prescriber's office to verify and documented the patient's diagnosis code.

Tang questioned respondent about Dr. B. Respondent said he may have initially talked to Dr. B. once or twice on the phone, but the communication was typically with his nurses. Respondent said he stopped filling Dr. B.'s prescriptions once he became more familiar with the area and determined Dr. B.'s office was too far away. All of Dr. B.'s prescriptions were picked up by the patient. Respondent obtained diagnosis codes either from phone or fax.

Respondent provided Tang a computer note maintained under Dr. B.'s profile stating, "DO NOT FILL ANYMORE CONTROL SCRIPTS FROM THIS DOCTOR. REPORTED STOLEN SCRIPTS 08/05/2017 11:42:35 AM." According to Modern Drug's dispensing records, the last prescription dispensed under Dr. B.'s authority was on August 3, 2017.

12. Following the inspection, respondent provided Tang with Modern Drug's dispensing report from February 17, 2016, to August 1, 2018.[3] Tang extracted the following information from the report:

[3] The first prescriptions in the report were not filled until May 2, 2016.

- During this period, Modern Drug filled a total of 5,390 prescriptions, which Tang calculated was an average of eight prescriptions per day (excluding weekends and holidays).

- The three most frequent prescribers accounted for 44 percent of all prescriptions filled, and all three were located within a 5.5-mile radius.

- Approximately 79 percent of the prescriptions filled showed insurance or a coupon card, where the remainder were cash purchases.

- Of the 15 most commonly dispensed medications, seven were controlled substances. The top two prescribed medications were for oxycodone 30 mg (276 prescriptions or 5.12 percent) and promethazine/codeine (131 prescriptions or 2.43 percent). The three most frequent prescribers for Modern Drug had not prescribed any oxycodone 30 mg and accounted for only six promethazine/codeine prescriptions.

13. Tang researched Dr. B.'s online information produced by the Medical Board of California (Medical Board), which showed he was licensed in 1979 and self-identified his area of practice as family medicine and geriatric medicine secondarily. A postal box in Los Angeles was listed as the address of record. The address contained on Dr. B.'s prescriptions listed an address in Los Angeles that Google Maps calculated to be 30 miles from Modern Drug. When Tang attempted to contact the phone number listed on the prescription, an automated message from "Verizon Wireless" said the customer was not available. Tang believed that the 30-mile distance from the prescriber to the pharmacy was an irregularity because of the high density of pharmacies in the Los Angeles/Orange County metropolitan area.

14. Dr. B. wrote prescriptions for 15 patients that were dispensed by Modern Drug. Tang noted the following about the prescriptions dispensed under Dr. B.'s prescribing authority:

- Dr. B. was the fourth most frequent prescriber at Modern Drug and the top prescriber for oxycodone 30 mg. Modern Drug dispensed a total of 11,360 tablets for 15 patients. Each of the 82 scripts written by Dr. B. contained a prescription for oxycodone 30 mg. Oxycodone is available in strengths of 5, 10, 15, 20, and 30 mg tablets. Dr. B. only wrote prescriptions for 30 mg. Tang noted that prescribers typically attempt to treat patients with the lowest dose of medication. She believed it was an irregularity for Dr. B. to only prescribe the highest dose.

- Approximately 19 percent of Dr. B.'s prescriptions were written for promethazine/codeine. Modern Drug dispensed 8,400 mL (approximately 17 to 18 pints) of promethazine/codeine to 13 of the 15 patients.

- Approximately 55 percent of Dr. B.'s prescriptions were cash payments, with no insurance or prescription benefit card. In addition to being a red flag identified in *Pacifica,* Tang viewed this as irregular because 79 percent of the total prescriptions filled by Modern Drug were through insurance or prescription benefit card.

- Tang believed it irregular that a family doctor would not have a more varied prescription profile. Dr. B. prescribed only six drugs: oxycodone 30 mg, promethazine/codeine syrup, carisoprodol 350 mg, Doc-Q-Lace (a stool softener used to counteract constipation following opiate use), alprazolam 2 mg, and (on just one occasion) ibuprofen 800 mg. There

were no prescriptions for common conditions such as hypertension, diabetes, or high cholesterol.

15. Tang collected the original 82 prescriptions issued under Dr. B.'s prescribing authority for 15 patients. All the prescriptions lacked the following security features required under the 2011 version of Health and Safety Code section 11162.1: a watermark on the back stating "California Security Prescription" (the forms instead contained a watermark on the front stating "DocuGard"); an identifying number assigned to a DOJ-approved security printer; a lot number; and check boxes for the number of refills (the forms instead listed refill numbers to be circled). Of the 82 prescriptions, there were 154 prescriptions for controlled substances. In addition to it being illegal to dispense a controlled substance from a non-complying prescription, Tang believed that this also constituted a red flag under *Pacifica* as an irregularity on the face of the prescription itself. Tang testified that when a pharmacist encounters a prescription lacking required security features, a pharmacist should contact the provider; it is insufficient to merely speak to the provider's staff.

16. In the case of all but one patient, Modern Drug maintained one or more "Justification for Prescribed Medication (Controlled Substances)" forms (Justification Form), purporting to be from Dr. B.'s office. The forms were scanned into each patients' profile in the pharmacy's computer system. Tang reviewed these forms, which she concluded contained some irregularities. The form indicated "Pain Management" under Dr. B.'s name, though there was no reference to pain management as one of Dr. B.'s specialties on the Medical Board website. The fax header for each page showed it was faxed by "[Dr. G.]." The forms were faxed from two different numbers, one matching the fax number listed on Dr. B.'s prescriptions, and the other with a different area code. Tang was familiar with Dr. G., who was a physician associated with other

investigations by the board for illegitimate controlled substance prescribing. In those cases, Dr. G. used the same Justification Forms. The Justification Form contained a pre-printed list of controlled substances and dosages. Tang noted that many of the drugs/strengths had been removed from the market, there were multiple spelling errors of drug names, and there were errors in dosages available. Thus, rather than serving to justify a prescription, Tang believed these forms only created additional red flags that undermined the legitimacy of the prescriptions.

17. Tang located three chain pharmacies and one independent pharmacy located within a 1.2-mile radius of Modern Drug. Tang reviewed CURES reports for each of these pharmacies for the same time frame she reviewed for Modern Drug. Tang did not find a single reported controlled substance dispensed by Dr. B. for any of these four pharmacies.

18. Tang reviewed the prescriptions and other documents maintained by Modern Drug for each of the 15 patients who received controlled substances prescribed by Dr. B. The dispensing report shows that the first prescription Modern Drug dispensed for a Dr. B. prescription was for patient B.L., on December 14, 2016, for 150 tablets of oxycodone 30 mg and Doc-Q-Lace. This prescription contained a handwritten notation stating, "Olivia verified." There was also a note in the patient's profile that CURES was reviewed and the last fill was on November 17, 2016. Tang verified that this was indeed the last fill for the patient.

This patient later received prescriptions for oxycodone and Soma, and oxycodone and promethazine/codeine. Tang believed that the use of oxycodone with promethazine/codeine syrup was "duplicative therapy" and unusual, since both medications have opioids which could suppress a cough. She explained that a 30 mg dose of oxycodone is approximately equal to a 300 mg dose of codeine. A dose of

promethazine/codeine contains 10 mg of codeine. Tang believed that this drug combination constituted an irregularity and is a red flag under *Pacifica*, especially since both drugs are frequently abused. For this patient, respondent dispensed three prescriptions with the oxycodone and promethazine combination from February through April 2017. A note in the patient's profile stated that diagnosis codes for muscle spasm and spinal pain were verified with "Jessica" on January 23, 2017. Respondent dispensed prescriptions for this patient though July 18, 2017.

19. A.C.J. was the next patient to receive medication from Modern Drug with a Dr. B. prescription. On December 19, 2016, Modern Drug dispensed 150 tablets of oxycodone 30 mg and a 240 ml bottle of promethazine/codeine. In the computer profile, it was noted that the last fill of oxycodone 30 mg was on September 27, 2016. Tang verified this information and found the patient had received 150 tablets on this date prescribed by Dr. G. Although Tang noted that the patient did appear to have familiarity with oxycodone, it had been approximately three months before he received his last fill. Tang noted there was no evidence respondent contacted Dr. G. or the last pharmacy the patient had received oxycodone from. On cross-examination, Tang admitted the standard of care does not require a pharmacist to call a patient's previous provider, nor is there any legal requirement to do so. However, she herself has contacted previous providers in an attempt to resolve a questionable prescription.

A note in the patient's profile timestamped on January 26, 2017, stated that the patient lived 10 miles from Modern Drug. As discussed previously, Tang believed that in a metropolitan area, this distance was far because most people live within a couple miles of multiple pharmacies. There was a note timestamped on July 5, 2017, indicating diagnosis codes for spinal pain and sciatic nerve pain were "verified by Dr. B."

There was one Justification Form saved in the profile dated July 5, 2017. Although the prescription had been written for oxycodone and promethazine/codeine, the Justification Form listed oxycodone and Soma. Tang believed it was an irregularity for the medicines not to match. There was no documentation of any conversation between respondent and Dr. B.

A.C.J. received a total of five fills each of 150 tablets of oxycodone with the last fill on July 6, 2017, for 120 tablets.

20. A.C. was the next patient to receive medication from Modern Drug prescribed by Dr. B. On December 21, 2016, A.C. received 150 tablets of oxycodone 30 mg and Doc-Q-Lace. There were several notes documented in the patient's profile. On January 26, 2017, it was noted that the patient lived 6.6 miles from Modern Drug. On January 27 and June 20, 2017, it was noted that diagnosis codes for sciatic nerve lesion and anxiety disorder were "verified with doctor."

Tang noted there was no documentation regarding respondent accessing the patient's CURES report. Tang checked the report and found that the patient had no history of oxycodone prescriptions before those of December 21, 2016. This suggested to Tang that the patient was potentially opioid naïve, yet he was prescribed the highest available dose of 30 mg. Tang viewed this as irregular and a possibly erroneous dosage that could cause patient harm. She noted that in her interview with respondent, he indicated knowledge and awareness that 30 mg of oxycodone was not the starting dose. She noted there was no documentation by respondent recognizing this issue.

There were two Justification Forms saved in the patient's profile. On the January 27, 2017, form, which referred to the prescription written on January 21 for oxycodone

30 mg and alprazolam 2 mg, the "Drugs Tried and Failed" section was completely blank. Tang believed it was an irregularity for these dosages to be prescribed without a patient having a history of trying other medications first. Moreover, the information on the form would not reassure a reasonably prudent pharmacist that a prescription for oxycodone 30 mg was appropriate for a potentially opioid naïve patient. Similarly, the form completed on June 19, 2017, regarding a prescription for oxycodone 30 mg and Soma 350 mg did not list any previously tried drugs.

A.C. received four fills of 150 tablets of oxycodone 30 mg until March 22, 2017, and then fills of 120 tablets on May 2 and July 21, 2017.

21. From January 2 through 10, 2017, Modern Drug dispensed 150 tablets of oxycodone 30 mg (in addition to alprazolam, and/or Soma) to seven additional patients (R.H., I.J., S.H., P.R., V.P, C.S., D.W.). According to Modern Drug's dispensing report for all drugs, during this same time period, Modern Drug dispensed prescriptions for a total of 23 patients. Thus, the seven patients who received oxycodone 30 mg accounted for approximately 30 percent of Modern Drug's patients during that period.

22. A review of Modern Drug's dispensing reports shows that on approximately 28 occasions, respondent filled prescriptions for oxycodone 30 mg written by Dr. B. for two different patients on the same day. Examples include:

- On February 23, 2017, respondents processed prescriptions – minutes apart – for oxycodone 30 mg and Soma for A.C. and oxycodone and promethazine/codeine for A.C.J. Respondents processed prescriptions for only two other patients on that day.

- On March 22, 2017, respondents processed prescriptions for the same drugs for A.C. and A.C.J., again minutes apart. Respondents processed prescriptions for eight other patients that day.

- On May 15, 2017, respondents processed prescriptions for oxycodone 30 mg and Soma for A.C.J., oxycodone 30 mg and Soma for S.M., and oxycodone 30 mg and promethazine/codeine for T.H. Respondents processed prescriptions for only three other patients that day.

- On June 21, 2017, respondents processed prescriptions - within minutes of each other – for oxycodone 30 mg and "Phenegan w/ codein" for both A.C. and S.M. Respondents processed prescriptions for only two other patients that day.

23. In her report, Tang identified in detail each of the irregularities she found concerning each of the 15 patients. Based on her review, she found several consistent trends and irregularities, as follows:

- Approximately 55 percent of the prescriptions were purchased in cash, without insurance or prescription assistance.

- There were approximately 35 prescriptions for both oxycodone and promethazine/codeine, which Tang believed were unusual and constituted duplicative therapy. On cross-examination, Tang agreed that oxycodone is not FDA-approved for the treatment of cough, and there could be some circumstances where a patient on opioids could be legitimately prescribed codeine for a breakthrough cough. However, she still believed that it constituted a red flag such that the prescriber should

be contacted. Moreover, the frequency of the two drugs being prescribed in this case was an additional red flag.

- Based on notes made by respondent, he appeared to have reviewed the CURES profiles for each of the patients before dispensing the initial prescription. Although respondent did not save copies of the reports, Tang reviewed the CURES profiles for each of the patients. Six patients had no record of having received any oxycodone in the 12 months preceding the initial fill by Modern Drug, and thus, were potentially opioid naïve, yet were dispensed 150 tablets of the highest strength oxycodone. On cross-examination, Tang was unsure if during that time period a pharmacist could look at the previous 12-month history for a patient. However, she was sure that a pharmacist could access the previous 90-day history. She believed that a patient with no record of any opioid prescriptions in the preceding 90 days would be opioid naïve. However, she also agreed that during that time period, it was possible many pharmacies were not reporting to CURES as required, since pharmacies were not required to register until July 2016.

- Except for one patient, the Justification Forms all omitted a list of "tried and failed" medications, which Tang believed was irregular considering oxycodone 30 mg is not a starting dose.

- In most of the patient records, respondent noted the distance of the patient's address from Modern Drug. The closet patient lived 3.8 miles away. However, almost all the other patients lived greater than 10 miles away. In Tang's opinion, the trade area for respondent's pharmacy was 5 to 10 miles, with 10 miles being the outer limit. She based this on her

experience working in a retail pharmacy and conducting other investigations, where patients typically fill prescriptions at a more local pharmacy. However, Tang admitted that she did not know if any of the patients worked near Modern Drug.

- I.J., D.W., and L.W. shared the same address, which was approximately 14 miles away from Modern Drug. D.C. and S.H., also shared the same address, which was 17.8 miles away from Modern Drug. Tang believed that multiple patients sharing the same address was a factor that respondent could have recognized.

24. Tang noted that respondent maintained the controlled substance prescriptions in a plastic box. Because of the low volume of dispensing at Modern Drug, Tang believed it would have been reasonable for respondent to have gone through the box to compare prescriptions written by Dr. B. and thus ascertain many of the irregularities noted above.

25. Tang believed that simply calling the phone number listed on Dr. B.'s prescription might not be sufficient to verify the authenticity of a questioned prescription because the prescriptions themselves could be counterfeit, with a false medical office phone number. This is especially so when a prescription lacks multiple required security features. In such a situation, the pharmacist might have to do some research, including checking online, to determine if the number listed on the prescription is legitimate.

26. Ultimately, Tang did not believe that the prescriptions for the 15 patients were for a legitimate medical purpose. However, she was not able to offer an opinion

as to whether the prescriptions were provided by Dr. B. or were instead counterfeit using his credentials only.

27. On cross-examination, when asked how she formulated an opinion that none of the 15 patients were taking the oxycodone for a legitimate medical purpose, Tang said that in addition to the multiple red flags, respondent also received information in August 2017 that Dr. B.'s prescription pads were stolen, which he documented in his computer system. Tang attempted to contact Dr. B. by letter and by phone, with no response. Although the board predicated its investigation in this case on issues with Dr. B.'s prescriptions lacking security features, Tang was not aware of any other attempts by the board to contact Dr. B. about these features. In fact, there was no evidence at hearing that any follow-up was made with Dr. B. by either the board or the Medical Board.

28. Tang admitted that while the board does regularly send emails to pharmacies and pharmacists regarding discipline against prescribers, it does not provide notice when it learns of non-compliant prescriptions. Tang acknowledged from her experience working in a community pharmacy that it was often difficult for a pharmacist to personally speak to a doctor. It has also happened that a doctor would chastise the pharmacist about questioning his or her judgment and then hang up. Nevertheless, she believed that it is the professional responsibility of a pharmacist to consult with the prescriber to resolve any uncertainties, and if this does not occur, then the prescription should not be filled. A result of the increased focus in corresponding responsibility over recent years, is that doctors are beginning to understand this as well and are becoming more responsive. Tang also noted that there is often more research and investigation required with the patient's first prescription. Tang agreed

that respondent did document multiple steps he took in his verification of prescriptions; however, Tang believed there were still too many unanswered questions.

29. Tang testified as follows about a number of red flags identified in *Pacifica* that were not applicable in this case:

- There was no evidence that any of the patients presented with a nervous demeanor, attempted to obtain early refills, and came in large groups.

- There was no evidence to indicate any patient engaged in doctor and pharmacy shopping during the period the patient was filling controlled substance prescriptions at Modern Drug. According to the patients' CURES reports, no patient (with the exception of one nursing home patient) received controlled substances from a doctor other than Dr. B. or filled controlled substance prescriptions at any other pharmacy while getting prescriptions from Modern Drug. Tang admitted that doctor/pharmacy shopping is a significant red factor. However, she did not discuss the absence of it in her report because of the other red flags. Moreover, she believed that many of the patients did show patterns of doctor or pharmacy shopping before the first fill at Modern Drug.

- Regarding the red flag of youthful patients seeking chronic pain medications, Tang admitted she did not focus on the patients' ages because of the existence of so many other red flags. After going through the records on cross-examination, she agreed that most of the patients were in their 40s and 50s.

- Tang admitted that there was no easy method for respondent to have ascertained that two patients shared the same address. She did believe

that with the limited number of prescriptions, respondent could have gone through the box containing controlled substance prescriptions. However, this was not her practice when she was a retail pharmacist.

30. Tang admitted that respondent did take some steps to verify the legitimacy of the prescription and resolve certain red flags. She agreed it was not often that a pharmacist would note the distance of the patient's address from the pharmacy in the patient's profile. Respondent also made copies of the patients' driver licenses, which was not required by law. Respondent also checked CURES, which was not (and is still not) required. Tang agreed that asking questions directly to the patient about his or her diagnosis are things a reasonable pharmacist would do to ascertain that a prescription is for a legitimate medical purpose. She did not have any reason to dispute that respondent evaluated the patients in this matter. She agreed that for many of the patients, there was no evidence in the CURES reports that they had been doctor/pharmacy shopping in the 90 days before filling prescriptions at Modern Drug. While Tang agreed that respondent exercised greater diligence in attempting to comply with his corresponding responsibility duties than do many other pharmacists she investigated, his inquires raised additional irregularities that she believed needed to be resolved (e.g., Justification Forms with red flags).

31. Tang admitted that after respondent stopped filling prescriptions for the 15 patients, according to CURES, many of them continued to obtain oxycodone prescriptions from chain pharmacies prescribed by a Dr. C., in La Jolla. However, Tang did not believe this proved that the prescriptions were for legitimate medical conditions. She also noted her belief that Dr. C. had pending discipline with the Medical Board for excessive prescribing.

32. Tang has not accessed CURES as a pharmacist since she worked in a retail pharmacy in 2016. It was not until July 2016 that pharmacies were required to register with CURES, and many pharmacies during the time period at issue in this case did not report prescriptions as required. Information on fills could thus have been absent from a CURES report at that time. There is no law requiring a pharmacist to consult with CURES prior to dispensing a controlled substance; that is part of a pharmacist's professional judgment.

Respondent's Testimony

33. Respondent's testimony is summarized as follows: Respondent was exposed to pharmacies from a young age as his parents are pharmacists and own two pharmacies in Fresno, also named Modern Drug. While an undergraduate at the University of California, Irvine, respondent worked as a pharmacy clerk and technician. Respondent received his Doctor of Pharmacy degree from Temple University in 2010 and was licensed in California in 2011. After licensure, he joined the family business and became pharmacist in charge (PIC) of a Modern Drug pharmacy in Fresno. In 2016, he moved from Fresno to Garden Grove, where he opened another branch of Modern Drug, the one at issue in this proceeding. This latter pharmacy did not become operational until the summer of 2016, several months after the pharmacy received its permit. In 2020, he closed Modern Drug in Garden Grove and sold its file. The primary reason for its closure was the decrease in business due to COVID. Respondent returned to Fresno and is currently working as a staff pharmacist at one of the Fresno locations, alongside his parents and brother.

34. Respondent was responsible for launching the Garden Grove location. He initially focused on marketing, personally delivering medications within a five-mile radius, hosting brown-bag events, and consulting with patients in their homes in an

effort to establish a community network. He tried to network with local doctors and spent a lot of time performing community outreach and marketing. When the pharmacy opened, he spent a lot of time trying to build the business. All of his clerks and technicians would go door-to-door dropping off door-hangers and trying to engage customers. Thus, he spent much time on tasks other than dispensing prescriptions. Respondent was the only pharmacist, usually assisted by a technician or clerk.

35. Respondent first learned of Dr. B. when patient B.L. was referred to him by a former patient. B.L. lived in a home care facility and was bedridden. Respondent spoke to B.L. several times over the phone, but when she said she needed a pain-relieving mediation, respondent told her he needed to see her in person. His store policy was to meet the patient in person and verify identification for all patients. Eventually, she came to the pharmacy by medical transport, with oxygen, just to provide her identification. He learned that the patient had a terminal condition. She also brought in a lot of paperwork and medical records, which he reviewed.

36. Respondent consistently maintained a store policy of contacting the doctor if the prescription was for a controlled substance and to confirm a patient's stated reason for the medication. When he documented "verified" and placed a name in a patient's profile, that indicated the name of the person he spoke to at Dr. B.'s office. When he called the office, after verifying the patient's information, he asked the office to tell him the dose, frequency, quantity, and dates of the medication and whether the patient had taken the medication previously. He asked the staff open-ended questions to verify the information respondent had already received.

37. Respondent used a scale ranging from negative-three to positive-three to evaluate a patient seeking an opioid. Negative-three was most suspicious and zero

was neutral. He always regarded an initial patient as a negative-two. As he obtained more information about a patient, his suspicions would increase or decrease. In sum, he always regarded patients seeking a controlled substance as suspicious. From what he knows about the opioid crisis, he believes it is a pharmacist's responsibility to ensure these prescriptions are legitimate.

38. It was respondent's practice to tell patients that he would check CURES, so that he could gauge their reaction. He would then ask patients for their "story" to find out what was going on. He also required identification. Respondent would then tell the patient that he would be contacting their doctor to verify the story. He told them that if at any point things did not match up, he would not fill the prescription. Respondent wanted to be up-front with the patient regarding all the checks he would make. He also told patients that anytime his check of CURES reflected that a patient was pharmacy shopping (i.e., obtaining controlled substances from another pharmacy), respondent would not fill the prescription.

39. Respondent registered for CURES when he became licensed in 2011. He had a policy as early as 2014 to check CURES for all Schedule II prescriptions. He is a "firm believer" in CURES and its goal of reducing drug abuse. In the early stages of CURES, there were many glitches and information was unavailable. He believes at that time, he could only search back three or six months, and the system would not allow him to search the previous 12 months until 2018. He also noticed that CURES was not always accurate, because it often did not indicate a controlled substance had been dispensed when he knew this had in fact occurred. For example, respondent was prescribed a controlled substance when his wisdom teeth were removed, but this did not appear in his own CURES profile. Respondent did not save the CURES reports for patients at the time, because he did not believe it was required and it was sufficient for

him to document that he checked. Since Tang's inspection, he now checks CURES for all controlled substances (which was not required until recently). He also prints copies of the reports and saves them to a flash drive.

40. When respondent checked the CURES report for a patient, his main priority was to check for early fills or a history of early refills. He admitted he was not very concerned about a gap in prescribing history.

41. It was very difficult to get in touch with Dr. B. When asked what attempts he made to reach him, respondent said, "We called the clinic. We sent faxes out. Tell [*sic*] the nurses." Respondent became "more aggressive" with his approach when he attempted to taper down patients, i.e., reduce their dosage of oxycodone. He estimated he spoke to Dr. B., personally, five to a dozen times. He spoke to the office staff many more times. He never got the sense that the people he was talking to were not legitimate medical staff. Respondent explained that the Justification Forms were something the office provided when he began to start requesting medical records to verify a diagnosis. Initially, the pharmacy called for "verbals" and asked questions such as what the medication was for, the history of the patient taking the medication, and how long the doctor had been treating the patient. Although respondent was not precise on the time, sometime in Spring 2017, the pharmacy started to send "random" fax requests to Dr. B. requesting medical records with diagnosis codes. Although respondent always called the office to verify the prescription, he sometimes also faxed a request for medical records with a diagnosis code. In response, Dr. B.'s office faxed back to the pharmacy the Justification Form, which respondent scanned and saved in the patient's profile. Respondent testified several times that the pharmacy was evolving or refining its processes during this time period. Respondent was asked if he ever noticed any of the discrepancies between the medication listed on the

Justification Forms and the prescription, as noted by Tang in her investigation. Respondent could not recall for sure, but indicated his primary focus was on the oxycodone, which was always listed.

On cross-examination, respondent was asked about Tang's investigation report, in which she indicated that respondent told her he had talked to Dr. B. only one or two times. Respondent admitted that is what he told Tang at the time, but on further review of the documentation, it was more than that.

42. Respondent verified controlled substances with the doctor's office every single time he dispensed a Schedule II drug, even if it had been previously filled. He testified that he documented the initial verification in the patient's profile. However, he would only document subsequent verification if there were no changes. He also testified that he checked CURES every time patients presented a controlled substance prescription to ensure they were not doctor or pharmacy shopping, but did not always document this in the absence of notable findings.

43. Dr. B.'s prescriptions listed "pain management" under his name. When asked if he took any steps to verify this, respondent said he spoke to the patients and asked them where the clinic was. Some patients said Dr. B. was considering expanding into Orange County. Respondent was not concerned by the fact that Dr. B.'s office was 30 miles away, because that distance was less than an hour's drive from the pharmacy. At the time, he did not focus so much on the distance of the prescriber as he did on the distance of the patient. Respondent did not have a specific distance that would trigger a red flag in his mind, because people often had to travel substantial distances to find a specialist. He believed an hour's drive would be too far.

44. Respondent was not concerned that some of the patients lived as far as 17 or 18 miles away because he did not think it was a long distance to drive. During questioning by the ALJ, respondent was asked why, in an area such as urban Orange County, where there is likely a pharmacy within any one-mile radius, a patient would choose to go to *his* pharmacy, many more miles away. Respondent explained there is a shortage of controlled substance inventory, and often times a pharmacy near a patient's home would not have the drug in stock. In addition, pharmacies deal with controlled substances in different ways, and many are reluctant to fill them, forcing people to travel farther away. When asked if this was something patients actually told him, he said he would ask what happened to their other pharmacy and why they were filling the prescriptions at Modern Drug. Patients told them their pharmacy was out of stock or they would have to wait another week or two. When asked if he thought it strange or unusual that many patients suddenly started coming to Modern Drug from outside his geographic area, respondent replied that it was "definitely something I looked at" and a reason to "start out suspicious." In hindsight, he would have been more rigorous and done things differently. However, he did recognize the distance as an issue, which is why he looked up and documented the distance in the patient's profile.

45. When asked what he did to verify prescriptions were legitimate, respondent said he talked to the patients, "got to know them as much as he could," verified the stories from the doctor's side, and looked for red flags related to the patient's demeanor. One of respondent's top priorities was to figure out whether the patient was a doctor or pharmacy shopper. He told patients that if he found them switching pharmacies after he began filling prescriptions, "you're done."

46. Respondent admitted he did not document every encounter or conversation with a patient. Questions he would ask but not document were open-ended questions used to ascertain a patient's history. He also admitted that he did not appreciate that all the prescriptions lacked certain security features. He said he was "mixed-up" about some of these features. For instance, he would rub the back of the prescription with a coin to verify the heat-sensitive ink would change color. This is what he believed the "DocuGard" related to. Respondent also believed that there were industry-wide issues with prescription documents lacking the latest security features and believed the board had yet to decide how it would deal with the problem. As evidence of this, respondent submitted an email from the board to licensees on November 28, 2017. The email stated:

> In recent years, the board has continued to identify noncompliant California Security Forms in use that have been filled by California pharmacies . . . The board's response upon identification of noncompliant forms having been used to dispense controlled drugs is to educate the licensee, and to cite and fine the pharmacy/pharmacists involved. Typically the licensing board for the prescriber is advised as well.

The email then stated that some pharmacies had begun to refuse to fill prescriptions written on noncompliant forms because of missing checkboxes for number of refills and missing watermarks. The board stated it had received complaints from patients and prescribers who had been denied medication because of noncompliant forms. The board then provided "interim solutions" including that: prescribers and dispensers should become familiar with the required features; prescribers with noncompliant

forms should reorder compliant forms; and prescribers should consider using e-scripts. Finally, the board noted that controlled substances, with the exception of Schedule II, might be filled if the pharmacist treated it as an oral prescription and verified orally with the prescriber. However, when there was no alternative except to prescribe a Schedule II medication using a noncompliant form to allow patients to receive their pain medication timely, prescribers and dispensers should communicate about why a noncompliant California Security Form was being used on a temporary basis.

47. Respondent observed the demeanor of all the patients who received prescriptions from Dr. B. They were all age-appropriate, did not come in groups, and did not act abnormally. He observed nothing out of the ordinary that would have caused him any concern. He never had a concern that the prescriptions would be diverted to the streets or were not for a legitimate purpose.

48. Respondent disagreed that codeine and oxycodone constituted duplicative therapy, because the two medications work on different receptors. He thus did not think a combination of the two drugs was unusual. Respondent also disagreed that a patient who had been off an opioid for three months would be opioid naïve. He believed so long as a patient had been on an opioid, a three-month lapse would not constitute naïveté. There is no maximum dosage of oxycodone, which is dependent on a patient's tolerance. Doses of oxycodone of 20 mg and 30 mg are the most commonly prescribed. He was not concerned by multiple patients receiving 30 mg doses because the prescriptions came from pain management specialists, who treated patients with chronic pain, who were responsible for monitoring their patients, and who typically prescribed such relatively high doses of these medications. By way of contrast, respondent would be concerned if a prescription was instead from an urgent care provider.

49. Respondent testified in detail about most of the patients at issue in this case. For many patients, he testified about certain medical conditions they had. For example, S.H. claimed she had been in a car accident. Respondent did not believe her at first and made her produce supporting evidence. She brought in paperwork such as her insurance claim. Respondent verified the prescription with the doctor. Respondent testified about other injuries various patients reported and his memories of conversations with them. He did not believe any of their stories were concocted, and he required them to bring in supporting documentation. Nor did respondent think it unusual that almost all the patients received promethazine/codeine in addition to oxycodone. Respondent explained that the quantity dispensed, eight ounces, was not large when dispensed every couple of months. When pressed as to why he did not think it unusual, respondent explained that he looked at the dosage, which was low, and because Dr. B. was also in family medicine, these prescriptions would be within his practice area. Moreover, codeine is one of the "go-to" treatments for a cough. When it was noted that multiple patients had multiple refills of promethazine/codeine, which is not a maintenance drug, respondent said the two-to-three-month time interval between refills made it less suspicious, even for a patient already on high doses of opioids.

50. Respondent was questioned about the note he entered in his system that he would no longer fill Dr. B.'s prescriptions because his pad was stolen. The note was placed in Dr. B.'s profile, so that any prescriptions entered under his name would show the note. When asked why he made the note and whether he recalled the conversation that prompted it, respondent said he spoke to the "clinic" (Dr. B.'s office), whose staff told him they had reported stolen prescription pads and he should discard any future fills. That is all they said, and it was all respondent needed to hear. Respondent was surprised at the call and had not previously suspected any issues with regard to Dr. B.'s

prescriptions. When asked if he had reviewed any of the prescriptions he filled for Dr. B. after receiving this information, respondent's response was not entirely clear. He stated that he did review previous prescriptions, and, based on the knowledge of the stolen prescriptions, recognized "certain patterns." When it was noted that he had filled a prescription by Dr. B. two days before, he said he did look to see if there was anything of concern, but he "suspected a lot more," after learning of the stolen pads. Learning the pads were stolen did cause him concern, which he described as an "OS moment." When asked if he ran any dispensing reports for Dr. B.'s prescriptions, respondent said, "Most likely." Respondent said he did question the validity of some of the recent prescriptions based on the information that pads were stolen. The ALJ questioned respondent about why he would have been concerned that he had issued a prescription from a stolen pad, if in fact he had been calling Dr. B.'s office and verifying every prescription. Respondent's answers were not entirely clear, except that it caused him to "re-think various possibilities."

51. Since Tang's inspection, respondent has made many changes regarding how he deals with controlled substances. One area was to implement the Centers for Disease Control and Prevention (CDC) guidelines regarding treatment of chronic pain management.[4] Consistent with those guidelines, respondent now calculates patients' morphine milligram equivalents (MME), and if the patient is above 90 MME, he requests that the doctor begin tapering the patient and trying alternative therapies. These guidelines came out in late 2016, and in March or April 2017, respondent engaged with his patients and the prescribers about tapering. Respondent submitted a

[4] Respondent produced a copy of the CDC Guidelines for Prescribing Opioids for Chronic Pain, issued in March 2016.

sample letter he sends to a prescriber stating that the patient is currently taking more than 90 MME of opioids, and it will be the last pharmacy fill unless the patient reduces dosages by at least 10 percent before the next fill. This letter also refers the prescriber to the CDC guidelines.

Respondent was questioned about the MME for the patients in this case, who were all directed to take oxycodone 30 mg every four to six hours, or four to six times per day. Thus, if taken as directed, their MME would range from 180 to 270, significantly higher than set forth in the CDC guidelines. Respondent initially stated the CDC guidelines did not come out until several months later, although this conflicted with the evidence that they came out in 2016, a year before. At the time, respondent did not believe these dosages were a cause of concern for a patient with chronic pain. Based on his conversations with the patient and doctor, respondent believed these patients had been on opioids previously. When asked if he had an explanation for why many of the patients had been off an opioid during the 90-day period before being dispensed by respondent, he said some of the patients also tried alternative therapies such as massages and chiropractors. He also noted a patient on a high level of drug could have tapered down, thus extending the life of an old prescription.

Respondent testified that after April 2017, he began sending "tapering notices" indicating his intent to reduce the quantity of opioids. Respondent had previously testified that he spoke to Dr. B. personally several times. These calls occurred in part because Dr. B. wanted to "chew us out for questioning why we were issuing these tapering notices." Respondent said the conversations were argumentative because he told Dr. B. he could "take it or leave it," meaning he would not fill the prescription unless it was tapered. He told Dr. B. if the dosages were not tapered in the next couple of months, he would not fill the prescriptions. Dr. B. was not happy and asserted

respondent had no right to question a doctor. Nevertheless, Dr. B. did begin to taper the prescriptions for some patients. Modern Drug's dispensing report showed that in the Summer of 2017, oxycodone 30 mg was reduced from 150 tablets to 120 tablets and the refill interval extended from one to two months.

52. Beginning in late 2017, respondent also implemented a policy of requiring electronic prescriptions (e-scripts) for chronic pain patients receiving greater than 90 MME. He created a timeline by which physicians needed to comply. If they did not meet the timeline, the pharmacy would not process the prescription. Respondent reasoned that doctors who are in the field of pain management should have e-scripts by now. E-scripts also reduce the concern about non-compliant prescription forms.

53. After the inspection, respondent also began providing patients with information about Narcan, a narcotic antagonist. Respondent submitted as evidence flowsheets he uses listing the mandatory checks the pharmacy performs based on whether the patient is higher or lower than 90 MME. Such checks include verifying security features (or requiring e-scripts for greater than 90 MME), checking CURES, obtaining a diagnosis code, obtaining photo ID, and creating a tapering plan for prescriptions greater than 90 MME. Respondent testified about the process he now uses when obtaining a controlled substance prescription. He talks with the patient, discusses the process, tells the patient it might take several days to fill and informs the patient he will verify in CURES. However, respondent has essentially stopped accepting chronic pain patients since the accusation was filed. He said he will not get involved with chronic pain prescriptions greater than 60 MME. He will still handle acute pain management, such as a short-term prescription from a dentist, but he does not want the stress of having to question every decision as he has had to do with this case.

54. In conclusion, respondent stated he is a safe pharmacist, who is in touch with his patients and understands the need to evolve and stay ahead of the opioid crisis. He is committed to doing what is right and developing new processes. He has been going through the pharmacy's data more frequently trying to ascertain any new patterns. As an example, he submitted a bar graph he prepared showing dispensing trends for controlled substances through 2019. Respondent submitted copies of various prescriptions he refused to fill because of irregularities, including lack of the required "California Security Feature" watermark. In that latter instance, respondent called the physician, who was defensive and questioned why respondent was calling him. Respondent now denies more Schedule II prescriptions than he fills. The biggest reason for denying a prescription is because he is not able to reach the prescriber. For promethazine/codeine, respondent will refuse to fill a prescription for large quantities by telling patients he is out of stock, so that they will not argue with him.

55. At the conclusion of the hearing, there was some confusion about the significance of the dates contained in Modern Drug's dispensing reports reviewed by Tang. Respondent clarified the process for dispensing a controlled substance prescription. First, a patient would drop-off the prescription. The pharmacy would not enter the prescription into the system until certain checks were performed, such as CURES and verification by the prescriber. This could be the same day, but often, as was the case with Dr. B., it could be several days later before the prescription was verified. Once the verification occurred, respondent or an employee would enter the information into the system, at which time a prescription number and label were generated. The time and date when this occurred was what was listed in the dispensing report, on the prescription label itself, and what is submitted to CURES. Respondent verified that all the prescriptions listed in the dispensing report were

picked-up by patients, because he filtered out of the dispensing report prescriptions that were filled, but returned to stock because they went unclaimed.

RESPONDENT'S EXPERT WITNESS JEB SYDEJKO

56. Jeb Sydejko testified at hearing and prepared an expert report. Relevant portions of his testimony and report are summarized as follows: Sydejko obtained his Doctor of Pharmacy from USC in 1985 and then a law degree from Whittier Law School in 1993. He has been a licensed pharmacist in California for over 35 years and has been licensed to practice law since 1995. From 1985 to 2012, Sydejko worked as a dispensing pharmacist at various retail operations. He has dispensed over one million prescriptions and consulted with thousands of patients. In 2012, Sydejko formed a consulting service for pharmacists and drug wholesalers regarding regulatory matters related to the practice of pharmacy. He has consulted for over 600 pharmacists, published a pharmacy practice handbook, performed hundreds of mock inspections, worked as an expert reviewer for the board, testified twice as a board expert witness (on corresponding responsibility), and served as a probation practice monitor on four cases.

57. Sydejko testified about the evolution of the corresponding responsibility obligation after *Pacifica*, prior to which corresponding responsibility was a term rarely used in pharmacy and almost never discussed in board publications. Post-*Pacifica*, the board has taken a more active role in educating pharmacist as to how pharmacists can incorporate the criteria of corresponding responsibility into their every-day practice. Two to three times per year, the board publishes the "Script," an on-line newsletter highlighting various aspects of pharmacy law. Sydejko outlined the references to *Pacifica* in the Script and other board publications, beginning in the Spring of 2014. In the winter of 2015, the board introduced a brochure that explains what corresponding

responsibility means and lists red flags that may alert a pharmacist that a prescription may not be for legitimate purposes. The board also posted a video on its website. Thereafter, no issue of the Script discussed corresponding responsibility until March 2018, when the board again discussed corresponding responsibility in connection with eight disciplinary decisions the board had issued. Subsequently, the board has taken a much more active role in educating pharmacists about their corresponding responsibility obligations. However, during the period relevant to this case, Sydejko believed that the concept of corresponding responsibly was still very rarely discussed.

58. Sydejko believes the concept of corresponding responsibility has been difficult for pharmacists to employ because it essentially involves two standards: first, pharmacist's professional judgment, and second, the pharmacist's documentation of his or her efforts to resolve red flags. Sydejko noted that traditionally, pharmacists are not note-takers. There is typically little room in a pharmacy's computer system to document notes, and pharmacists might also jot a short note on the back of the prescription. There is no uniform standard as to how, or how much, notetaking is required to satisfy corresponding responsibility. Thus, one of the things Sydejko highlights to his clients is the importance of documentation, especially concerning conversations with patients. On cross-examination, Sydejko clarified that there is one standard of care relating to professional responsibility, but the standard for what is required to be documented is what is evolving.

Sydejko noted that PICs are required by regulation to complete a regular self-assessment of the pharmacy's compliance with state and federal law. There is a section in the assessment dealing with corresponding responsibility, but there is no substantive detail regarding red flags or what a PIC should be doing to monitor compliance with this provision. He thinks the board should make more explicit its

expectations in this regard. In conclusion, while Sydejko believes that the board has recently done a great deal to educate pharmacists about their corresponding responsibility duties, at the time at issue in this case, the board provided very little information to educate pharmacists as to how to exercise their corresponding responsibility.

59. Post-*Pacifica*, pharmacists are required to play a different role than what has been traditionally required: they are now expected to question both the patient and the doctor with a level of skepticism that the patient might be a drug seeker. A consequence of this expanded role, and increasing board enforcement, is that many pharmacies have begun to refuse to fill certain controlled substances, turning away legitimate patients in need of medication.

60. Sydejko defined the standard of care as what a reasonable pharmacist would do based on his knowledge and experience in the same or similar circumstances. The standard changes as the general population of pharmacists become more educated about an issue. Thus, the standard has changed from before *Pacifica*, and has changed even more since the period covered in this case, due to increasing awareness and education by the board in this area.

61. Sydejko disagreed with Tang that promethazine/codeine and oxycodone are duplicative therapies. In his experience as a pharmacist, the term is used to refer to two drugs being prescribed for the same treatment. The term, as used in *Pacifica*, referred to OxyContin and another long-lasting opioid. In the matter at issue in this proceeding, codeine is not being prescribed to treat pain, but instead for its antitussive characteristics. Oxycodone can have antitussive qualities as well, but if a patient who is already taking it develops a cough, this demonstrates that the oxycodone is not suppressing the cough. It would then be appropriate, and more

effective, to treat the cough through another drug, and codeine is the gold standard. In rare cases, a cough is actually a side effect of oxycodone.

Sydejko was aware that almost all of the 15 patients in the present case had dual prescriptions for oxycodone and promethazine/codeine. As a pharmacist who is presented with this type of prescription regimen, the standard of care requires the pharmacist to interact with the patient to assess demeanor and question medical history and alternatives tried. The pharmacist can also call the prescriber to discuss concerns, but it is very rare to be able to speak to a physician immediately or even get a return call. The pharmacist must balance the inability to immediately get in touch with a doctor with the patient's need to obtain the medication. In short, a reasonable pharmacist might deal with encountering this situation differently. On it's face, the combination of the two drugs might be considered suspicious, but the suspicion can be resolved through inquiry with the patient.

62. In reviewing the material in this case, Sydejko noted multiple notes by respondent that he checked with the provider, obtained diagnosis codes, and reviewed CURES. Respondent made copies of patients' identification, which many pharmacies today still do not do. Of course, in hindsight, there are things that respondent could have done better. For example, documenting conversations with patients would have been helpful to show the inquires respondent made.

63. Sydejko agreed that the limited prescribing profile of Dr. B. was a concern that constituted a red flag. Respondent thus needed to take this concern into account in exercising his professional judgement whether to fill the prescription, which is based on the totality of circumstances. Sydejko acknowledged that Dr. B. only prescribed the highest dosages of oxycodone and alprazolam. He also agreed that dual prescriptions for oxycodone and promethazine/codeine would be a concern. But

it is the interaction between the pharmacist and patient that is critical in resolving these concerns. More importantly, the lack of documentation of this interaction back in 2016 and 2017 was not a deviation from the standard of care.

64. Sydejko did not believe a non-compliant prescription form constituted a red flag for purposes of corresponding responsibility. The red flag identified in *Pacifica* dealt with irregularities on the face of the prescription – incorrect information that would make the prescription unfillable. Sydejko noted that there had been issues with printers not providing check boxes for the number of refills, which caused a great deal of uncertainty with how to deal with irregularity. In this case, Sydejko did not believe the absence of the four security features was a red flag. He believed that if the board meant to include absence of security features as a red flag in *Pacifica*, it would have so stated. Moreover, many of the security features are on the back, not the "face," of the prescription.

65. A patient's prior dispensing history is a very important consideration for a pharmacist who is asked to fill a prescription for a controlled substance. A patient's prior history helps to inform the pharmacist as to not only the previous controlled substance prescriptions the patient has been prescribed, but also those medications that the patient is currently taking. The question the pharmacist must then consider is whether the prescription to be filled is consistent with what the patient had previously been prescribed and/or is currently taking. Sydejko believed Tang's report failed to identify the information that respondent took into consideration before filling the controlled substance prescriptions at issue in this case. Specifically, 11 of the 15 patients did have a previous history of receiving oxycodone 30 mg. This is an important piece of information because it shows the patient received the same dosage of the same drug in the past.

In assessing whether respondent exercised appropriate corresponding responsibility with respect to the patients at issue in this case, it is important to take into account many factors including the pharmacies that previously filled oxycodone 30 mg prescriptions, the number of times they were filled, the quantity of each prescription filled, and the number of days before the next fill date. More importantly, for many of the patients, respondent was decreasing the frequency and quantities of the oxycodone 30 mg dispensed. Some examples are as follows:

- A.C.J. received four prescriptions of 150 tablets from a chain pharmacy, and then four prescriptions of 150 tablets from an independent pharmacy. Modern Drug filled six prescriptions. After the first four prescriptions, the subsequent two prescriptions were filled two months (as opposed to 30 days) apart, with the final prescription for a quantity of 120 tablets, instead of 150.

- D.C. received four prescriptions from a pharmacy for quantity 150 and 120 before Modern Drug. Modern Drug filled four prescriptions of 150 tablets, but each were for a 60-day supply (based on subsequent fill date), with the final quantity 120.

- S.H. received four prescriptions for 150 tablets from a chain pharmacy. Modern Drug filled five prescriptions, but after the third encounter, the frequency was reduced to a 60-day supply, and the last two were for 120 tablets.

Sydejko similarly reviewed the prescribing history of oxycodone for an additional eight patients. Similar patterns existed such as the patient receiving multiple prescriptions for 150 tablets or more from various chain and independent pharmacies

before Modern Drug. At Modern Drug, the frequency of fills decreased, with the last fills also deceasing the quantity to 120 tablets. Sydejko noted that CURES does not flag disciplinary histories of pharmacies, which would place a pharmacist on notice that there might be issues with a previous pharmacy's dispensing. At the time he authored his report, he noted that three of the independent pharmacies who filled prescriptions for the above patients had pending disciplinary action by the board based on corresponding responsibility. Five of the chain pharmacies that had filled prescriptions had no discipline pending. Sydejko opined that the board disciplines independent pharmacies, but takes no action against chain pharmacies, who in this case dispensed the same amount or more of oxycodone than did Modern Drug. Finally, Sydejko noted that after Modern Drug stopped dispensing for these patients, nine of the patients continued to obtain multiple prescriptions of oxycodone from chain pharmacies, none of which have been subjected to disciplinary action by the board.

66. Sydejko was questioned about the fact that comparing the CURES reports of all the patients demonstrated a pattern that these patients all filled oxycodone prescriptions written by Dr. G., Dr. B., and Dr. C. (who is now the subject of an accusation). Thus, based on these CURES reports, dozens of pharmacies filled these prescriptions, each exercising their professional responsibility, with only a couple independent pharmacies subject to disciplinary action. Sydejko believes this information is relevant because it informs upon the standard of care – hundreds of pharmacists reviewed and dispensed the same prescriptions as did respondent.

67. One of the red flags discussed in the investigation report was the distance that Dr. B.'s patients travelled to Modern Drug. Tang identifies this red flag as the patient being outside the trade area of the pharmacy. Sydejko noted that many

pharmacies are reluctant to fill controlled substance prescriptions because of possible scrutiny from the board, the DEA, or the wholesaler. Many chain pharmacies deny patients the opportunity to fill their controlled substance prescriptions due to rules set forth by their corporate management. Sydejko believed that the trade area for a retail pharmacy such as Modern Drug is greater than an arbitrary five-mile radius. When questioned if he thought it unusual that a patient would travel more than 10 miles to a pharmacy in urban Orange County, Sydejko said one has to look at the whole picture. When he worked in an independent pharmacy, he had patients who indicated that chain pharmacies would not fill a controlled substance prescription. He believed that when patients have difficulty filling prescriptions, some doctors communicate to their patients the names of pharmacies that will fill them. Sydejko believed that respondent was in fact cognizant of patient distance and asked his patients about this. But distance is a flexible variable because there are many reasons why a person would go to a pharmacy more than 10 miles away from their residence.

68. Sydejko opined that respondent did not violate his corresponding responsibility with respect to the prescriptions from Dr. B. that respondent dispensed. Instead, respondent was proactive and inquired into the legitimacy of the controlled substances that are at issue in this case, especially compared to the issues in other disciplinary decisions such as *Pacifica*. Respondent and Modern Drug took additional precautions, many of which are not legally required, including:

- Modern Drug had in place specific guidelines when receiving a controlled substance prescription, such as using CURES data.

- Modern Drug required its patient to produce a valid form of identification and then scanned into its computers.

- Modern Drug mandated getting a physical address from each of its patients and did not accept a PO Box address for patients.
- Modern Drug verified the ICD-10 diagnosis codes.
- Modern Drug required patients to sign a consent when the patient designated a person to pick up the medication and the respondents required that the designated person have a valid photo ID.

Additionally, Modern Drug was very strict on the early refilling of controlled substances. Evidence supports this fact in that early refills of controlled substances were not an issue at Modern Drug. Early refills are a very common occurrence in pharmacies who fail to exercise their corresponding responsibility because generally in those situations the pharmacist is not concerned about the legitimacy of the prescription. Modern Drug did not exhibit this behavior, and in many cases, the length of time before the next fill date exceeded what was expected.

Modern Drug took the initiative by contacting the prescribers to verify the authenticity of controlled substance prescriptions, including those issued by Dr. B. In addition, there are many notes in the patient profiles that demonstrate respondent's diligence, such as additional information regarding the distance from the patient's home to the pharmacy as well as diagnosis codes verified by the prescribing physician. Modern Drug requested Justification Forms, which is evidence that respondent was reviewing more than just the four corners of the prescription.

Modern Drug discussed with the prescribing physician dose adjustments and alternative methods of treatment. It is quite evident from the dispensing histories of the patients that quantities prescribed were in the process of being decreased from

quantities of 150 to quantities of 120 for oxycodone 30mg during the last few months before he stopped dispensing Dr. B.'s prescriptions.

In sum, Sydejko believed it evident that respondent did in fact make the required reasonable inquiry required under the corresponding responsibility law. While such an inquiry can differ from pharmacist to pharmacist, it was Sydejko's opinion that respondent did not fall below the standard of care of a reasonable prudent pharmacist when exercising his corresponding responsibility.

69. On cross-examination, Sydejko was asked about the data tabulated by the board showing the high volume of controlled substance prescriptions dispensed at Modern Drug, the number of cash prescriptions, and the high percentage of oxycodone 30 mg prescriptions. Sydejko was reluctant to give an opinion on whether this was unusual and offered a litany of reasons why a pharmacy might have a high volume of controlled substances. He cautioned against looking at aggregate numbers and said corresponding responsibility must be determined based on the original prescriptions. He gave very little weight to the aggregate numbers in Tang's report because a pharmacist is not privy to the metadata at the time, and it is the prescriptions themselves, and how the pharmacist treats them, that are relevant.

70. Sydejko discussed Tang's belief that at least six of the patients were opioid naïve because they had not had oxycodone 30 mg prescriptions filled within at least three months before Modern Drug filled the prescriptions. First, Sydejko noted that just because a patient has a 30-day supply of 150 tablets does not mean they use the entire amount within 30 days. Patients take opioids as needed, so the fact that a prescription had not been filled within the past 90 days does not imply the patient last took the medication more than 90 days earlier. Sydejko has also known of doctors who attempted to assist a cash patient financially by prescribing a higher dosage than what

the patient is taking so that the patient split tablets in half to make the medication more cost effective. In other words, simply looking at a refill history does not necessarily give a complete picture of what a patient is actually taking. This is why communication between the patient and the pharmacist is so important.

RESPONDENT'S EXPERT AFROUZ NIKMANESH

71. Afrouz Nikmanesh's testimony at hearing is summarized as follows: Nikmanesh received her Doctor of Pharmacy from USC and his been a licensed pharmacist in California since 1996. Since then, she has been a retail pharmacist for most of her career, primarily as a PIC. In that capacity she worked in primarily high-volume pharmacies, processing between 200 and 250 prescriptions per day. From 2014 to 2015, for little more than a year, she worked for the board as an inspector. She is currently approved by the board to serve as a probation monitor. Her first six months as a new board inspector were considered training, and as a trainee she rotated through the different board inspection teams. After six months, she was assigned to the prescription drug abuse team. In this role, she worked on corresponding responsibility cases.

72. For this case, Nikmanesh reviewed the original 82 prescriptions issued by Dr. B. to determine whether there were any irregularities with regard to the security features. She agreed that the four cited features in Tang's report were absent from these prescriptions. However, she did not believe the absence of any of these features constituted a red flag for purposes of corresponding responsibility. In support of her conclusion, she stated that the absence of the cited security features is not an enumerated red flag in the brochure created by the board (based on *Pacifica*). Additionally, multiple emails by the board to pharmacists have indicated that in certain

circumstances, pharmacists may fill prescriptions that are noncompliant in the interest of serving the patient.

73. Nikmanesh did notice that in some of the prescriptions, codeine was misspelled. She did not believe this was an irregularity because spelling errors happen all the time. Indeed, she confessed that she herself often misspelled codeine in the same manner, which is why she uses the abbreviation "COD." If a spelling error is legible, there is no need to contact the prescriber to verify.

74. Nikmanesh testified that promethazine/codeine and oxycodone are not duplicative therapies, which is the prescribing of multiple medications of the same class. For example, prescribing two beta blockers to treat hypertension would be duplicative and would warrant inquiry. In this case, codeine is the gold standard for the treatment of cough. Another frequently used cough medicine, dextromethorphan, can have a rare but potentially severe interaction with oxycodone. Thus, if a patient who is on oxycodone develops a cough, it is appropriate to treat the cough with promethazine/codeine. This is because even though oxycodone has antitussive features, they have clearly not prevented the cough in this instance, so the second opioid medication (promethazine/codeine) is not inappropriate.

75. Nikmanesh briefly testified about some of her frustrations with exercising corresponding responsibility. For example, when she suspected a doctor was dispensing unlawful controlled substances, she contacted the board but was told it was outside its jurisdiction. She contacted the DEA and was told they would "get to it when they get to it." She even contacted the corporate headquarters of her chain store but was told they could not block the prescriber's prescriptions. It was not until a year-and-a-half later that the doctor's dispensing of unlawful controlled substances was ultimately blocked.

TESTIMONY OF EDDIE COVARRUBIAS

76. Eddie Covarrubias started working at Modern Drug as a clerk in 2016 and then as a pharmacy technician in 2018. He worked there until 2020 when the pharmacy closed. He worked with respondent daily. He described respondent as very meticulous and a stickler for details, with high standards and a diligent work ethic. Covarrubias worked at the pharmacy when it dispensed Dr. B.'s prescriptions, but he did not have much of a recollection of any of the patients. He did recall one patient who came into the pharmacy by medical transport. At respondent's request, she brought in some paperwork, including medical records. The pharmacy's policy with regard to a patient presenting with a controlled substance prescription was for Covarrubias to check his identification, verify the prescription with the doctor, and receive an ICD-10 code, with which "they" would then verify the diagnosis. Respondent also checked CURES for all controlled substances to verify there were not early refills and did not involve switching pharmacies. Respondent ran CURES reports for all patients, whether they were new or existing. After the inspection, respondent also began requiring tapering of patients who were above 90 MME, and then 60 MME. Covarrubias spoke to the nurses at Dr. B.'s office. Covarrubias never was under the impression that the people with whom he was speaking were not legitimate nurses. Covarrubias would relay the information to respondent or make an entry in the patient profile. Covarrubias confirmed that when a patient came in with a controlled substance prescription, respondent would interview the patient himself.

TESTIMONY OF ROBERT TRAN

77. Robert Tran's testimony at hearing and supplemental letter are summarized as follows: Tran met respondent in pharmacy school, and they both

interned at the same pharmacy. The two have remained friends since. Tran praised respondent's work ethic and integrity. He believes respondent is a safe pharmacist.

TESTIMONY OF CAROLINE TRAN

78. Caroline Tran's testimony and supplemental letter are summarized as follows: Tran is a Major in the United States Air Force. She met respondent in 2015 when she was a volunteer on a medical mission in Vietnam with the Project Vietnam Foundation. Respondent ran the pharmacy and Tran worked with him closely. She worked with him on two other medical missions as well. Tran praised respondent's abilities as a leader and his work ethic. He consistently showed dedication to serving rural communities in need of medical attention. Tran is aware of the allegations against respondent, but she believes he is of high character and committed to patient safety.

ADDITIONAL EVIDENCE

79. Respondent submitted a character reference letter from Paul Tran, who has volunteered with respondent at Project Vietnam. He praised respondent's passion and commitment to patient care.

80. Respondent submitted certificates showing completion of continuing education courses in 2019 for Pharmacy Law and in 2020 for Ethics.

Cost Recovery

81. Complainant submitted certifications of costs and requested cost recovery pursuant to Business and Professions Code section 125.3. A certification by complainant and declarations by Tang and her supervisor outlined the board's investigation costs in the amount of $13,430. A declaration by the deputy attorney

general contained information related to services provided by the Office of the Attorney General and included costs of prosecution in the amount of $26,035. The certifications of cost satisfied the requirements of California Code of Regulations, title 1, section 1042, subdivision (b).

LEGAL CONCLUSIONS

Burden and Standard of Proof

1. The standard of proof in an administrative action seeking to suspend or revoke a professional license is "clear and convincing evidence." (*Ettinger v. Bd. of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) Clear and convincing evidence requires a finding of high probability, or evidence so clear as to leave no substantial doubt; it requires sufficiently strong evidence to command the unhesitating assent of every reasonable mind. (*Katie V. v. Sup. Ct.* (2005) 130 Cal.App.4th 586, 594.) The burden of proof is on complainant.

Purpose of License Discipline

2. The business of compounding prescriptions and selling drugs is intimately connected with and has a vital relationship to the health, safety, and welfare of the public. Public safety must be regarded as superior to private rights. (*Brodsky v. California State Board of Pharmacy* (1959) 173 Cal.App.2d 680, 688-689.) Protection of the public is the board's highest priority in exercising its disciplinary functions; whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public is paramount. (Bus. & Prof. Code, § 4001.1.) The main purpose of license discipline is protection of the public through the prevention of future harm and the improvement and rehabilitation of the licensee. It is far more

desirable to impose discipline before a licensee harms any patient than after harm has occurred. (*Griffiths v. Sup. Ct.* (2002) 96 Cal.App.4th 757, 772.)

Relevant Statutory Authority

3. Business and Professions Code section 4301 authorizes the board to take action against any holder of a license for unprofessional conduct. Unprofessional conduct includes, but is not limited to, the following:

> (c) Gross negligence.
>
> [¶] . . . [¶]
>
> (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
>
> [¶] . . . [¶]
>
> (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency. . . .

4. Under Business and Professions Code section 4113, subdivision (c), the PIC is responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

5. Business and Professions Code section 4306.5 provides that unprofessional conduct for a pharmacist includes:

> (a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.
>
> (b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.
>
> (c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function. . . .

6. Health and Safety Code section 11153, subdivision (a), provides in part:

> 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 . . . .

7. Health and Safety Code section 11164, subdivision (a), prohibits filling or dispensing a prescription for a controlled substance unless it complies with certain requirements, including that the prescription must be made on a controlled substance prescription form as specified in Section 11162.1.

8. Health and Safety Code section 11162.1 as amended in Stats. 2011 Ch. 418, (SB360), lists the security features that must be contained on prescription forms for controlled substances, and include: a watermark printed on the backside of the prescription consisting of the words "California Security Prescription," (subd. (a)(2)), six quantity check off boxes on the front allowing the prescriber to indicate quantity by checking the appropriate box (subd. (a)(7)(A)); an identifying number assigned to the approved security printer by the Department of Justice (subd. (a)(13)); and a printed lot number (subd. (b)).

9. California Code of Regulations, title 16, section 1761 provides:

> (a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall

contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

Evaluation of Corresponding Responsibility

10. At the heart of this case is whether Modern Drug and respondent failed to comply with their corresponding responsibility to ensure that controlled substances were dispensed for a legitimate medical purpose as required under Health and Safety Code section 11153. That provision provides that 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. While the responsibility for the proper prescribing of controlled substances is upon the prescribing practitioner, a corresponding responsibility rests with the pharmacist who fills the prescription. Furthermore, an order purporting to be a prescription which is not issued in the usual course of professional treatment is not a legal prescription.

11. As discussed throughout the testimony, the board's precedential decision in *Pacifica* clarified the role pharmacists have regarding their corresponding responsibility to determine the legitimate medical purpose before dispensing controlled substance prescriptions. "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." (*Id.* at p. 27.)

> 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. (*Pacifica* at p. 30.)

Moreover, to establish a violation of the corresponding responsibility standard, complainant is not required to establish that a prescription for a controlled substance was in fact written by a prescriber for an illegitimate purpose; rather, complainant need only 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." (*Id.* at p. 31.) "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." (*Ibid.*)

12. To establish that respondent failed to abide by his responsibilities under Section 11153, complainant must prove: 1) 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 2) that respondent failed to make reasonable inquiry, i.e., that respondent failed to use professional judgment or reasonable care to determine how to further proceed. (*Pacifica* at p. 31.)

STEP ONE – RED FLAGS TO SUGGEST THE PRESCRIPTIONS WERE NOT FOR A LEGITIMATE MEDICAL PURPOSE

13. Complainant must establish 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. In *Pacifica*, the board identified several red flags or irregularities to aid pharmacists with identifying potential problems with a prescription. However, the red flags identified in *Pacifica* are not exhaustive criteria for determining whether a prescription is for an illegitimate medical purpose; it is within the pharmacist's professional judgment to make that determination. In other words, while the red flags serve as tools to guide a pharmacist, the absence of an irregularity from the *Pacifica* list does not render its existence unimportant.

The red flags identified in *Pacifica* can be grouped into three categories: 1) irregularities within the four corners of the prescription document, 2) irregularities regarding an individual prescription and patient, and 3) cumulative or aggregate irregularities related to the prescriber and multiple patients/prescriptions. The significance of any particular red flag must be evaluated in the context of the totality of the circumstances. Some red flags can be more significant when occurring in conjunction with other red flags.

Irregularities with the Prescription Itself

14. *Pacifica* cites irregularities on the face of the prescription itself as a red flag. The parties disagree about whether the absence of statutorily mandated security features constitutes a red flag for purposes of corresponding responsibility. Specifically, respondent contends that the red flag relates to irregularities with the

contents of the prescription, i.e., missing information required of a valid prescription, and not security features. Respondent contends that if absence of security features was a red flag, the board could have simply stated that in its decision. However, in trying to exclude the absence of security features as not falling within the *Pacifica* red flag misses the point. The only issue is whether the absence of the four security features in the 82 prescriptions was a factor that a reasonable pharmacist would consider in questioning whether a controlled substance prescription was legitimate. Here, respondent did not appreciate that these prescriptions were missing security features. Because it is a statutory violation to dispense a controlled substance from a nonconforming prescription, it is a per se duty and standard of care for a pharmacist to recognize a nonconforming prescription and proceed accordingly (either by rejecting the prescription or seeking to "legalize" the prescription through alternative means, such as a phone order for Schedule II through V). Moreover, part of a pharmacist's corresponding responsibility is to treat a prescription lacking required security features as potentially illegitimate for the obvious reason that a counterfeit prescription might lack any number of these features, the recognition of which would prompt a reasonable pharmacist to make further inquiry. Thus, the absence of statutorily required security features is a red flag, the significance of which is determined by the type of security features that are absent.

Irregularities Regarding an Individual Prescription/Patient

15. The next group of red flags relate to individual patients and the medications prescribed to each. Included in the *Pacifica* list of red flags are: nervous patient demeanor, age or presentation of the patient; cash payments; requests for early refills; unusually large quantity of drugs; prescriptions for potentially duplicative drugs; initial prescriptions written for stronger opiates (or opioids); long distance

travelled from patient's home to prescriber and/or pharmacy; irregularities with the prescriber's qualifications in relation to medication prescribed; and medications with no logical connection to diagnosis or treatment. In this case, there were multiple red flags that are not applicable because they did not exist, such as the age of the patients. The red flags that *are* applicable are:

Cash Payments The majority of the prescriptions were paid in cash. While there might be reasonable explanations for this difference, it is still a factor a reasonable pharmacist should consider in evaluating the legitimacy of a controlled substance prescription.

Duplicative Therapy For the prescriptions containing both promethazine/codeine and oxycodone, there was much testimony at the hearing about whether this constituted "duplicative therapy." While respondent and his experts were more persuasive than Tang that the medication combination does not constitute "duplicative therapy" as the term is used in the practice of pharmacy, that does not mean that the combination would not have aroused a reasonable pharmacist's suspicions. Even if codeine and oxycodone are not duplicative therapies per se, and there could be legitimate therapeutic reasons for such a combination, the combination should raise a degree of concern requiring further inquiry because both drugs are common drugs of abuse and diversion.

Distance from Pharmacy to Patient A reasonable distance from the pharmacy to the patient's home is not fixed and is patient and circumstance specific. However, a reasonably prudent pharmacy should recognize that long distance or *travel time* warrants further inquiry. Modern Drug is located within a densely populated metropolitan area. In fact, there were four pharmacies located with a 1.2-mile radius of Modern Drug. Most of the 15 patients travelled farther than 10 miles from their

residence to go to Modern Pharmacy. In other words, there were likely dozens, if not more, pharmacies that would have been closer. Thus, a reasonably prudent pharmacist would have appreciated some degree of suspicion as to the reason the patient was utilizing Modern Drug, and further inquired.

Initial High Dose Opioids All of the prescriptions in this case were written for the highest dose of oxycodone available. Several of the patients showed no history of having received oxycodone prior to the initial prescription for oxycodone 30 mg. Other patients appeared to have not received oxycodone for several months. This constitutes a red flag that required further inquiry.

Unusually Large Quantities Whether a quantity of drug is unusually large is a clinical question that is circumstance specific. In this case, it was not established that the quantity was unusually large; however, as with an initial high dose of oxycodone 30 mg, the prescription of 150 tablets for all 15 patients warranted additional scrutiny, especially considering the high MME if taken as directed.

Irregularities with Prescriber Qualifications Complainant contends that because Dr. B.'s online profile maintained by the Medical Board did not reference pain management, his volume of controlled substance prescriptions were suspicious. While this criterion relates more to aggregate prescriptions than to single prescriptions, Dr. B.'s prescriptions listed his specialty as pain management. Thus, the prescriptions for oxycodone were written within Dr. B.'s qualifications, and if taken in isolation, the standard of care in 2016 through 2017 did not require respondent investigate further. However, as the prescription volume for Dr. B. increased (to the point that he became one of the pharmacy's most frequent providers), and because of the existence of other red flags, respondent became increasingly obligated to perform some due diligence about Dr. B.'s practice, as discussed further below.

16. In addition to the red flags listed in *Pacifica*, the following are also red flags, or irregularities, that should cause a reasonably prudent pharmacist to make further inquiry:

Prescriptions containing multiple controlled substances of frequently abused medication The primary concern with multiple prescriptions of promethazine/codeine and oxycodone is that multiple controlled substances are not medically indicated, especially where both are frequently abused. The degree that this constitutes a red flag is circumstance specific. A low degree of suspicion would be warranted for two controlled substances with relatively low levels of abuse. A high degree of suspicion is warranted for medications of frequent abuse; that are prescriptions for "cocktails" such as an opioid, benzodiazepine, and muscle relaxant; are medically contraindicated; and are drugs with opposite effects (e.g., stimulants and depressants). In this case, both oxycodone and promethazine/codeine are frequently abused, warranting a greater degree of inquiry.

Distance from Provider to Pharmacy The distance of the provider to the pharmacy is also a red flag that is not explicitly listed in the *Pacifica* decision. However, it is clearly a red flag that requires further inquiry. In this case, Dr. B.'s office was 30 miles away from Modern Drug. In *Pacifica*, the distance from the prescriber to the respondent pharmacy was 24 miles, which the board determined to be "significantly far." As with the distance from the pharmacy to the patient's home, a reasonably prudent pharmacist in respondent's situation would make further inquiry.

Significant Errors or Discrepancies in Prescription-Related Documentation Tang noted a number of irregularities in the Justification Forms received from Dr. B.'s office, including: misspelling of drugs, incomplete information, outdated/discontinued drugs, and non-conforming fax header. Respondent's expert, Sydejko, disagreed that any of

these were materially significant. However, because they exist, and because of the other red flags, it is an element that requires further inquiry, because it casts doubt on the legitimacy of Dr. B.'s operation.

Aggregate Irregularities with Patients and Prescribers

17. The final group of red flags relate across multiple patients and prescriptions that would raise concern about the type of prescriptions being issued by a particular provider. In *Pacifica*, the board specifically identified two red flags: multiple patients at the same address and the same combination of drugs prescribed for multiple patients. Additionally, several of the other red flags previously discussed are also red flags when viewed in the aggregate such as: multiple patients travelling far distances; multiple prescriptions of potentially duplicative drugs; multiple prescriptions with the same irregularities on the face of the prescription (e.g., different signatures, handwriting, spelling errors); multiple prescriptions containing multiple controlled substances of frequently abused medication; and multiple patients with the same diagnosis code(s).

18. Complainant relies heavily on aggregate data to argue that respondents failed in their corresponding responsibility duty. Reviewing the data Tang collated from Modern Drug's dispensing reports certainly raises alarms, in hindsight, as it relates to Dr. B.'s prescribing:

- The top two total dispensed medications at Modern Drug were for oxycodone 30 mg and promethazine/codeine. All of the oxycodone 30 mg and almost all of the promethazine/codeine was prescribed by Dr. B.
- Dr. B.'s prescription profile consisted of only six medications, 49 percent of which was oxycodone 30 mg and 19 percent promethazine/codeine.

- Each of the 82 prescriptions issued by Dr. B. contained oxycodone 30 mg. Dr. B. did not prescribe any other opioids (except promethazine/codeine) and no other dosages of oxycodone.

- 13 of the 15 patients were prescribed oxycodone 30 mg and promethazine/codeine, which constituted 35 out of the 82 prescriptions.

- Almost all the patients lived more than 10 miles from Modern Drug, some significantly further.

- 45 percent of Dr. B.'s prescriptions were paid through insurance, compared to 79 percent of the total prescriptions filled at Modern Drug.

- Two separate groups of patients shared the same address.

19. Respondent, on the other hand, dismisses the use of aggregate data. Sydejko was especially skeptical of the use of metadata because it was not available to respondent in real time when he filled each prescription. He believed that the pharmacist's duty is based on an individual patient and prescription, because the pharmacist is not privy to the metadata at the time. He also noted that the board does not require PICs to collect or review the type of data harvested from Tang's inspection.

20. As with most aspects of this case, the answer lies between the two ends of this spectrum. The data presented by complainant reflects a top-down, retrospective analysis of Modern Drug's dispensing over months. There is no law or regulation currently in effect that requires, nor is it within the standard of care, for a PIC to perform the type of analysis of controlled substance dispensing presented by Tang. This represents a top-down, retrospective review of aggregate data that would be unavailable to a pharmacist at the time he was dispensing the prescriptions. On the

other hand, respondents' position that aggregate data can never be included as red flags is rejected because there are clearly circumstances where a reasonably prudent pharmacist would recognize certain patterns of prescribing by a physician. The standard of care for exercising corresponding responsibility is what a reasonably prudent pharmacist would do in the *same or a similar situation*. Put another way, would a reasonably prudent pharmacist have recognized certain red flags as they existed for multiple patients? In answering this, the most relevant question is whether respondent was in the position of being able to ascertain irregularities across multiple patients. Here, the answer is the affirmative. The following are such examples:

On Wednesday, December 14, 2016, respondents processed the first prescription by Dr. B. for patient B.L. There were several red flags with this patient that warranted further inquiry, including the high dosage and amount of oxycodone 30 mg, and the 30-mile distance from Dr. B.'s office to the pharmacy.

On Monday, December 19, 2016, respondents processed a prescription for patient A.C.J. for oxycodone 30 mg and promethazine/codeine. According to respondent's dispensing report, between the time respondent processed prescriptions for B.L. and A.C.J. he only processed prescriptions for a total of eight patients.

Patient A.C. was dispensed oxycodone 30 mg on December 21, 2016, two days later. Respondents processed prescriptions for five other patients during this two-day interval.

Finally, from January 2 through 10, 2017, respondents processed oxycodone 30 mg #150 (in addition to alprazolam, and/or Soma) to seven additional patients (R.H., I.J., S.H., P.R., V.P., C.S., D.W.). During this period, these patients constituted 30 percent of respondents' total patients. Respondent was the only pharmacist at Modern Drug

and dispensed each of these prescriptions. Similarly, on 28 separate days until August 2017, respondents processed prescriptions for oxycodone 30 mg written by Dr. B. for two different patients on the same day (many of which were for the exact same prescription). Contrary to Sydejko's belief that respondents were filling an average of 50 prescriptions per day, on several days where respondents processed multiple prescriptions issued by Dr. B., respondents only processed prescriptions for two other patients.

A reasonably prudent pharmacist under these circumstances – involving multiple patients, all with prescriptions from Dr. B., most of whom lived outside the immediate vicinity of respondent's pharmacy, all of whom received the exact same prescription for oxycodone 30 mg, and most of whom received oxycodone and promethazine/codeine combinations – would ascertain a pattern warranting scrutiny and inquiry. This is especially so in this case, because respondent claimed that he spent time meeting with the patients and verifying each prescription with Dr. B.

Again, it is worth highlighting that the ability to ascertain patterns amongst patients is based on the circumstances of the individual pharmacist. While there is a single standard of care, the standard is situationally based. For example, if these 82 prescriptions had been issued at a high-volume pharmacy dispensing hundreds of prescriptions per day, the ability to recognize aggregate patient patterns would reasonably be reduced. As a consequence, single pharmacists at low volume pharmacies are in a better position to recognize aggregate patterns.

In conclusion, there are multiple red flags in this case that a reasonably prudent pharmacist in respondent's situation would have recognized and further investigated. Although the existence (and non-existence) of red flags was the subject of much of the evidence at this hearing, respondent credibly testified that he treated *all* the controlled

substance prescriptions with suspicion, which is why he undertook additional steps of inquiry. Put another way, respondent admits the prescriptions required further inquiry because he was initially skeptical that they were not for a legitimate purpose. Moreover, the facts of this case are vastly different than those in *Pacifica*, where the pharmacist believed that his only duty was to evaluate whether a prescription was valid and legitimate on its face. Beyond this, the *Pacifica* pharmacist recognized no further duty. To the contrary, respondent did not simply verify the four corners of the prescription and dispense the prescription; he presumed that the controlled substance prescriptions were not legitimate and took steps to verify its legitimacy. To put this in the language of *Pacifica*, respondent did "question whether a prescription for a controlled substance was issued for a legitimate medical purpose." (*Pacifica* at p. 31.)

STEP TWO- REASONABLE INQUIRY AND DECISION TO DISPENSE PRESCRIPTION

21. Having identified that the prescriptions from Dr. B. warranted further inquiry, the next step is to determine whether respondent made reasonable inquiry, in other words, whether he exercised professional judgment and reasonable care in concluding the prescriptions were for a legitimate medical purpose. While *Pacifica* articulated red flags to assist pharmacists with questioning the validity of a controlled substance prescription, because the pharmacist in that case "did nothing in the face of circumstances that require that some positive action be taken," the board provided little guidance on the steps a reasonably prudent pharmacist should take when suspecting an illegitimate prescription. (*Id.* at p. 31.) Similarly, earlier caselaw provides little guidance except that a pharmacist is required to use "common sense and professional judgment." (*Vermont & 110th Medical Arts Pharmacy v. Board of Pharmacy* (1981) 125 Cal.App.3d 19, 25.)

22. The exercise of professional judgment is based on reason and the totality of circumstances. The more reasons to be skeptical of the legitimacy of a prescription, the greater the inquiry required of a pharmacist before filling the prescription. And in some situations, the quality and quantity of the irregularities will be such that no reasonable pharmacist could justify filling the prescription. In discharging his or her duty, the standard of care requires a pharmacist to assess, verify, and document.

The assessment can include things such as verifying identity of the patient; obtaining information from the patient to determine medical history, present diagnosis, past medications tried, history taking the prescribed controlled substance, reason for travelling to a particular pharmacy and/or leaving past pharmacy (especially if patient is outside pharmacy's typical trade area), history of seeing current prescriber; and assessing the patient's demeanor and responsiveness to the questions.[5]

Verification involves such things as checking CURES for medication and dosage history, prescriber history, early refills, and pharmacy/prescriber shopping; questioning prescriber about the prescription and any irregularities;[6] and performing internet

[5] Pursuant to Assembly Bill 2789, effective January 1, 2022, electronic prescribing will be mandated by all prescribers with some narrow exceptions. While electronic prescribing will undoubtedly reduce the prevalence of certain fraudulent or forged prescriptions, it does not relieve a pharmacist of his or her corresponding responsibility duties, including directly interacting with the patient when appropriate.

[6] A common refrain amongst the witnesses was the difficulty and push-back pharmacists receive when contacting physicians for additional information. However, the refusal of a physician to engage with a pharmacist undertaking his or her corresponding responsibility duties is not grounds for dispensing the prescription.

queries as appropriate, especially when receiving prescriptions from an unfamiliar provider outside the customary trade range for the pharmacy, which can include searching Breeze license verification for information on prescriber and disciplinary record, verifying prescriber phone/fax numbers through other sources than what is listed on the prescription form, and calling other pharmacies who had filled the prescriber's prescriptions.

Finally, because the exercise of corresponding responsibility decisions are within a pharmacist's professional judgment, the standard of care requires some degree of documentation of the pharmacist's evaluation and inquiries. At a minimum, there should be sufficient contemporaneous documentation to show what inquiries were made.

23. In this matter, the subject prescriptions were issued during an approximate eight-month period in 2016 through 2017. Thus, respondent's actions are to be judged by the standard of care relating to corresponding responsibility four years ago, and not by today's standard. Complainant does not dispute that respondent took certain steps to make sure the prescriptions were legitimate before filling them. However, complainant argues that those steps were insufficient to resolve the numerous red flags and that there was little by way of documentation in the patients' records.

Physicians share in this responsibility. Prescribing controlled substances places an additional burden on the prescriber that they may be contacted by a pharmacist as part of the pharmacist's legal duty.

24. Respondent testified that he obtained and copied patients' identification; verified a physical address (not postal box number); spoke to the patients about their conditions and occasionally requested corroborating documents; ran CURES reports on each patient; verified each prescription with Dr. B.'s office; obtained diagnosis codes and frequently requested faxed documentation of the codes; spoke to Dr. B. from between 5 to 12 times; and began requiring the tapering of medication for some patients.

Unfortunately, while there was some documentation in the patients' profiles of the inquiries respondent made, respondent admitted he did not fully and completely document each of these. Despite a lack of documentation, respondent's testimony was generally credible. Moreover, *no evidence was produced to the contrary*, which could only have come from a more thorough investigation into the actual circumstances by which the prescriptions were issued, i.e., whether Dr. B. was involved in their issuance or whether they were counterfeit.[7] Finally, there was some independent corroboration of the steps respondent took. For example, while respondent did not print out CURES reports, his notations about CURES entries were corroborated by Tang's independent search of the patients' CURES records. Also, at the time of the inspection, respondent

[7] Even Tang could not offer a theory about the providence of the prescription. Based on respondent's testimony, it appears that Dr. B. had knowledge of the prescriptions. Other evidence, such as the phone number listed on the prescriptions belonging to a *cell* phone number; differences in handwriting and spelling mistakes throughout the prescriptions; and the errors in the Justification Forms, and fax number listing Dr. G., suggest that the prescriptions were counterfeit.

provided Tang a copy of the flow sheet he employed for dispensing controlled substances.

Perhaps the most significant action respondent took to demonstrate his concern about the high dosages of oxycodone, is that he began requiring tapering of patients several months after initially filling prescriptions. For multiple patients, the quantity of oxycodone was reduced in addition to the time between fills, which were extended by approximately one month. This corroborates his testimony that he told Dr. B. that he would not continue to fill prescriptions unless Dr. B. began tapering the patients. These actions are also inconsistent with a pharmacist knowingly, or even negligently, filling illegitimate controlled substance prescriptions. In other words, respondent exercised his professional judgment to require Dr. B. to have a plan to draw down the dosage of oxycodone his patients were receiving.

In sum, there are many irregularities about the prescriptions Dr. B. issued, especially in the aggregate, that in hindsight, raise significant concern that the prescriptions were not legitimately issued. But this case is decided on whether respondent acted as a reasonably prudent pharmacist would have done in the same or similar situation four years ago. While respondent did not have access at the time to the type of meta-review provided in Tang's investigation, there were multiple red flags, combined with his low prescription volume, that justifiably should have raised suspicions about Dr. B.'s prescriptions. Respondent did take multiple steps and inquiries in an attempt to ensure that he was dispensing legitimate prescriptions. However, given all the irregularities, it is slightly more likely than not that a reasonably prudent pharmacist in respondent's shoes would have recognized these and taken further steps to resolve the irregularities, or not dispense the prescriptions. Notwithstanding, the evidence that a reasonably prudent pharmacist at the time

should not have dispensed Dr. B.'s prescriptions is not "so clear as to leave no substantial doubt." (*Katie V., supra*, at p. 594.) Therefore, the weight of the evidence did not clearly and convincingly establish that respondent failed to exercise his corresponding responsibilities within the standard of care at the time.

Causes For Discipline

FIRST CAUSE FOR DISCIPLINE – CORRESPONDING RESPONSIBILITY

25. Cause does not exist to discipline respondent's license and Modern Drug's permit pursuant to Business and Professions Code section 4301, subdivision (j), based on a violation of Health and Safety Code section 11153. Clear and convincing evidence did not establish respondents failed to comply with their corresponding responsibility.

THIRD CAUSE FOR DISCIPLINE- ERRONEOUS OR UNCERTAIN PRESCRIPTIONS

26. Cause does not exist to discipline respondent's license and Modern Drug's permit pursuant to Business and Professions Code section 4301, subdivision (o). Clear and convincing evidence did not establish that respondents violated California Code of Regulations, title 16, section 1761, by dispensing prescriptions containing any significant "error, omission, irregularity, uncertainty, ambiguity or alteration," or which respondent should have reasonably known was not issued for a legitimate medical purpose.

FOURTH CAUSE FOR DISCIPLINE – DISPENSING NON-COMPLIANT CONTROLLED SUBSTANCE PRESCRIPTION

27. Cause exists to discipline respondent's license and Modern Drug's permit pursuant to Business and Professions Code section 4301, subdivisions (j) and (o). Clear and convincing evidence established that respondents violated Health and Safety Code section 11164 for filling and dispensing controlled substances from forms that did not comply with the requirements of Section 11162.1. Specifically, all of the 82 prescriptions filled by respondent and Modern Drug lacked a "California Security Prescription" watermark, six quantity check off boxes on the front allowing the prescriber to indicate quantity by checking the appropriate box, an identifying number assigned to the approved security printer by the Department of Justice, and a printed lot number. (Health & Saf. Code, § 11162.1, subds. (a)(2), (a)(7)(A), (a)(13) & (b).)

FIFTH CAUSE FOR DISCIPLINE – UNPROFESSIONAL CONDUCT

28. Cause does not exist to discipline respondent's license and Modern Drug's permit pursuant to Business and Professions Code section 4301. Unprofessional conduct has been defined as "conduct which indicates an unfitness to practice medicine . . . 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 and n.5.) The nature of the established violations did not establish that respondent engaged in unprofessional conduct.

SIXTH CAUSE FOR DISCIPLINE – GROSS NEGLIGENCE

29. Cause does not exist to discipline respondent's license pursuant to Business and Professions Code section 4301, subdivision (c). Gross negligence is defined as "want of even scant care" *or* "an extreme departure from the ordinary standard of conduct." (*Gore v. Board of Medical Quality Assurance* (1980) 110 Cal.App.3d 184, 195-197.) Clear and convincing evidence did not establish the violation of either standard.

SEVENTH CAUSE FOR DISCIPLINE – FAILURE TO EXERCISE BEST PROFESSIONAL JUDGMENT

30. Cause does not exist to discipline respondent's license pursuant to Business and Professions Code section 4301, subdivision (o), based on a violation of Section 4306.5, subdivision (a), (b) or (c). Clear and convincing evidence did not establish respondent committed an act or omission that involved the "inappropriate exercise of his or her education, training, or experience as a pharmacist"; the failure to exercise or implement his best professional judgment or corresponding responsibility; or the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

EIGHTH CAUSE FOR DISCIPLINE – ALLOWING UNLICENSED CLERK TO PERFORM LICENSED TASKS

31. Cause exists to discipline respondent's license pursuant to Business and Professions Code section 4113, subdivision (c), for permitting unlicensed clerks to count medication, which can only be performed by a licensed pharmacy technician pursuant to Section 4115.

Appropriate Discipline

32. California Code of Regulations, title 16, section 1760, provides that in reaching a decision in a disciplinary action under the Administrative Procedure Act, the board must consider its "Disciplinary Guidelines" (Rev. 2/2017).

The factors relevant to this matter that were considered in reaching a decision in this matter are: actual or potential harm to the public; actual or potential harm to any consumer; prior disciplinary record (including citations); number and/or variety of current violations; nature and severity of the acts under consideration; aggravating evidence; mitigating evidence; rehabilitation evidence; time passed since the acts; whether the conduct was intentional or negligent, demonstrated incompetence, or, if respondent is being held to account for conduct committed by another, respondent had knowledge of or knowingly participated in such conduct; and financial benefit to respondent from the misconduct.

The Guidelines identify four categories of violations and provide recommended minimum and maximum discipline. For each violation category, the board has given offense descriptions and examples where violations would typically merit the recommended range of minimum to maximum penalties for that category. These descriptions and examples are representative, and they are not intended to be comprehensive or exclusive. The violations in this matter most closely correspond to Category II violations, due to the "violation of controlled substance secure prescription requirements." The minimum recommended discipline is a stayed revocation with three years' probation. The maximum discipline is revocation.

33. Rehabilitation is a "state of mind" and the law looks with favor upon rewarding with the opportunity to serve one who has achieved "reformation and

regeneration." (*Pacheco v. State Bar* (1987) 43 Cal.3d 1041, 1058.) Acknowledgement of the wrongfulness of one's actions is an essential step toward rehabilitation. (*Seide v. Committee of Bar Examiners* (1989) 49 Cal.3d 933.) While a candid admission of misconduct and full acknowledgment of wrongdoing is a necessary step in the rehabilitation process, it is only a first step; a truer indication of rehabilitation is presented if an individual demonstrates by sustained conduct over an extended period of time that he or she is rehabilitated. (*In re Trebilcock* (1981) 30 Cal.3d 312, 315-316.) Administrative proceedings to impose discipline on a licensee are noncriminal and nonpenal; they are not intended to punish the licensee, but to protect the public. (*Sulla v. Bd. of Registered Nursing* (2012) 205 Cal.App.4th 1195, 1206.)

34. Respondent admitted that he made mistakes and has taken the accusation to heart. Even before the inspection prompting this disciplinary action, he implemented policies to ensure his and Modern Drug's compliance with their corresponding responsibility duties. For example, he has implemented the CDC guidelines for reducing MME for chronic pain patients. After the inspection, he also appears much more vigilant in ensuring all controlled substance prescriptions contain the required security features and ensuring that unlicensed clerks do not perform tasks requiring a license. In sum, it is unlikely that respondent will engage in the same misconduct again. His actions are consistent with the general principles of rehabilitation, and he has established that he is a safe and competent pharmacist. The imposition of probation would be punitive and would not advance public protection.

35. Business and Professions Code section 495 provides that the board may publicly reprove a licensee for any act that would constitute grounds to suspend or revoke a license. Under the circumstances of this case, a public reproval is appropriate.

Cost Recovery

36. The California Supreme Court in *Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, held that a regulation imposing costs for investigation and enforcement under California Code of Regulations, title 16, section 317.5, which is similar to Business and Professions Code section 125.3, did not violate due process. But it was incumbent on the board in that case to exercise discretion to reduce or eliminate cost awards in a manner such that costs imposed did not "deter [licensees] with potentially meritorious claims or defenses from exercising their right to a hearing." (*Ibid.*)

The Supreme Court set forth five factors to consider in deciding whether to reduce or eliminate costs: whether the licensee used the hearing process to obtain dismissal of other charges or a reduction in the severity of the discipline imposed; whether the licensee had a "subjective" good faith belief in the merits of his or her position; whether the licensee raised a "colorable challenge" to the proposed discipline; whether the licensee had the financial ability to make payments; and whether the scope of the investigation was appropriate in light of the alleged misconduct. The reasoning of *Zuckerman* must be applied to Business and Professions Code section 125.3 since the language in the cost recovery regulation at issue in *Zuckerman* and section 125.3 are substantially the same.

Applying the *Zuckerman* criteria, respondent obtained dismissal of the most serious causes for discipline and raised a colorable challenge to the proposed discipline. Respondents are ordered to pay cost recovery in the amount of $3,000.

ORDER

1. This decision constitutes the public reproval of respondents Quon Chan Luong (RPH 65421) and Modern Drug, Inc. (PHY 53920).

2. Respondent shall pay to the board its costs of investigation and prosecution in the amount of $3,000 within 30 days of the effective date of this decision.

DATE: October 1, 2021

Adam Berg (Oct 1, 2021 09:51 PDT)

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

In the Matter of the Accusation Against**:** **MODERN DRUG, INC.,** **DBA MODERN DRUG** **10672 Chapman Ave, Suite 5** **Garden Grove, CA 92840** **Pharmacy Permit No. PHY 53920,** **and** **QUOC CHAN LUONG** **1205 E. Via Roma Drive** **Fresno, CA 93730** **Pharmacist License No. RPH 65421,** Respondents.	Case No. 6677 **ACCUSATION**

PARTIES

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

2. On or about February 17, 2016, the Board of Pharmacy (Board) issued Pharmacy Permit Number PHY 53920 to Modern Drug, Inc., dba Modern Drug. The Pharmacy Permit was

in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2020, unless renewed.

3. On or about April 25, 2011, the Board issued Pharmacist License Number RPH 65421 to Quoc Chan Luong. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2021, unless renewed.

JURISDICTION

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

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

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

7. Section 4300.1 of the Code states:

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

STATUTORY & REGULATORY PROVISIONS

8. Section 4301 of the Code states in pertinent part:

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

…

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or any other state or federal regulatory agency.

…

9. Section 4113, subdivision (c), of the Code states:

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

10. Section 4115 of the Code states in pertinent part:

(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

(e) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

11. Sections 4306.5, subdivisions (a), (b) and (c) of the Code states:

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

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

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

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

…

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

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.

...

13. Health and Safety Code section 11162.1 states, in pertinent part:

(a) The prescription forms for controlled substances shall be printed with the following features:

...

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

...

(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.

...

(13) An identifying number assigned to the approved security printer by the Department of Justice.

...

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within the batch shall be numbered sequentially beginning with the numeral one.

...

14. Health and Safety Code section 11164 states, in pertinent part:

Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number . . .

15. Section 1761 of title 16, California Code of Regulations states:

> (a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.
>
> (b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

16. Section 1793.2 of title 16, California Code of Regulations states:

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

17. Section 1793.3, subdivision (a), of title 16, California Code of Regulations states in pertinent part:

> (a) In addition to employing a pharmacy technician to perform the tasks specified in section 1793.2, a pharmacy may employ a non-licensed person to type a prescription label or otherwise enter prescription information into a computer record system. . . .

COST RECOVERY

18. 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

19. Phenergan with Codeine Syrup is the brand name for promethazine with codeine syrup, a Schedule V controlled substance pursuant to Health and Safety Code section 11058(c)(1), and a dangerous drug pursuant to Business and Professions Code section 4022.

20. Roxicodone is the brand name for oxycodone, a Schedule II controlled substance pursuant to Health and Safety Code section 11055(b)(1)(M), and a dangerous drug pursuant to Business and Professions Code section 4022.

21. Soma is the brand name for carisoprodol, a Schedule IV controlled substance pursuant to Code of Federal Regulations, title 21, section 1308.14(c)(6), and is a dangerous drug pursuant to Business and Professions Code section 4022.

22. Xanax is the brand name for alprazolam, a Schedule IV controlled substance pursuant to Health and Safety Code section 11057(d)(1), and a dangerous drug pursuant to Business and Professions Code section 4022.

BACKGROUND

23. Pharmacists serve an important role in preventing drug diversion and limiting illegitimate use of controlled substances. The Board of Pharmacy, the Drug Enforcement Administration, the National Institute on Drug Abuse, and other governmental and non-governmental organizations publish and disseminate information to assist pharmacists in fulfilling their responsibility to dispense only medically legitimate controlled substances prescriptions. Among the information disseminated by these organizations, are descriptions of common "red flags" that should alert pharmacists there may be a problem with a prescription.[1]

24. Moreover, California law requires controlled substance prescriptions to be written on tamper-resistant prescription forms that contain statutorily enumerated security features. The security features are intended to assist pharmacists in recognizing counterfeit or invalid controlled substance prescriptions. A pharmacist should not fill any controlled substance prescription that lacks a required security feature or otherwise does not meet the statutory requirements.

25. The Controlled Substance Utilization Review and Evaluation System (CURES) is California's Prescription Drug Monitoring Program. Pharmacies in California are required to

[1] Common "red flags' include, but are not limited to, irregularities on the face of a prescription, multiple patients listing the same address, cash payments, prescriptions written for potentially duplicative drugs, the same combination of drugs prescribed for multiple patients, initial prescriptions written for strong opiates, longer than typical distances traveled from a patient's home and the prescriber's office or pharmacy, prescriptions written outside of a prescriber's medical specialty.

report all prescriptions filled for Schedule II, III and IV controlled substances to the CURES database on a weekly basis. The data is collected statewide and can be used by healthcare professionals to evaluate and determine whether patients are utilizing controlled substances safely and correctly.

FACTUAL ALLEGATIONS

26. At all times relevant herein, Respondent Luong was the Pharmacist-in-Charge of Respondent Modern Drug.

27. The Board analyzed the controlled substance dispensing data Respondent Modern Drug reported to CURES, and determined an investigation was warranted with regard to prescriptions written by Dr. J.B. From December 14, 2016 through August 3, 2017, Respondents filled 180 prescriptions written by Dr. J.B., 154 of which were for controlled substances. Many of the prescriptions exhibited "red flags" and other irregularities. For example:

Dr. J.B.'s office address was approximately 30 miles from Modern Drug.

Many of Dr. J.B.s alleged patients travelled significantly further to fill their prescriptions than is typical in a metropolitan area.

Multiple patients picking up the same high potency pain medication listed the same home address.

Patients paid "cash" and did not seek reimbursement from an insurance company or government agency for 55% of Dr. J.B.'s prescriptions.

Many of the prescriptions contained misspellings or errors in the drug list, or a fax header that did not match Dr. J.B's office information.

Dr. J.B.'s prescribing profile was unusually limited with a small number of controlled substances accounting for a relatively large percentage of the total prescribed medications.

Dr. J.B. wrote an unusually high number of pain medication prescriptions for a doctor that did not specialize in pain management.

/ / /

/ / /

Dr. J.B. primarily wrote prescriptions for controlled substances of high abuse and diversion potential including: (1) alprazolam 2mg; (2) oxycodone 30mg; (3) carisoprodol 350 mg; and (4) promethazine with codeine syrup.

Approximately 35 of Dr. J.B.'s prescriptions were for oxycodone 30mg and promethazine with codeine syrup, which is duplicative and unusual since both medications have an opioid and cough suppressant.

None of the patients purportedly being treated by Dr. J.B. received a long acting pain medication to control their baseline pain, and all but one were prescribed only the highest dosage of oxycodone without any history of first being prescribed lower strength pain relievers.

Six of Dr. J.B.'s 15 patients filling at Modern Drug appeared to be opioid naïve, but presented prescriptions for the maximum dosage of high strength opioid pain medication.

28. In addition to the foregoing red flags, 82 of the prescription documents written under Dr. J.B.'s authority lacked required statutory security features including, without limitation:

A watermark on the backside consisting of the words, "California Security Prescription."

Pre-printed check boxes for the prescriber to indicate the number of refills ordered. An identifying number assigned by the Department of Justice to the approved security printer.

The lot number of the applicable batch of prescription forms.

29. As a result of the investigation, the Board investigator determined Respondents repeatedly filled controlled substance prescriptions written on non-compliant forms, failed to verify the legitimacy of controlled substance prescriptions by, among other things, conferring with the prescriber, and filled controlled substance prescriptions notwithstanding multiple red flags. The Board investigator also determined Respondents had an unlicensed pharmacy clerk perform pharmacy technician nondiscretionary tasks that require licensure by the Board.

/ / /

FIRST CAUSE FOR DISCIPLINE

(Failing to Ensure Legitimacy of Controlled Substance Prescriptions)

30. Respondents are subject to disciplinary action under Code section 4301, subdivision (j), because they failed to comply with their corresponding responsibility to ensure that they dispensed controlled substances only for a legitimate medical purpose in violation of Health and Safety Code section 11153, subdivision (a), all as more fully set forth in paragraphs 26 through 29 above, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Clearly Excessive Furnishing of Controlled Substances)

31. Respondents are subject to disciplinary action under Code section 4301, subdivision (d), for clearly excessive furnishing of controlled substances in violation of Health and Safety Code Section 11153, subdivision (a), as set forth in paragraphs 26 through 29 above, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Dispensing Prescriptions with Errors, Omissions,

Irregularities, Uncertainties, Ambiguities or Alterations)

32. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for dispensing prescriptions for controlled substances containing significant errors, omissions, irregularities, uncertainties, ambiguities and alterations, in violation of title 16, California Code of Regulations, sections 1761, subdivision (a) and subdivision (b), as set forth in paragraphs 26 through 29 above, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Dispensing Non-Complying Controlled Substance Prescriptions)

33. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for dispensing prescriptions for controlled substances that lacked statutorily required features, Health and Safety Code Sections 11162.1 and 11164, subdivision (a), as set forth in paragraphs 26 through 29 above, which are incorporated herein by reference.

/ / /

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

34. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct in that they engaged in the activities set forth in paragraphs 26 through 29 above, which are incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Gross Negligence against Respondent Luong)

35. Respondent Luong is subject to disciplinary action under Code section 4301, subdivision (c), for gross negligence in connection with dispensing controlled substances, as set forth in paragraphs 26 through 29 above, incorporated herein by reference.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Exercise and Implement Best Professional Judgment and Corresponding Responsibility against Respondent Luong)

36. Respondent Luong is subject to disciplinary action under Code section 4301, subdivision (o), for failing to exercise and implement his best professional judgment and corresponding responsibility when dispensing controlled substances, in violation of Code section 4306.5, subdivisions (a), (b) and (c), in that he, as set forth in paragraphs 26 through 29 above, incorporated herein by reference.

EIGHTH CAUSE FOR DISCIPLINE

(Allowing Unlicensed Clerk to Perform Licensed Tasks against Respondent Luong)

37. Respondent Luong is subject to disciplinary action under Code section 4113, subdivision (c), for allowing an unlicensed pharmacy clerk to perform tasks required to be performed by a licensed pharmacy technician in violation of Code section 4115, as set forth in paragraphs 26 through 29 above, incorporated herein by reference.

OTHER MATTERS

38. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 53920 issued to Modern Drug, Inc., dba Modern Drug, Respondent Modern Drug shall be prohibited from serving as a manager, administrator, owner, member, officer, director,

associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 53920 is placed on probation or until Pharmacy Permit Number PHY 53920 is reinstated if it is revoked.

39. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 53920 issued to Modern Drug, Inc., dba Modern Drug, while Quoc Chan Luong has been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Respondent Luong shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 53920 is placed on probation or until Pharmacy Permit Number PHY 53920is reinstated if it is revoked.

40. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 65421 issued to Quoc Chan Luong, Respondent Luong shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 65421 is placed on probation or until Pharmacist License Number RPH 65421 is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 53920 issued to Modern Drug, Inc., dba Modern Drug;

2. Revoking or suspending Pharmacist License Number RPH 65421 issued to Quoc Chan Luong;

3. Prohibiting Respondent Modern Drug, Inc., dba Modern Drug from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 53920 is placed on probation or until Pharmacy Permit Number PHY 53920 is reinstated if Pharmacy Permit Number PHY 53920 issued to Respondent Modern Drug, Inc., dba Modern Drug is revoked;

4. Prohibiting Respondent Quoc Chan Luong from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy

Permit Number PHY 53920 is placed on probation or until Pharmacy Permit Number PHY 53920 is reinstated if Pharmacy Permit Number PHY 53920 issued to Modern Drug, Inc., dba Modern Drug is revoked;

5. Prohibiting Respondent Quoc Chan Luong from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 65421 is placed on probation or until Pharmacist License Number RPH 65421 is reinstated if Pharmacist License Number RPH 65421 issued to Quoc Chan Luong is revoked;

6. Ordering Modern Drug, Inc., dba Modern Drug, and Quoc Chan Luong, 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; and,

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

DATED: August 1, 2019

ANNE SODERGREN
Interim Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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