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

In the Matter of the Accusation Against:	)	
	)	
TOT PHARMACY,	)	Case No. 2683
dba ALL MED DRUGS,	)	
CAROL ZALEZ-SIMON,	)	OAH No. L2003120195
Pharmacist-in-Charge,	)	
Pharmacy Permit No. PHY 45269,	)	
	)	
and	)	
	)	
CAROL MARIE ZALEZ-SIMON,	)	
Pharmacist No. RPH 41523,	)	
	)	
Respondents.	)	
	)	

DECISION AFTER NONADOPTION

Daniel Juárez, Administrative Law Judge with the Office of Administrative Hearings, heard this matter on July 18-20, and 23-27, 2007, in Los Angeles, California.

Michel W. Valentine, Deputy Attorney General, represented Virginia K. Herold (Complainant), Acting Executive Officer of the Board of Pharmacy (the Board). Patricia F. Harris was the Board's Executive Officer and the original complainant when the Accusation was signed, on October 21, 2003.

Victor Sherman, Attorney at Law, Victor Sherman & Janet Sherman, represented Carol Marie Zalez-Simon (Respondent Simon). Respondent Simon was present during each day of hearing.

Hemal Master, Attorney at Law, Frandzel Robins Bloom & Csato, represented Respondent TOT Pharmacy (Respondent TOT).

At hearing, Complainant amended the Accusation (dated October 21, 2003) as follows. On page 11, line 19, the date, "July 24, 2002" was replaced with "June 24, 2002."

The proposed decision of the Administrative Law Judge was submitted to the Board on August 23, 2007. After due consideration thereof, the Board declined to adopt said proposed decision and thereafter on November 5, 2007 issued a Notice of NonAdoption of Proposed Decision and subsequently issued an Order Fixing Date for Submission of Written Argument on May 6, 2008 and an Amended Order Fixing Date for Submission of Written Argument on May 16, 2008. The time for filing written argument in this matter having expired, written argument having been filed by all parties and such written argument, together with the entire record, including the transcript of said hearing, having been read and considered, pursuant to Government Code Section 11517, the Board hereby makes the following decision and order[1]:

FACTUAL FINDINGS

1. On October 21, 2003, Complainant Patricia F. Harris, authorized the Accusation; this action then ensued. On August 2, 2006, Complainant Virginia K. Herold, authorized the First Supplemental Accusation. On December 22, 2006, Complainant Herold signed the First Amended and Supplemental Accusation. On October 28, 2003, Respondent TOT, through its then-attorney, signed its Notice of Defense. On November 17, 2003, Respondent Simon, through her then-attorney, signed her Notice of Defense.

The Parties' Contentions

2. Complainant contends Respondent Simon's actions merit revocation of her pharmacist license for unprofessional conduct, and because Respondent TOT (also referred to herein as All Med Drugs) was the licensed pharmacy under which Respondent Simon worked, Complainant also seeks discipline against Respondent TOT's pharmacy license. Complainant's case focused largely on her allegation that Respondent Simon dispensed excessive amounts of controlled substances to various patients; the nature of the excess included quantity, in some cases, and dosage in others. In addition, Complainant alleged that Respondents excessively furnished controlled substances to a patient when a prescription was dispensed prior to the consumption of the previous prescription and when Respondents failed to properly fill prescriptions from February 6, 2002 to March 11, 2003 by dispensing large quantities of multiple controlled substances concurrently for a patient. (State's Ex. 1; p. 7:24-26, p. 8:9-11.) Regarding Respondent Simon, Complainant more specifically alleged that Respondent Simon knew or had reason to know that the prescriptions at issue were not for legitimate medical purposes, acted incompetently by failing to consult with the patients or prescribing physicians regarding the allegedly excessive prescriptions, and failed to review patient profiles before furnishing the medications. Complainant also alleged Respondent Simon changed the dosage and strength of a prescription without authorization, acted with gross negligence by dispensing early refills, and wrote a check to herself under false pretenses. Complainant further alleged that Respondent Simon failed to maintain accurate accountability of certain

[1] Citations to the record are included throughout this decision where the factual findings differ substantively from those in the Proposed Decision of the Administrative Law Judge.

controlled substances, failed to submit prescription information for Schedule II controlled substances, as required, and filled prescriptions without authorization. Complainant additionally alleged Respondent Simon failed to remove expired drugs from the pharmacy, and failed to maintain adequate security of controlled substances, resulting in the dispensing of unauthorized prescriptions and refills by a pharmacy technician.

3. Respondent Simon denied Complainant's allegations, and despite several stipulations to the facts alleged, she nonetheless contended Complainant's Accusation should be dismissed. Respondent TOT argued that it placed its confidence in Respondent Simon, took no active part in the alleged misdeeds, and therefore, Respondent TOT's license did not merit discipline.

Respondents' Certification

4. (a) The Board issued pharmacist license number RPH 41523 to Respondent Simon, on April 23, 1988; it expires on May 31, 2009, unless renewed. The Board issued pharmacy permit number PHY 45269 to Respondent TOT on July 27, 2001; it expires on July 1, 2008, unless renewed. Respondents' two licenses were in full force and effect at all times relevant to the charges brought by Complainant in this action. The Board has never disciplined either of Respondents' licenses before the filing of the instant Accusation.

Respondent Simon's Background

(b) Respondent Simon graduated from the University of Southern California in 1982 with a Bachelor's Degree in Biology. She graduated from the University of the Pacific's School of Pharmacy in 1987, with a Doctorate of Pharmacy. She has consistently worked as a pharmacist since her graduation, and has been the Pharmacist-in-Charge in six or seven different pharmacies during her career. At times (the evidence did not determine exact dates), Respondent Simon has had membership in both state and national pharmacist associations. Respondent Simon has been involved in various volunteer activities in her community. Respondent Simon takes pride in being a pharmacist and loves the field of pharmacy.

(c) On a date uncertain, in approximately 2001, Respondent Simon and two other individuals purchased the pharmacy, All Med Drugs, in Thousand Oaks, California. The pharmacy was not particularly profitable, and over a period of time, her relationship with her two co-owners deteriorated. In approximately December 2003, Respondent Simon sold her interest in the pharmacy.

(d) Respondent Simon was the Pharmacist-in-Charge at All Med Drugs from July 27, 2001 to June 30, 2003, and then again from July 14, 2003 to October 10, 2003.

The Original Complaint

5. On or about November 6, 2002, the father of R.S.,[2] a patient for whom Respondent Simon had filled and dispensed medications at All Med Drugs, filed a complaint with the Board, alleging Respondent Simon had dispensed unauthorized refills of pain medications to R.S. That complaint led to the Board investigation that eventually led to this action against Respondents. The Board's investigation yielded voluminous records regarding prescriptions filled and dispensed at All Med Drugs to various patients by Respondent Simon and/or by pharmacy staff while Respondent Simon was the Pharmacist-in-Charge.

The Sizeable and Copious Prescriptions

6. The evidence established that, as set forth in Tables A and B, (Factual Findings 7 and 8), a Dr. Michael Huff prescribed the dosages and quantities of medications for the various patients noted, and that those prescriptions were filled and dispensed at All Med Drugs to the patients while Respondent Simon was the Pharmacist-in-Charge. With the exception of Prescription No. 842666, Table A lists prescriptions that Complainant alleged were beyond the recommended dose and dosing frequency. [3] Table B lists prescriptions that Complainant alleged were filled for large quantities.

7. TABLE A

Patient	Medication	Rx #	Rx Date	Quantity	Dosage	Estimated Supply
B.B.	OxyContin (80 mg.)	835221	8/28/02	300 tablets	2-3 tablets, 3 times per day and as needed[4]	Not established.
T.M.	OxyContin (80 mg.)	847302	2/13/03	450 tablets	5 tablets, 3 times per day	30 days
	OxyContin (80 mg.)	846241	1/31/03	300 tablets	5 tablets, 3 times per day, as needed	20 days
	OxyContin (80 mg.)	842666	12/12/02	300 tablets	4 tablets, 3 times per day	25 days
J.R.	OxyContin (80 mg.)	836087	9/10/02	1,200 tablets	12 tablets, 3 to 4 times per day	30 days

[2] In lieu of their names, the initials of all patients discussed in this Proposed Decision are used to protect their privacy.

[3] Complainant alleged that Prescription No. 842666 was dispensed prior to the consumption of the previous prescription. (State's Ex. 1, p. 7.)

[4] The insert publication from the drug manufacturer of OxyContin reads that OxyContin is not intended to be used as an "as needed for pain" analgesic.

D.S.	Actiq (1,600 mcg.)	824507	4/1/02	360 lozenges	2-3 lozenges, every 2 hrs., as needed for pain	10 days
	Actiq (1,600 mcg.)	833274	7/30/02	360 lozenges	1 or 2 lozenges, every 2-3 hrs.	30 days
	Actiq (1,600 mcg.)	833855	8/7/02	360 lozenges	1-2 lozenges, every 2-3 hrs.	15 days
	Actiq (1,600 mcg.)	835399	8/29/02	360 lozenges	1-2 lozenges, every 2-3 hrs., as needed for pain	16 days
	Actiq (1,600 mcg.)	837795	10/4/02	360 lozenges	1-2 lozenges, every 2 hrs., as needed for pain.	15 days
	Actiq (1,600 mcg.)	839696	11/1/02	360 lozenges	1-2 lozenges, every 2 hrs., as needed for pain	15 days
	OxyContin (80 mg.)[5]	841656	11/26/02	1,000 tablets	7-8 tablets, 3 times per day	42 days
	Actiq (1,600 mcg.)	842511	12/10/02	360 lozenges	1-2 lozenges every 3 hrs., as needed for pain	22 days
	Actiq (1,600 mcg.)	844496	1/7/03	360 lozenges	2-3 lozenges, every 1-2 hrs.	15 days
	OxyContin (80 mg.)	833275	7/30/02	1,000 tablets	7-10 tablets, 4 times per day	25 days

8. TABLE B

Patient	Medication	Rx #	Rx Date	Quantity	Estimated Supply
K.B.	Roxicodone (30 mg.)	836842	9/20/02	500	12 days
	Roxicodone (30 mg.)	839522	10/29/02	500	16 days
	OxyContin (80 mg.)[6]	841553	11/26/02	360	30 days
J.R.[7]	OxyContin (80 mg.)	835044	8/26/02	800	30 days
	OxyContin (80 mg.)	836087	9/10/02	1,200	30 days

[5] Complainant identified this prescription as Actiq (1,600 mcg.) in the Accusation, however, the evidence established the prescription was OxyContin, as noted in Table A.

[6] Complainant identified this prescription as Roxicodone (30 mg.) in the Accusation, but the evidence established the prescription was OxyContin, as noted in Table B. (State's 10 sub 44, p. 186.)

[7] Complainant alleged in the Accusation that Respondent Simon filled large quantities of Dilaudid (8 mg.) for J.R. as prescription number 835671 (State's Ex. 1.). At hearing, Complainant explained that the prescription number should have read "842671," (RT 7/23/07 185:6-9.) The evidence did not show that prescription 842671 fell below the standard of care (RT 7/23/07:183-184). Consequently, that prescription is not listed in Table B.

	OxyContin (80 mg.)	837624	10/2/02	1,100	15 days
	OxyContin (80 mg.)	839323	10/28/02	1,000	8 days
	Roxicodone (30 mg.)	835045	8/26/02	300	30 days
	Roxicodone (30 mg.)	836089	9/10/02	1,000	12 days
C.S.	OxyContin (80 mg.)	836420	9/13/02	500	30 days
	OxyContin (80 mg.)	847020	2/10/03	450	30 days
	Roxicodone (30 mg.)	847022	2/10/03	360	30 days
D.S.[8]	Actiq (1,600 mcg.)	Includes Table A entries.			
	OxyContin (80 mg.)	821977	3/1/02	1,000	30 days
	OxyContin (80 mg.)	824509	4/1/02	1,000	47 days
	OxyContin (80 mg.)	832350	7/17/02	1,000	30 days
	OxyContin (80 mg.)	833857	8/7/02	1,000	25 days
	OxyContin (80 mg.)	835400	8/29/02	1,000	25 days
	OxyContin (80 mg.)	837796	10/4/02	1,000	35 days
	OxyContin (80 mg.)	842572	12/11/02	1,000	31 days
	OxyContin (80 mg.)	843535	12/23/02	1,000	30 days
	OxyContin (80 mg.)	844495	1/7/03	1,000	30 days
L.T.	Dilaudid (8 mg.)	848840	3/6/03	800	33 days

9. OxyContin and Roxicodone are the brand names for the generic drug, Oxycodone. (OxyContin and Roxicodone, as produced, serve distinct analgesic purposes. See Factual Finding 22, post.) Actiq is the brand name for the generic drug, Fentanyl. Dilaudid is the brand name for the generic drug, Hydromorphone. All of these medications are considered narcotic analgesics; they are all Schedule II controlled substances.

Respondents' Pharmacy Practices

10. Respondent Simon testified regarding her regular pharmacy practices. She made sure that all pharmacists, clerks and technicians knew that every new prescription required consultation. (RT 7/26/07 112:5-8.) To keep staff informed of that requirement, All Med Drug's policy required every new prescription to receive a yellow sticker or rubber stamp that said "Patient consultation required." (RT 7/26/07 112:3-23; 113:19-22.) According to Simon, after verbal consultations, each patient was required to sign a "signature log" as proof of consultation. (RT 7/26/07 142:14-18; 143:10-24.) Each patient would receive a computer-generated consultation sheet for their medications. (RT 7/26/07 112:24-25; 113:1-7.)

11. When a Schedule II prescription was presented, the clerk would take down the address, date of birth, drug allergies and insurance (RT 7/26/07 116:9-11). A typist would input the information into the computer to create a label (RT 7/26/07 119:6-19). Once the label was created, the computer would generate instructions about using that particular medication (RT 7/26/07 120:11-14.) The typing clerk would then place the information in a plastic container or "boat" for the pharmacist to fill (RT 7/26/07 120:15-21).

[8] D.S.'s Actiq prescriptions noted in Table A are included in Table B.

12. Once Respondent Simon received a prescription, she would check her stock to see if she had the medication, check the expiration date on the medication and compare the patient's name to the name on the prescription. (RT 7/26/07 121:4-9, 18-25.) She would "look at the drug itself," "the quantity" and "the dosage." (RT 7/26/07 125:18-19.) If she had no questions about a prescription, she would fill the prescription if she had the drug in stock. (RT 7/26/07 128:4-10.). If she had a question about the prescription itself, she would contact the doctor, look at the patient's drug history in the computer, or ask the patient. (RT 7/26/07 125:19-25; 126:13-18; 126:4-8.) Reviewing the entire patient drug history was something that Respondent Simon testified that she "always" did (RT 7/26/07 127:4-17; 199:25, 200:1-3). Regardless, for the reasons set forth in Factual Findings Nos. 20 to 26, it was not established that the foregoing processes or procedures were actually followed for the prescriptions at issue in this case.

13. Respondent Simon testified at hearing that it was a regular practice of the pharmacy to input into the computer information about some patients that needed "a little bit more work." (RT 7/26/07 145:2-21.) However, Respondent's testimony was extremely vague in this area. It was not established that there was any standard regarding what kinds of information were placed into the computer or which patients were considered "a little bit more work". As a result, Respondent Simon's testimony did not establish what kinds of patient information, if any, were regularly maintained by Respondents' pharmacy to assist the pharmacists working there with patient issues.

14. Respondent Simon further claimed that, depending on the situation and the patient and medication, she maintained a "clipboard" on which she made notations on particular patients for particular things that were going on and to remind her in the future of her concern. (RT 7/26/07 145:22-25; 146:19-25; 147:1.) When pressed about why she had not produced the clipboard at hearing, Respondent Simon implied that her "notes" from the clipboard were taken by the Sheriff's Office during a raid on Respondents' pharmacy on March 11, 2003. (RT 7/27/07 46:3-15.)[9]

15. However, other evidence in the record casts doubt on Respondent Simon's representation that she maintained a clipboard. The Board's investigator testified that during an inspection on March 13, 2003 she questioned Respondent Simon about her documentation and patient drug profile practices relating to the dispensing of controlled substances. Specifically, she asked Respondent Simon whether she kept a file on each patient who was receiving large quantities of controlled substances and if she knew the patient's diagnosis for the use of the controlled substances. According to the Board's investigator, Respondent Simon's response to her was "we are busy, we don't have time to review everyone's profile and how do you expect us to fill prescriptions." (RT 7/20/07 66:1-14; State's Ex. 10, p. 41.) At hearing, Respondent Simon denied saying those exact words to the Board's investigator (RT 7/27/07 42:1-10), but stopped short of accusing the investigator of lying. Respondent never explained what she "exactly said" to the

[9] Two days after the hearing began in this matter, Respondent's counsel served a subpoena on the Custodian of Records for the Ventura County Sheriff's Department (Respondent's Ex. I). However, the records sought by the subpoena do not include any "notes" taken from a clipboard.

investigator on March 13, 2003. The documentary evidence lends support, however, to the Board investigator's representations. While the investigator's reports of the inspection recite the alleged admissions by Respondent Simon and other correspondence and conversations she had with Respondent Simon regarding the handling of controlled substances, the reports do not mention Respondent's maintenance of any "clipboard" or "notes" for patient issues relating to controlled substances. (State's Exs. 10, 7, 7 sub 26.) Other inspection and investigative reports and Respondent Simon's statements to the Board regarding new documentation practices are similarly silent. (State's Exs. 8, 9, 9 sub 1.) Regardless, Respondent's testimony regarding the alleged clipboard was neither probative nor persuasive. Respondent was vague about when or what type of "situation" or "particular thing" would warrant inclusion on her "clipboard." As a result, it was not established what types of concerns, if any, would be documented on the alleged clipboard.

16. Respondent Simon considered herself "very knowledgeable" about OxyContin and Roxicodone in 2002 and 2003 because she made it a point to study and learn medications (RT 7/26/07 129:13-18). She read "package inserts quite a bit," took continuing education classes, subscribed to magazines, and questioned Dr. Huff about the medications. (RT 7/26/07 129:20-25; 130:1.) Respondent Simon maintained that she was "anal" about her job duties as a Pharmacist-in-Charge. (RT 7/26/07 29:21-24.) However, Respondent Simon admitted that sometimes she would sign, log and submit prescriptions to the Drug Enforcement Administration (DEA) that another pharmacist had filled. (RT 7/27/07 71:4-14.)

17. Respondent Simon understood that pharmacists have a corresponding responsibility to determine that prescriptions written for controlled substances are for legitimate medical purposes only. (RT 7/26/07 130:17-24; 7/27/07 61:11-21.) At various times during her career, Respondent Simon had refused to fill and dispense prescriptions for patients in cases where she determined the prescription was invalid or where she otherwise concluded that the patient was attempting to obtain medications under false pretenses. Respondent understood a prescription was valid "If the prescription is written for legitimate use and if everything on the prescription fulfills what is required for a prescription to be legal and valid." (RT 7/26/07 152:8-12.) To determine whether the prescription was being written for a legitimate use, she would call the doctor, talk and look at the patient, and look at the prescription to make sure it had all of the information, including doctor's signature, drug name, dosage, quantity, date of the prescription and the doctor's information. (RT 7/26/07 152:13-25.) She understood an illegal prescription was one that was not issued for "legitimate use or a prescription, again, that didn't have all the information, signature that was required on the face of the prescription itself." (RT 7/26/07 153:1-6.) Regardless, no one refused to fill the prescriptions listed in Tables A and B while Respondent Simon was the Pharmacist-in-Charge at All Med Drugs.

Past Practices and General History Concerning Medications Prescribed by Dr. Huff

18. On a date uncertain in 2001, Respondent Simon testified that she became concerned about patients presenting prescriptions for the types of drugs discussed in this case (Schedule II type drugs similar to those noted in Tables A and B) at All Med Drugs. (RT 7/26/07 80:6-12; 82:16-24.) Specifically, she was concerned about the large doses of the various medications (RT 7/26/07 82:13-25, 83:1-25; 88:9-10). She noted that all of the prescriptions emanated from one physician, Dr. Michael Huff. On a date uncertain, in approximately September 2001, Respondent Simon telephoned the Medical Board of California inquiring about Dr. Huff (RT 7/26/07 80:13-17). Respondent Simon specifically inquired as to whether Dr. Huff was a licensed physician in good standing with the Board, and whether the Board had ever disciplined Dr. Huff in any way; the Medical Board's responses were not established by the evidence, but it was established that the Medical Board's responses allayed Respondent Simon's concerns. In approximately July 2001, Respondent Simon also telephoned the Board of Pharmacy regarding the large doses and quantities of Schedule II narcotics being prescribed (RT 7/26/07 193:6). The evidence did not establish what the Board told her during the phone call, but after the phone call, Respondent Simon believed it was appropriate to use her professional judgment in filling and dispensing prescriptions from Dr. Huff. Respondent Simon did not document her telephone calls to the Medical and Pharmacy Boards.

19. Sometime thereafter, possibly in September 2001, Respondent Simon met Dr. Huff in person. (RT 7/26/07 190: 10-17.) She told Dr. Huff about her concerns with the quantity and frequency of his narcotic prescriptions. They discussed generally Dr. Huff's pain medication philosophy and his work with patients with chronic pain and cancer (RT 7/26/07 89:12-14). After their meeting, Respondent Simon developed respect for Dr. Huff's philosophy on pain control and considered his prescriptions a rational way to treat patients with chronic pain. Respondent Simon did not document her meeting with Dr. Huff. After that meeting, whenever a prescription from Dr. Huff raised a concern for Respondent Simon, she would call Dr. Huff and speak to him or to his staff. Respondent Simon testified that when she was able to speak to Dr. Huff himself, she was satisfied with his answers and disagreements were resolved when he would take the time to explain what he was doing for the patient (RT 7/26/07 94:5-25, 95:1-3). The evidence did not establish how often or which subsequent prescriptions concerned Respondent Simon. Further, the evidence did not establish that Respondent Simon documented her consultations with Dr. Huff and the rationale he provided for prescribing any of the specific medications at the doses, frequencies or quantities established in this case.

Prescriptions Dispensed in this case and Respondent Simon's Testimony

20. Respondent Simon estimated that approximately 200,000 prescriptions were filled during the time she was Pharmacist-in-Charge. (RT 7/26/07 161:15-21.) When questioned at hearing regarding specific prescriptions at issue in this case, Respondent Simon admitted that she could not remember the prescriptions (RT 7/27/06 54:10-24; 161:8-10; 72:7-16; 75:1-12; 89:22-25; 90:16-17).

21. Respondent Simon repeatedly stated in response to questions about the prescriptions listed in Tables A and B, that there was no "high end upper limit" for prescribing or dispensing Schedule II drugs as long as the package insert said there was no limit. (RT 7/26/07 132:8-23; 201:2-6.). Respondent Simon agreed, nevertheless, that "at some point she had a responsibility to monitor the patient to make sure the patient did not completely over utilize." (RT 7/26/07 135:19-25; 136:2-3; 138:2-3.) Respondent Simon agreed that hypothetically it would be irresponsible for a patient to take one million pills in one day. (RT 7/26/07 135:15-18.)

22. Respondent Simon testified generally about her pharmacy practice and how she exercised her professional judgment in deciding whether to fill prescriptions, particularly Schedule II prescriptions (See Factual Findings 10-19). Respondent Simon then opined that the filling of various kinds of prescriptions at the times, and for the dosages and quantities alleged in this case were "not a problem" and of "no concern" to her. (RT 7/26/07 133:17-25; 134:1-2; 136:16-25; 137:17-25; 7/26/07 149:10-16; RT 7/26/07 140:3-19.) However, the record did not establish that Respondent had any foundation for her opinions, as she could not determine whether she had handled any of the prescriptions in this case. Respondent admitted that because of her practice of signing prescriptions that she did not fill, she could not say "who did work on what prescription when." (RT 7/27/07 71:4-19.) Thus, her opinions are not entitled to any weight.

23. Respondent Simon also provided conflicting testimony regarding her ability to recall patients and their medication. When presented with Prescription No. 839323 for J.R. in the amount of 1,000 Oxycontin with directions to take up to 125 tablets per day, Respondent Simon first stated that she did not remember the prescription or the patient "per se." (RT 7/27/07 72:8-16.) However, she later remembered J.R. "clearly" and the fact that she did consult with a doctor before dispensing the prescription. (RT 7/27/07 74:1-19.) Thus, her opinions are not entitled to any weight.

24. The record further demonstrated that Respondent Simon provided conflicting testimony regarding who was responsible for dispensing prescriptions in this case. When questioned about the filling of unauthorized prescriptions for R.S., Respondent Simon testified that she didn't "fill any of these five prescriptions. These are not my writing. My initials are not on them." (RT 7/27/07 57:19-21.) However, when later questioned regarding a prescription that did show her signature (Prescription No. 839323 for patient J.R.), Respondent Simon said she did not know whether she filled that prescription (RT 7/27/07 70:18-22; State's Ex. 10 sub 68 p. 10 of 13.). Respondent Simon explained that "I signed the prescriptions but that doesn't mean I filled it." (RT 7/27/07 71:1-2.) Respondent Simon then testified that another pharmacist would fill some of the prescriptions but refused to sign them or was "lazy" and that he would leave them for her to sign, log and submit to the DEA. (RT 7/27/07 71:4-14.) As a result, Respondent admitted that she could not say "who did work on what prescription when." (RT 7/27/07 71:15-19.) This conflicting testimony makes Respondent Simon less credible.

25. The record also demonstrates that Respondent Simon had a selective memory and was evasive when questioned about prior statements that she provided to law enforcement. On March 11, 2003, the Ventura County Sheriff's Department raided Respondents' pharmacy. (RT 7/26/07, 166-169.) Respondent Simon gave a statement to investigators regarding prescriptions that she filled for Dr. Huff's patients. (RT 7/26/07 195:22-25; State's Ex. 10 sub 125.) Respondent was questioned regarding these statements, some of which appeared to conflict with her testimony at hearing. Respondent had previously testified that she believed Dr. Huff had a "great" reputation and learned he was considered a pain management specialist from other pharmacists in the area (RT 7/26/07 95:14-19; 96:3-19; 7/27/07 12:22-25, 13:1-2.) She previously maintained that there was no "high end upper limit" for prescribing or dispensing Schedule II drugs as long as the package insert said there was no limit. (RT 7/26/07 132:8-23; 201:2-6.) The investigator's memorandum indicated that Respondent Simon made the following statements to law enforcement: (1) that she was told it was appropriate to fill the large quantity prescriptions for Dr. Huff by the "State Medical Board of Pharmacies" (State's Ex. 10 sub 125, p. 3 of 8); (2) that she feels that "she has no responsibility whatsoever when it comes to drug diversion" (State's Ex. 10 sub 125, p. 4 of 8); (3) that there is a "high-end limit to triplicate prescriptions" (State's Ex. 10 sub 125, p. 4 of 8); (4) that she was aware that some of Dr. Huff's prescribing practices are "not accepted by other doctors in the area" (State's Ex. 10 sub 125, p. 2 of 8), and, (5) that she will turn away a patient if she felt "the prescription was not warranted or if it's not within the legal therapeutic range" (State's Ex. 10 sub 125, p. 3 of 8). When questioned about these statements at hearing, Respondent Simon said she did not remember making those statements. (RT 7/26/07 198:3-8, 200:8-14, 201:8-22, 202:3-6; 7/27/07 11:5-13.)

26. Upon later questioning by her attorney, however, Respondent Simon was specifically able to recall details about what she told law enforcement on March 11, 2003, despite her previous claimed inability to remember what she said. She remembered that she told the investigator that she called the "State Medical Board of Pharmacy" (RT 7/27/07 93:9-25). Respondent Simon recalled telling law enforcement that whenever she felt the prescription dosage was very high, she called the doctor to verify the amount (RT 7/27/07 94:12-16.) Consistent with the statement prepared by investigators, Respondent Simon further recalled that she had told the investigators about looking up an unnamed drug with another pharmacist and learning that there was "no high end limit" (RT 7/27/07 94:25; 95:4-7; State's Ex. 10 sub 125, p. 7 of 8). When questioned whether her March 11, 2003 statement was honest, Respondent Simon stated "I don't remember what I said. I was so angry and upset." (RT 7/26/07 196:21-24.)

Standards of Care for Pharmacy Practice -- The Opinions of Pharmacist Jeb Sydejko

27. Complainant called Jeb Sydejko, a licensed pharmacist (licensed in California and Nevada) to testify as an expert on the standard of pharmacy practice in this matter. Complainant engaged Sydejko to review and assess Respondents' actions in this matter. Sydejko graduated from the University of Southern California, School of Pharmacy in 1985. His employment experience includes the following: Staff Pharmacist at Sav-On Drug Store (Sylmar, California), from 1985 to 1987; Chief Pharmacist at Saugus Drugs,

Inc. (Santa Clarita, California), from 1987 to 1998; and Pharmacist-in-Charge and Pharmacy Manager at Sav-On Drug Store (Sylmar, California), from 1998 to 2002. From 1999 to the present, Sydejko has been the Chief Pharmacist at Sayre Medical Pharmacy, in Sylmar, California. Since 1996, he has been a pharmacy consultant on various issues, including prescription drug profiles, and an expert witness and reviewer in civil and criminal cases, including disciplinary cases and actions for the California State Board of Pharmacy ("Board"). (RT 7/23/07 128:20-25; 129:1-19.) Sydejko has provided opinions for the Board regarding the standard of care for a reasonably prudent pharmacist in the practice of pharmacy and the standard of care for a pharmacist that involved the dispensing of large numbers of narcotics, including OxyContin and Hydrocodone derivatives (RT 7/23/07 121:6-17; 7/23/07 122:5-9;7/24/07 161:19-25; 164:2-20). Sydejko wrote two publications (TCB Publishing), a consumer-oriented book regarding how to avoid medication errors entitled, "Four Steps to a Safer Prescription," (2001) and "AccuRx" (2003). (RT 7/23/07 126:18-23.) While Sydejko could not specifically recall all of the continuing education courses that he had taken, he testified that he had taken a course in 2006 relating to opiate medications entitled "Use of Long Acting Opiates for Chronic Pain: An Update on Issues, Research, and Treatment Trends." (RT 7/24/07 146; 7/26/07:9:10-21; State's Ex. 16B.) Sydejko generally recalled taking courses developed by pharmaceutical companies to help him understand new drugs, new trends or new developments (RT 7/24/07 147:15-19.) Through his employment, he receives literature and materials on pain management from a colleague who is a member of the Pharmaceutical Association of California and the North East Valley Pharmaceutical Association of California (RT 7/24/07 158:18-25; 159:1-4). He also holds a Juris Doctorate from the Whittier College School of Law (1993).

28. At hearing, Respondent's counsel objected to the admission of Sydejko's opinion and testimony for the following reasons. Sydejko belongs to no national, state, or local professional pharmacist associations. He did not establish that he has taken any significant number of continuing education courses or written any publications on subject matters related to the issues in this case. Sydejko did not provide evidence that he has taught any academic courses in related subject matters at any institution of higher learning. Additionally, the Administrative Law Judge in this matter concluded that Sydejko only "maintains contact and knows the pharmacists that are within an approximate five mile radius of his employment." The Administrative Law Judge then determined that Sydejko did not demonstrate he had a knowledge base regarding how pharmacists in the greater community practice. As a result, the Administrative Law Judge believed Sydejko's opinion was entitled only to "moderate weight" as an expert in the field of pharmacy.

29. However, there was no evidence in the record that Sydejko, who practices in Sylmar, could not testify as to the standard of care in Thousand Oaks, the location of All Med Drugs. Both communities are urban and located in neighboring Southern California counties (Ventura and Los Angeles). More importantly, there was no evidence in the record that a pharmacist's knowledge base regarding the proper dispensing of federally regulated Schedule II narcotics would vary from city to city or community to community. Sydejko's background showed 22 years of experience as a pharmacist dispensing thousands of Schedule II narcotics (RT 7/24/07 157:15-21). Sydejko has also testified as

an expert witness in cases involving the dispensing of large quantities of narcotics, including OxyContin, a drug at issue in this case. Sydejko was also the only expert witness presented in this case. Therefore, Sydejko's opinions are conclusive and cannot be disregarded as an expert in the field of pharmacy.

30. The standard of pharmacy practice was established through the testimony of Jeb Sydejko. Except as noted herein, Sydejko opined that Respondent Simon departed from the standard of care (of a reasonable and prudent pharmacist) by filling and dispensing the medications in Tables A and B.[10] Whether Respondent Simon actually filled and dispensed the medications, or another pharmacy staff person did so, Sydejko opined that, as the pharmacist-in-charge, Respondent Simon was responsible for the actions of the pharmacy staff and the safety of the medications. According to Sydejko, the pharmacist-in-charge is ultimately responsible for the pharmacy's actions, and has the obligation to maintain the standard of care for the pharmacy as a whole. Regarding the prescriptions in Tables A and B, Sydejko considered the quantities, dosages, and the frequencies of the fills and refills to be excessive, to such a degree, that Respondent Simon should have refused to fill and dispense those prescriptions. Sydejko further opined that even though no law or rule specifically requires a pharmacist to document a consultation with a patient or physician, the standard of care would compel a reasonable and prudent pharmacist to do so; and in this matter, with the extraordinary quantities and dosages of narcotic medications at issue, failing to do so demonstrated incompetence. Sydejko opined that Respondent Simon departed from the standard of care in all actions alleged by Complainant in the Accusation, the First Supplemental Accusation, and the First Amended and Supplemental Accusation (except as noted herein).

31. Sydejko reviewed the evidentiary documents in this case, including patient drug histories (though he did not review the medical charts of any patient in this case, nor was he aware of any patient's diagnosis or previous drug therapies). Sydejko produced a written report that was admitted into evidence and included his opinions on Respondent Simon's actions. (State's Ex. 16.) Sydejko set forth the standards he used to assess Respondent Simon. He first clarified that it would be "unconscionable" to conclude that a pharmacist had violated laws or departed from the standards of practice, based solely on the quantities of controlled drugs dispensed. An assessment of a pharmacist's dispensing practice requires consideration of a number of factors, particular to each patient, to determine if a large quantity, high dosage and/or too frequently refilled prescription should be dispensed. (See Factual Findings 32, 34.)

32. Pharmacists must accept or honor a valid prescription for a narcotic analgesic and refuse invalid prescriptions (State's Ex. 16, p. 3). To be valid, a prescription must be for a legitimate medical purpose. Factors that a pharmacist should consider in determining if a prescription is for a legitimate medical purpose include, but are not limited to, the following: the physician's prescribing habits, the physician's reputation, the type,

---

[10] Two prescriptions (alleged in the Accusation) were not included in Table A because Sydejko opined those prescriptions did not fall below the standard of care; the evidence did not prove otherwise. Similarly, 15 prescriptions were not included in Table B for the same reason.

quantity, and directions of the prescribed medication, the pharmacist's relationship with the patient and with the prescribing physician, the demeanor and appearance of the patient, whether there is a history of excessive refills, communications with the patient, and the nature of the patient's payment. (State's Ex. 16, p. 3.)

33. In describing this responsibility further, Sydejko wrote (italics in original, below),

> Pharmacists may also at times be presented with a valid prescription, but due to surrounding circumstances, the pharmacist may choose not to fill the prescription. This situation is most evident where in the judgement of the pharmacist, filling the prescription in effect will cause more harm to the patient compared to the potential harm caused by not filling the prescription. As indicted above, *'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'* [citing 21 C.F.R., § 1306.04(a)]. In laymen's terms, if in the judgement of the pharmacist, filling and dispensing a valid prescription would not be proper under the circumstances, then the pharmacist must not fill that prescription. If the pharmacist receives further information from the patient or physician indicating the prescription was for a legitimate medical need, a pharmacist must still look at the totality of the circumstances in deciding whether to fill the prescription in question. (State's Ex. 16, p. 4.)

34. Sydejko agreed that the Board's July 2001 and October 2003 editions of the Board's newsletter, "The Script" provided some guidance to pharmacists regarding what they should consider in exercising professional judgment. (RT 7/25/07 6:17-25; 7:1-6.) Aside from contacting the prescriber, pharmacists should also ask themselves questions about the drug history of the patient, the prescribing patterns of the physician, the type of drugs and their frequency and volume, the therapeutic appropriateness of the prescription, and how the length and quantity of the prescribed drug therapy compares to recognized and accepted prescribing practices. (RT 7/25/07 15, 33, 48, 49; State's Ex. 10 sub 3; Respondent's Ex. "E".) (RT 7/25/07 26:19-25; 27:1-13 regarding *Script* in July 2001; State's Ex. 10 sub 3.)

35. While Sydejko agreed the process by which a pharmacist determines whether a prescription is for a legitimate medical purpose is left to the discretion of the individual pharmacist, his report and testimony make it clear that there are certain established standards of practice that measure whether that discretion or judgment to dispense narcotics was exercised appropriately. (RT 7/25/07 15:7-12; 49:14-22; State's Ex, 16, p. 13.) Pharmacists must take an active role in monitoring and assessing the patient for effective pain therapy outcomes (State's Ex. 16, p. 13). Computers and software programs enable the pharmacist to monitor the patient for possible drug/drug interactions, drug/diet or drug/disease interactions as well as problems related to noncompliance or excessive use of narcotics. (RT 7/23/07 145:3-9; *Id.* at p. 14.)

36. Pharmacists taking on a specialty, such as pain management, should become educated in the specialized field (State's Ex. 16, p. 13, 15). Pharmacists must comply with state-mandated requirements for reporting the filling of Schedule II narcotics through the "Controlled Substances Utilization Review and Evaluation System." (*Id.* at p. 15.) Due to concerns regarding drug diversion, pharmacy practice is more strictly scrutinized when dispensing controlled substances. (RT 7/23/07 145:10-17.) Pharmacists deny refills for controlled substances if such refill is prior to the expected date based upon the previous prescription and daily usage indicated by the physician (aka "early fills"). (*Id.* at p. 15.)[11] However, at times, pharmacists may dispense medications when a situation presents itself that it is in the best interests of the patient to do so. (*Id.* at p. 15.) This means that the pharmacist should obtain, retain and update appropriate information documenting the course of and need for ongoing opiate therapy or the rationale for early fills of prescriptions (*Id.* at p. 8,11,15). When dispensing large quantities, pharmacists should carefully discuss dosage regiments and addiction propensities with patients and physicians (*Id.* at p. 13). Large quantities dispensed with an increase in drug quantities and changes in dosing schedules is indicative of opiate tolerance, so pharmacists should maintain consultation records indicating conversations with the patient or physician as to why there is an increase and where the patient is going with respect to pain control. (*Id.* at p. 8.)

37. The pharmacist must be familiar with a patient's history of prescriptions, at least those that were filled at that pharmacy and not being presented for the first time. (RT 7/23/07 185: 23-25, 186:1-4, 201:12-15; 207:4-7.) Upon filling a prescription, pharmacists must conduct a Drug Utilization Review (DUR) for every prescription. The DUR is conducted to determine compliance, abuse, drug/drug interactions, drug/disease state interactions, and the appropriateness of drug therapy. (State's Ex. 16, p. 15; RT 7/24/07 110:5-20.) Pharmacists must consult with the patient and document such consultation on any new prescription. (State's Ex. 16, p. 16.)

In sum, the pharmacist does not merely function as a mere instrument of the physician, "rubber stamping" and automatically filling prescriptions. The pharmacist has an independent duty to protect the patient by working in concert with the prescribing physician to safeguard against inappropriate or excessive opiate prescribing.

38. Except as noted herein, Sydejko opined that Respondent Simon departed from the standard of care (of a reasonable and prudent pharmacist) by filling and dispensing the medications in Tables A and B.[12] Whether Respondent Simon actually filled and dispensed the medications, or another pharmacy staff person did so, Sydejko opined that, as the pharmacist-in-charge, Respondent Simon was responsible for the

---

[11] Sydejko clarified that whenever he used the word "refill" with reference to controlled substances like OxyContin, he meant "fill," since a prescription for these types of drugs can only be filled once. (RT 7/24/07 38:3-25.)

[12] Two prescriptions (alleged in the Accusation) were not included in Table A because Sydejko opined those prescriptions did not fall below the standard of care; the evidence did not prove otherwise. Similarly, 15 prescriptions were not included in Table B for the same reason.

actions of the pharmacy staff and the safety of the medications. According to Sydejko, the pharmacist-in-charge is ultimately responsible for the pharmacy's actions, and has the obligation to maintain the standard of care for the pharmacy as a whole. Those obligations cannot be delegated to another pharmacist or staff person (7/24/07 120:8-24). Regarding the prescriptions in Tables A and B, Sydejko considered the quantities, dosages, and the frequencies of the fills and refills to be excessive, to such a degree, that Respondent Simon should have refused to fill and dispense those prescriptions. Sydejko further opined that even though no law or rule specifically requires a pharmacist to document a consultation with a patient or physician, the standard of care would compel a reasonable and prudent pharmacist to do so; and in this matter, with the extraordinary quantities and dosages of narcotic medications at issue, failing to do so demonstrated incompetence. Sydejko opined that Respondent Simon departed from the standard of care in all actions alleged by Complainant in the Accusation, the First Supplemental Accusation, and the First Amended and Supplemental Accusation (except as noted herein).

39. Sydejko felt that when considering the factors set forth in Factual Findings 31 through 37, Respondent Simon departed from the standard of care by filling and dispensing those prescriptions in Tables A and B. Sydejko opined that Respondent Simon has a corresponding responsibility, that is, a responsibility as a pharmacist, independent of the physician, but working in concert with the healthcare professionals, to care for the patient's health. According to Sydejko, Respondent Simon's corresponding responsibility allows, indeed compels Respondent Simon, to refuse to fill and dispense prescriptions if she determines that the prescription is not for a legitimate medical purpose, or if she is sufficiently uncertain as to some aspect of the medication's utility for the patient. However, in this case, Respondent Simon did not properly execute her corresponding responsibility. This case deals with large quantities of drugs and drugs that were filled frequently that have the potential for high tolerance and drug diversion. As a result and for the reasons set forth in Factual Findings 40 through 63, Sydejko opined that the prescriptions in Tables A and B were not valid and Respondent Simon should not have dispensed them. (RT 7/24/07 96-97:1-19.) Sydejko's specific opinion regarding Respondents' handling of each patient's prescription is set forth more fully below.

Medications dispensed in Tables A and B – Expert Opinion and Defenses

Patient B.B.

40. It was established that Respondents dispensed Prescription No. 835221 in quantities and dosages that were beyond the recommended dose and dosing frequency for OxyContin. A review of the patient's drug profile would have revealed that the prior prescription for 180 tablets of 80 mg. OxyContin dosed at 2-3 times per day "as needed" was filled on August 6, 2002. (State's Ex. 10 sub 44, p. 34.) Respondents dispensed B.B.'s prescription (835221) on August 28, 2002 for 300 tablets of 80 mg. OxyContin, which reflected an increase in quantity from the prior prescription and an early frequency for the filling of this drug. Proper documentation must be noted for increases in drug quantities, other than what appears on the face of the prescription. This includes

documentation of communication between the pharmacist and the physician and the pharmacist and the patient to understand why this medication was being prescribed early and why this increase was the appropriate therapy. Additionally, the insert publication from the drug manufacturer of OxyContin reads that OxyContin is not intended to be used as an "as needed for pain" analgesic; this is due to the fact that this drug is highly addictive. Nevertheless, this prescription contained directions that permitted the patient to dose "as needed." (State's Ex. 10 sub 44, p. 35; State's Ex. 16; RT 7/23/07 139:4-16, 141-142, 143:7-13; 7/24/07 11:8-13.)

41. There is no pharmacy documentation that either Respondent Simon or another pharmacist at All Med Drugs noted the increase in quantity that occurred with Patient B.B., or that Respondent Simon or any other pharmacist at All Med Drugs contacted Dr. Huff regarding his rationale for increasing the quantity for this prescription (see Factual Findings 13-15). Respondent Simon could not determine who had handled the various prescriptions in this case and had no specific recall of the prescriptions at issue in this case (see Factual Findings 20-24). Nevertheless, Respondent Simon opined that filling B.B.'s prescription was not below the standard of care despite the manufacturer's recommendation because "there is no upper limit" to the dispensing of Schedule II narcotics; there is no "beyond the recommended dose." (RT 7/26/07 147-149.) Respondent believed that when a package insert said "no upper limit", that "it was meant for pharmacists or the doctor as well." (RT 7/26/07 132:14-23.) Respondent Simon provided no independent expert opinion to support her belief that disregarding the manufacturer's recommendations for a highly addictive drug was an accepted standard of pharmacy practice. Respondent Simon's testimony was unpersuasive.

Patient K.B.

42. It was established that Respondents dispensed large quantities of Roxicodone and OxyContin when dispensing Prescription Nos. 839522 and 841553 for Patient K.B.[13] Sydejko explained that in chronic pain cases, it was appropriate (and common) to have prescriptions with large quantities of Roxicodone and OxyContin (though Sydejko made clear, generally not as large as those in Tables A and B). OxyContin works as a sustained release analgesic, providing long lasting pain relief that raises a patient's pain threshold, while Roxicodone is a quick release pain analgesic for the immediate relief of pain spikes. However, Sydejko opined that an increase in one medication should generally be seen with a decrease in the other. Further, large fills of Roxicodone are acceptable provided that the OxyContin prescriptions are being filled timely; that, according to Sydejko, did not happen here. (RT 7/23/07 150-157.)

43. A review of the patient's drug profile would have revealed that patient K.B. had previously received early refills of OxyContin, i.e., prior to the expected date based upon the previous prescription and daily usage indicated by the physician. Three

[13] It was not established that Respondent's dispensing of Prescription No. 836842 was below the standard of care because it was dispensed on September 20, 2002, before the pattern of "early fills" of large quantities of OxyContin had been established.

hundred tablets of 80 mg. OxyContin dosed at one to two tablets per day, given as a 30-day supply, was filled on September 5, 2002. (RT 7/23/07 152:18-23; State's Ex. 10 sub 44, p. 25.) On September 25, 2002, K.B. was dispensed another 300 tablets of OxyContin, a 25-day supply, ten days early. (State's Exs. 10 sub 44 p. 26, 10 sub 48.) On October 29, 2002, patient K.B. was dispensed 500 tablets of Roxicodone[14] (Prescription No. 839522) and 800 tablets of OxyContin, a 30-day supply (State's Exs. 10 sub 44, 10 sub 48.) On November 26, 2002, less than a month after the 800 tablets of OxyContin were filled, the patient received another 360 tablets of OxyContin (Prescription No. 841553). (State's Exs. 10 sub 44, 10 sub 48.) The directions for this prescription were to take the tablets three or four times a day. OxyContin is dosed, at the most, three times per day. (State's Ex. 16, p. 7; RT 7/23/07 156:10-25.) Patient K.B.'s drug history revealed that he had been prescribed anti-inflammatory medications in the past. As a result, a discussion with the physician to determine whether to use anti-inflammatory drugs might have been explored to see if it could help control the patient's pain (RT 7/23/07 158-159). Once again, proper documentation for the early fills and drastic increases in quantity and usage is required to demonstrate that the pharmacist met the standard of care in dispensing these medications. (State's Ex. 16, p. 7.)

44. There is no pharmacy documentation that either Respondent Simon or anyone at All Med Drugs noted the history of early fills for OxyContin when filling prescriptions for Roxicodone or consulted with Dr. Huff regarding his rationale for prescribing early fills. There is no pharmacy documentation that Respondent Simon or any other pharmacist at All Med Drugs noted the drastic increase in quantity of OxyContin that occurred with Patient K.B. or that Respondent Simon consulted with Dr. Huff regarding his directions to dose four times per day. Similarly, there was no pharmacy documentation that Respondent Simon or any other pharmacist at All Med Drugs had contacted Dr. Huff to explore the use of anti-inflammatory drugs to help control the patient's pain.

45. Respondent Simon opined that filling K.B.'s prescriptions for large quantities of Roxicodone was not below the standard of care. In September and October 2002, Respondent Simon did not feel that she was "somehow prevented in filling prescriptions for large quantities of Roxicodone." (RT 7/26/07 149:10-16.) She did not understand that there was any law, rule, or regulation of any state agency that prevented her from filling large quantities of Roxicodone. (RT 7/26/07 149:17-20.) In considering whether to fill large quantities of Roxicodone, she would look at the patient's history, talk to the pharmacist at the store and talk to the doctor. (RT 7/26/07 149:21-25; 150:1-4.) With respect to K.B., Respondent Simon did not feel that she was filling a prescription that was not written in the normal course of the medical practice of the doctor. (RT 7/26/07 150:13-17.) However, Respondent Simon could not determine who had handled the various prescriptions in this case and had no specific recall of the prescriptions at issue in this case. Respondent Simon provided no independent expert opinion to support her opinions,

[14] The quantity of the prior prescription (836842) for 30 mg. Roxicodone was 500 tablets.

particularly her opinion that only laws, rules or regulations of a state agency could set the standard of practice for pharmacists. Respondent Simon's testimony was unpersuasive.

Patient T.M.

46. It was established that Respondents dispensed Prescription Nos. 846241 and 847302 at amounts and frequencies that were beyond the recommended dose and dosing frequency. In addition, Respondents dispensed Prescription No. 842666 prior to the expected consumption of the prior prescription as stated by the physician for the same drug.[15] A prior prescription for 100 tablets of OxyContin (80 mg.), a 33-day supply dosed at 1 tablet, 3 times per day, was filled on December 4, 2002. (RT 7/23/07 164; State's Exs. 10 sub 44, 10 sub 63.) Only eight days later, Prescription No. 842666 was filled for 300 tablets of OxyContin, a 25-day supply dosed at 4 tablets, 3 times per day. (RT 7/23/07 172:15-21; State's Exs. 10 sub 44, 10 sub 63.)

47. Prescription No. 846241 for 300 tablets of 80 mg. OxyContin was dosed at 5 tablets, 3 times per day "as needed." (State's Ex. 10 sub 44.) The manufacturers insert states that OxyContin is not intended to be dosed "as needed." Further, "as needed" instructions are not used because it provides the patient with the opportunity to take more. (RT 7/23/07 165:18-25, 171:19-21.)

48. A review of the patient's drug history would have revealed that Prescription No. 847302 for 450 tablets of 80 mg. OxyContin, dosed at 5 tablets, 3 times per day, was filled on February 15, 2003,[16] seven days too early from the prior prescription. (State's Ex. 10 sub 44.) Additionally, on February 13, 2003, Respondents dispensed to Patient T.M. 300 tablets (21-day supply) of another long-acting, time-released opiate drug, MS Contin (100 mg. tablets, dosed twice per day). That would mean that Patient T.M. received more than 10 tablets per day of MS Contin at the same time as OxyContin. Sydejko opined that would be a "heavy drug dose" to be given at the same time as Prescription No. 847302, dosed at 5 tablets, 3 times per day. (RT 7/23/07 165:21-25, 168:16-25, 169:12-16.) Additionally, the increase in quantity and dosing schedule is indicative of opiate tolerance. (State's Ex. 16, p. 7.) Consultation records should indicate either conversations with the patient or the physician as to why the increases occurred and where the patient is going with respect to pain control. (Id. at p. 7-8.)

49. There is no pharmacy documentation that Respondent Simon or any other pharmacist maintained consultation records indicating either conversations with Patient T.M. or the physician as to why the increases occurred and where the patient was going with respect to pain control. With respect to T.M., Respondent Simon did not believe there was any recommended dose or dosing frequency set forth by any rule, regulation,

---

[15] Sydejko opined that Prescription No. 844299 did not fall below the standard of care because it was filled in a timely manner. (RT 7/23/07 172:10-12.)

[16] The prescription itself reflects that it was filled on February 13, 2003 and not February 15, 2003 as the patient profile indicates (State's Exs. 10 sub 44, 10 sub 63; RT 7/23/07 166-167.)

or law. (RT 7/26/07 151:5-10.) Respondent Simon felt there was no problem filling a prescription for whatever dose and dosing frequency that was, in her opinion, appropriate for the patient as long as it was a "valid" prescription. (RT 7/26/07 151:11-15.) As a result, Respondent Simon opined that there was not any "problem" filling T.M.'s prescription (RT 7/26/07 151:13-15.) In making that determination, Respondent Simon took into consideration the issues discussed above in Factual Findings No. 41 and 45, that there was no "upper limit" for prescribing Schedule II narcotics and no rule or regulation about dispensing large quantities of drugs. However, for the same reasons explained in Factual Findings Nos. 40 and 44, there is no basis for Respondent Simon's opinions regarding T.M.'s prescriptions. As a result, Respondent Simon's testimony is not persuasive.

Patient J.R.

50. It was established that Respondents dispensed Prescription Nos. 836087, 835044, 837624, 839323, 835045, and 836089 to J.R. in large quantities at doses and frequencies that were not recommended.[17] Using the patient's drug history at All Med Drug and prior prescriptions as a baseline, a prior prescription for 300 tablets of 40 mg. OxyContin was dispensed to J.R. on August 16, 2002, a 30-day supply. (RT 7/23/07 179:1-4; State's Exs. 10 sub 44, 10 sub 67.) Only ten days later, Patient J.R. was dispensed 800 tablets of 80 mg. OxyContin per Prescription No. 835044, which was "early" and twice the dose of the previous prescription. (RT 7/23/07 179:1-15.) At the same time, Patient J.R. was dispensed 300 tablets of 30 mg. Roxicodone (a 30-day supply) under prescription No. 835045, which was dispensed 10 days "early" from the previous prescription and represented an increase of 100 tablets from the prior prescription. (RT 7/23/07 187:2-18.) On September 10, 2002, only 16 days from the prior OxyContin prescription, J.R. presented prescription No. 836087 for 1,200 tablets of 80 mg. OxyContin dosed at 12 tablets, 3 to 4 times per day. OxyContin is not intended to be dosed four times per day. (RT 7/23/07 173:12-14, 174:9-22, 175:1-21, 178:7-9, 180:14-18.) At the same time, Patient J.R. was dispensed 1,000 tablets of 30 mg. Roxicodone, which was over three times higher in quantity than the previous prescription and fifteen days early from the expected fill date from the prior prescription. Considering the quantity of OxyContin being prescribed at the same time, Sydejko considered the quantities "inconceivably high." (RT 7/23/07 187:19-25, 188:3-13.)

51. On October 2, 2002, Patient J.R. was dispensed 1,100 tablets of 80 mg. OxyContin and dosed at up to 30 tablets, three times per day (a 15-day supply). (State's Exs. 10 sub 44, 10 sub 67.) This is a huge increase in the number of tablets, doubling the amount of tablets taken per day within less than a month. (RT 7/23/07 180:22-25, 181:1-11.) Increases in the dosing of OxyContin continued with the dispensing of

[17] Sydejko opined that Prescription Nos. 842671 and 837029 did not fall below the standard of care because they were filled timely. (RT 7/23/07 183-184, 188:18-25, 189:5-8.) Prescription No. 834513, was filled for the first time at the pharmacy, and was therefore also not below the standard of care (RT 7/23/07 185:23-25, 186:1-4.) Prescription No. 842670 was timely. However considering the quantity and the two and one-half month break from the prior prescription, Sydejko said he needed more information to render an opinion, but would not say that it fell below the standard of care. (RT 7/23/07 189:12-17.)

prescription No. 839323 on October 28, 2002, which permitted Patient J.R. to take up to 125 tablets daily of 80 mg. OxyContin. (State's Ex. 10 sub 44.) According to Sydejko, the role of the pharmacist is to involve themselves in drug therapy for the patient and to communicate their concerns to the patient and the physician. Dispensing without proper documentation of that communication is "inexcusable." (RT 7/23/07 182:1-18; State's Ex. 16, p. 8.) Further, the patient's overall drug history reflects large quantities of controlled substances dispensed, with an increase in the drug quantities and changes in the dosing schedules; this is indicative of opiate tolerance. Consultation records should indicate either conversations with the patient or physician as to why there are increases and where the patient is going with respect to pain control. (State's Ex. 16, p.8.)

52. There is no pharmacy documentation showing that Respondent Simon or any other pharmacist at All Med Drugs communicated their concerns regarding the large quantities and increases in the dosages and frequencies of Patient J.R.'s prescriptions to Dr. Huff. With respect to J.R., Respondent Simon opined that the dispensing of Patient J.R.'s prescriptions did not fall below the standard of care for the same reasons provided in Factual Finding No. 48. (RT 7/26/07 151:16-21.) However, for the same reasons explained in Factual Findings Nos. 41 and 45, there is no basis for Respondent Simon's opinions. As a result, Respondent Simon's testimony regarding Patient J.R.'s prescriptions is not persuasive.

Patient C.S.

53. It was established that Respondents dispensed prescriptions 836420, 847020, and 847022 in large quantities to C.S..[18] A review of the patient's drug profile would have revealed that Patient C.S. had a prior prescription filled for 100 tablets of 40 mg. OxyContin on August 23, 2002. The next prescription for OxyContin filled September 13, 2002, Prescription No. 836420, was filled for 500 tablets of 80 mg. OxyContin. This represents a drastic increase from the prior prescription. Considering the increases in amount and dosage, Sydejko equated it to a "900 tablet increase within a month." (RT 7/23/07 194:7-22.)

54. According to Sydejko, it is important to look at the other medications surrounding the filling of a prescription to determine if the pharmacist fell below the standard of care. Respondents filled a prior prescription on January 17, 2003 for 500 tablets of 80 mg. OxyContin, a 28-day supply. (State's Exs 10 sub 44, 10 sub 74.) Less than 28 days later, Respondents dispensed Prescription No. 847020 on February 10, 2003 for 450 tablets of 80 mg. OxyContin, a 30-day supply. At this time, other narcotic drugs were added. On the very same day that Respondents filled 847020, Respondents dispensed 360 tablets of Roxicodone under Prescription No. 847022, a 30-day supply.

[18] Sydejko opined that the filling of prescription Nos. 838347, 840637, 838346, 840636, 843317, 843987, and 845287 did not fall below the standard of care because they were timely (RT 7/23/07 195, 196:3-16, 202:22-25, 203:1-11.) He also opined that a prescription Nos. 843319, 845289, and 836419 were timely and the dosage increases were not drastically high. (RT 7/23/07 197:4-20, 198:10-18, 202:2-7. Prescription No. 834787 for Roxicodone was filled for the first time at this pharmacy. As a result, Sydejko said it did not fall below the standard of care for dispensing. (RT 7/23/07 201:12-15.)

Also on February 10, 2003, Respondents dispensed 360 tablets of 10-325 mg. Hydrocodone BIT APAP, a 30 day-supply that equates to up to 12 tablets per day. That prescription is a "dual" drug containing both the narcotic drug, Hydrocodone, and Tylenol. Pharmacists must be careful in filling prescriptions containing Tylenol at dosages that exceed 4 grams per day because of possible liver damage. Twelve tablets per day exceed the 4 grams per day minimum. As a result, Respondents' actions in filling these prescriptions at the same time in the quantities and dosages indicated, fell below the standard of care. (RT 7/23/07 199:2-25, 200:1-25, 201:1-2, 203:15-23, 205:13-16.)

55. With respect to C.S., Respondent Simon opined that the dispensing of Patient C.S.'s prescriptions did not fall below the standard of care for the same reasons provided in Factual Finding No. 52. (RT 7/26/07 151:16-21.) However, for the same reasons explained in Factual Findings Nos. 41 and 45, there is no basis for Respondent Simon's opinions. As a result, Respondent Simon's testimony regarding Patient C.S.'s prescriptions is not persuasive.

Patient D.S.

56. Respondents' filling of Prescription Nos. 824507, 833274, 833855, 835399, 837795, 839696, 842511, 844496 for Patient D.S. for large quantities of Actiq (360 lozenges, 1,600 mcg.) at dosing schedules that exceeded the manufacturers' recommendation of four per day, fell below the standard of care (see Factual Findings 7 and 8 for specific dosing schedules). (RT 7/23/07 210, 211:14-25, 213:1-25, 213:16-20, 214-216.) The standard of care with respect to dispensing Actiq requires that once the medication repeats, if consumption increases above four units per day, then the patient should be re-evaluated to determine if use of a long-acting opiate drug, such as OxyContin, is possible.[19] (RT 7/23/07 210:20-25, 211:1; RT 7/26/07 12:1-14, 13:1-6.) Sydejko also noted that prescription Nos. 833855 and 837795 were filled too early. Respondents filled Prescription No. 833855 eight days after the previous prescription, which was a 30-day supply. (RT 7/23/07 211:22-24.) Prescription No. 837795 was filled on October 4, 2002 six days later from the previous prescription. (RT 7/23/07 213:16-20.)

57. The standard of care requires that if the face of the prescription is for a huge amount and a review of a patient's drug profile reveals drug activity for heavy-duty drugs that are abusive in nature, like Actiq and OxyContin, then a pharmacist cannot just continue to dispense. (RT 7/24/07 23:14-22.) Patient D.S. was dispensed 1,000 tablets of 80 mg. OxyContin on March 1, 2002 for Prescription No. 821977. This was a very large quantity, which was dispensed the day after a large quantity of Actiq (384 lozenges) was dispensed on February 28, 2002. Similarly, Prescription No. 824509 for 1,000 tablets of 80 mg. OxyContin was dispensed on April 1, 2002 at the same time as a large quantity of Actiq (360 lozenges). (RT 7/24/07 21:15-16, 23:7-22.)

---

[19] Filling Prescription No. 821016 for 360 lozenges of Actiq did not fall below the standard of care because it was the first prescription of this type presented to the pharmacy. There was no "repeat" or pattern of prescribing as of that date. (RT 7/23/07 4-7.)

58. Respondents continued to dispense OxyContin, even when Patient D.S.'s drug history revealed that multiple narcotic drugs were being dispensed frequently and at or around the same time as OxyContin. On April 1, 2002, Respondents dispensed concurrently to D.S. the drugs OxyContin, Actiq, Clonazepam and Methadone. According to Sydejko, the prescription for Methadone, a drug used for pain and to detox from heroin, was written for a "huge" amount (500 tablets) considering the other narcotic drugs being dispensed and considering that Methadone was being introduced to Patient D.S. without "tapering up." (RT 7/24/07 51:52.) Under prescription No. 832350, Respondents dispensed 1,000 tablets of 80 mg. OxyContin to D.S. on July 17, 2002 while 120 tablets of Clonazepam, a drug similar to Valium, had already been dispensed. Patient D.S.'s drug history showed that while the OxyContin prescriptions in this case were being filled, either 120 or 200 tablets of Clonazepam were filled sixteen times between May 3, 2002 and January 13, 2003. Only thirteen days after the prior prescription for OxyContin, on July 30, 2002, Respondents dispensed concurrently OxyContin (Prescription No. 833275 for 1,000 tablets), Actiq (360 lozenges), and Clonazepam (an early refill of 200 tablets). (RT 7/24/07 24-26, 49:16-25, 50-52, 53:3-9.)

59(a). Despite the foregoing medications and Patient D.S.'s drug history, Respondents continued to dispense large quantities of OxyContin frequently and at high doses to Patient D.S. between August 7, 2002 and January 7, 2003. Just ten days after her prior OxyContin prescription, Patient D.S. was dispensed 1,000 tablets of 80 mg. OxyContin under Prescription 833857, with directions to take 7-10 tablets, 4 times daily (25-day supply). This means that Patient D.S. could take up to forty tablets per day. Twenty-two days later, on August 29, 2002, Patient D.S. was dispensed another 1,000 tablets of 80 mg. OxyContin (Prescription No. 835400), with the same directions. On December 23, 2002, Respondents continued to dispense large quantities of OxyContin under Prescription No. 843535 (1,000 tablets of 80 mg. OxyContin, a 30-day supply), which was dispensed seventeen to eighteen days too early. Fifteen days later, Respondents dispensed Prescription No. 844495 for 1,000 tablets of 80 mg. OxyContin with directions to take 7-8 tablets, four times per day. The standard of practice is not to dose more than three times per day. (State's Ex. 10 sub 44; RT 7/24/07 28-29, 31:13-20, 42:1-24, 43:23-25, 44:17-25, 48:12-23.)

59(b). Respondents also dispensed to D.S. other narcotic drugs frequently or for large quantities at or near the same time as the OxyContin prescriptions were filled from October 4, 2002 to December 11, 2002. On October 4, 2002, Respondents dispensed 1,000 tablets of 80 mg. OxyContin to Patient D.S. under prescription No. 837796 while also dispensing Actiq (an early fill of 260 lozenges) under Prescription No. 837795. Respondents then filled Prescription No. 841656 on November 26, 2002 for 1,000 tablets of OxyContin (42-day supply) around the same time that Patient D.S. had been dispensed Clonazepam. On December 11, 2002, Respondents filled Prescription No. 842572 for 1,000 tablets of 80 mg. OxyContin (31-day supply), which was filled fifteen days too early. On the same day or around the same time, Respondent dispensed to Patient D.S. 120 tablets of Clonazepam (an early fill of 120 tablets) and large quantities of Actiq (360 lozenges -- Prescription No. 842511). (State's Ex. 10 sub 44; RT 7/24/07 33:3-9, 34:3-6, 35:3-9, 35:20-24, 36:6-23, 42:1-24, 43:23-25, 44:17-25, 48:12-23.)

60. With respect to D.S., Respondent Simon opined that the dispensing of Patient D.S.'s prescriptions did not fall below the standard of care for the same reasons provided in Factual Finding No. 48. (RT 7/26/07 151:16-21.) Respondent Simon also specifically disagreed with Sydejko's opinion that dosage of Actiq is limited to four per day and if more was given, then the patient should be re-evaluated. Respondent stated that she understood that the insert "didn't state a limit." (RT 7/26/07 133:17-25; 134:1-2.) Hypothetically, if a prescription with respect to D.S., had been presented six months after she began working at All Med Drugs, Respondent Simon testified that she would have had no problem with a 1,000 tablet 80 mg. OxyContin prescription for D.S. if it had been presented six months after she began working there, "because it had been filled by prior pharmacists," "the patient was already there" and had "an established drug history," (RT 7/26/07 136:16-23.) She contacted the doctor and talked to him and D.S. on numerous occasions (RT 7/26/07 136:23-25.)

61. There is no pharmacy documentation that either Respondent Simon or another pharmacist at All Med Drugs noted the large quantities, dosages or frequencies that occurred with Patient D.S., or that Respondent Simon or any other pharmacist at All Med Drugs contacted Dr. Huff regarding his rationale for the quantity, dosage or frequencies for these prescriptions (see Factual Findings 13-15). Respondent Simon could not determine who had handled the various prescriptions in this case and had no specific recall of the prescriptions at issue in this case (see Factual Findings 20-24). Nevertheless, Respondent Simon opined that filling D.S.'s prescriptions were not below the standard of care. Respondent Simon provided no independent expert opinion to support her beliefs that accepted standards of pharmacy practice included disregarding the manufacturer's recommendations, or filling prescriptions for large quantities at high dosages because previous prescriptions had been filled by other pharmacists. Respondent Simon's testimony was unpersuasive.

Patient L.T.

62. It was established that Respondents filled Prescription No. 848840 for large quantities of Hydromorphone (Dilaudid) for Patient L.T. In determining whether dispensing this prescription fell below the standard of care, it is appropriate to examine the patient's drug history, including other medications that were dispensed around the same time, and the pattern of prescribing to determine if the quantity was large. If a review of the patient's drug profile had been done it would have revealed that Respondents had dispensed prior prescriptions to Patient L.T. authorized by another prescriber for, at the most, 405 tablets of 20 mg. OxyContin in December 2002 and January 2003. However, one month later, when L.T. began presenting prescriptions from Dr. Huff on February 7, 2003, that amount "bounced up" the strength from 20 mg. to 80 mg. OxyContin. Respondents also dispensed MS Contin and 100 tablets of 8 mg. Dilaudid. On March 6, 2003, Respondents dispensed to Patient L.T. 800 tablets of 8 mg. Dilaudid under

Prescription No. 848840 and 200 tablets of 80 mg. OxyContin. Increases in drug quantities require documentation of the prescriber's rationale regarding the patient's pain control. Considering the pattern of increasing amounts of OxyContin and Dilaudid and the fact that these drugs were dispensed concurrently without any documentation of communication with the prescriber, Respondents conduct fell below the standard of care in dispensing Prescription No. 848840. (RT 7/24/07 55:19-21, 55-56, 57:1-10.)

63. There is no pharmacy documentation showing that Respondent Simon or any other pharmacist at All Med Drugs communicated their concerns regarding the large quantity and increases in the amounts for Patient L.T.'s prescription to Dr. Huff or that there was any documentation of Dr. Huff's rationale for increasing the amount. With respect to L.T., Respondent Simon opined that the dispensing of Patient L.T.'s prescriptions did not fall below the standard of care for the same reasons provided in Factual Finding No. 49. (RT 7/26/07 151:16-21.) However, for the same reasons explained in Factual Findings Nos. 40 and 45, there is no basis for Respondent Simon's opinions. As a result, Respondent Simon's testimony regarding Patient L.T.'s prescriptions is not persuasive.

Dealings with Patient R.S.

64. Related to R.S.'s father's complaint to the Board (discussed at Factual Finding 5, ante), R.S. provided a statement on February 3, 2003. In her statement, and alleged by Complainant as an aggravating circumstance in the instant action, R.S. alleged, among other things, that on a day uncertain, Respondent Simon gave R.S. three small papers containing prescription information for Hydromorphone (8 mg.), Roxicodone (30 mg.), and OxyContin (80 mg.), each medication described on a separate paper. R.S. further alleged that Respondent Simon told R.S. that if R.S. could find a doctor to fill those three prescriptions, Respondent Simon would, in turn, buy them from R.S. According to R.S., Respondent Simon suggested to R.S. that Dr. Michael Huff would likely be willing to fill the prescriptions. The evidence did not establish R.S.'s allegations. (See Legal Conclusion 48 & fn. 28.)

65. R.S. is a woman who, for over a decade, has taken various narcotic pain medications for a joint disease problem. She has been addicted to narcotic pain medications for approximately the last 10 years. Her addiction has led her to seek out the drugs from various medical and dental professionals, whether medically indicated or not. On several occasions in the past, R.S. has pretended to be a doctor and telephoned false prescriptions to pharmacies to acquire narcotic medication without her prescribing physician's authorization. R.S. was convicted of a crime for these activities in the Ventura County Superior Court in the late 1990s. The parties did not proffer evidence of R.S.'s conviction.

66. At hearing, the Board's inspector in this matter was asked whether she considered R.S.'s admitted history of calling in false prescriptions an important fact to consider in pursuing R.S.'s allegations against Respondents. The Inspector refused to describe R.S.'s history as an important fact, and only agreed that she would consider it

"informative." The Inspector did not believe that R.S.'s admitted history would affect her reliance on R.S. in the investigation because, in the Inspector's view, R.S. was not the focus of the investigation. The Inspector acknowledged that she did not investigate R.S.'s background to make any determination regarding R.S.'s credibility.

67. It was established that at sometime uncertain, Respondent Simon hired R.S. as a front-end clerk at All Med Drugs, but that Respondent Simon terminated R.S. within a matter of days. The evidence did not conclusively establish the particulars of this employment action.

68. At hearing, the parties stipulated that Respondents filled and dispensed prescriptions for R.S. without the authorization of R.S.'s prescribing physician and without a valid prescription. Specifically, Respondent Simon (or someone under her supervision) filled prescription number 833105 for Lortab[20] (10-500 mg.), without a prescription, on July 29, August 14 and 29, and September 9, 2002.[21] The stipulation included the fact that Respondent Simon (or someone under her supervision) also refilled prescription number 828982 for Lortab (10-500 mg.) without obtaining authorization from the prescribing physician on June 19 and 24, 2002.

69. The evidence did not establish how R.S. went about presenting the unauthorized prescriptions. Respondent Simon could not remember the specific instances when these false prescriptions were filled and dispensed, but, at those times, Respondent Simon believed every prescription she had filled and dispensed to R.S. was legitimate and valid. She acknowledged at hearing that, in these instances (those in Factual Finding 68, including footnote 21), it was "unfortunate" and she wished she had "caught" R.S. sooner. (RT 7/27/07 63-64.)

70. Sydejko opined that even if R.S. phoned in false prescriptions, as Respondent Simon impliedly speculated at hearing, the prescriptions at issue were, nonetheless, early refills that Respondent Simon should not have filled for that reason alone. In the ninth cause for discipline in the Accusation, Complainant alleged that Prescription No. 828982 for R.S. was filled inappropriately early on June 19 and June 24, 2002. (State's Ex. 1, p. 11-12.)

Early Refills for Patient R.S.

71. At hearing, the parties also stipulated that Respondents dispensed the fills or refills of Lortab to Patient R.S. at All Med Drugs, as set forth in Table C. (7/19/07 52-54.)

---

[20] Lortab is the brand name of the generic drug, Hydrocodone, with Acetaminophen. It is an analgesic Schedule III controlled substance.

[21] Complainant alleged additional dates (September 13, and October 11, 2002) under prescription number 833105, to which Respondents' counsels stipulated at hearing, as noted in Factual Finding 68. However, the patient drug history established that the prescriptions for Lortab on September 13, and October 11, 2002, were under prescription number 836415.

72. TABLE C

Medication	Rx #	Rx Date	Previous Rx Date	Estimated Supply
Hydrocodone (10-500 mg.)	822513	3/8/02	3/6/02	7 days
	827367	5/10/02	5/7/02	15 days
	828982	5/31/02	5/29/02	10 days
	828982	6/19/02	6/11/02	10 days
	828982	6/24/02	6/19/02	10 days
	828982	6/27/02	6/24/02	10 days
	828982	7/1/02	6/27/02	10 days
	831578	7/5/02	7/1/02	10 days
	831578	7/8/02	7/5/02	10 days
	831578	7/15/02	7/8/02	10 days
	831578	7/18/02	7/15/02	10 days
	831578	7/19/02	7/18/02	10 days
	831578	7/22/02	7/19/02	10 days
	836415	9/13/02	9/9/02	10 days

73. In addition to those prescriptions in Table C, Complainant alleged that two other prescriptions for Lortab constituted early refills. However, in Sydejko's opinion, those refills, on April 5, 2002 (prescription # 822513), and May 29, 2002 (prescription # 828982), were not early refills and thus not below the standard of care. Sydejko reached this opinion after assessing that the former was dispensed four days after R.S. had received the previous prescription, a seven-day supply, and the latter was dispensed 19 days after having received the previous prescription, a 15-day supply. In all other cases of those listed in Table C, Sydejko agreed that Respondents early filling of these prescriptions for R.S. was an extreme departure from the standard of care. In particular, Respondent opined that a reasonably prudent pharmacist would not have filled these prescriptions because it was "too much of a pattern showing too many early refills." (RT 7/24/07 72:12-23.)

The Unauthorized Actions of a Pharmacy Technician

74. The parties stipulated at hearing that, in 2003 and 2004, a pharmacy technician at All Med Drugs, Christina Burgos, processed prescriptions and refills for family members and changed the quantity and refill availability on those prescriptions, without the authorization of the prescribing physician. Those prescriptions are set forth in Table D, *post.*

75. TABLE D

Medication	Rx #	Dispense Date	Refill Date	Unauthorized Change
Naproxen (250 mg.)	844083	1/2/03	4/8/03	unauthorized prescription
Lisinopril (10 mg.)	844333	1/6/03	2/3/03	unauthorized prescription

			3/7/03 4/3/03	
Metformin (500 mg.)	852471	4/29/03	6/21/03	unauthorized prescription
Lasix (20 mg.)	844506	1/8/03	4/3/03 7/23/03 10/17/03	210 unauthorized tablets dispensed
Lisinopril (1 mg.)	850914	7/14/03	9/24/03 1/12/04	120 unauthorized tablets dispensed
Metformin (500 mg.)	855939	7/23/03	9/24/03 11/11/03 1/12/04	100 unauthorized tablets dispensed
Metformin (500 mg.)	872252	2/16/04	5/5/04 7/8/04 9/8/04	120 unauthorized tablets dispensed
Vicodin H.O.	846718	2/21/03	3/12/03 3/26/03 6/26/03 7/22/03	unauthorized prescription
Vicodin H.P.	859159	8/13/03	9/11/03 10/9/03 10/29/03 12/3/03	unauthorized prescription
Vicodin H.P.	868000	12/19/03	1/20/04 2/4/04 4/8/04 4/28/04	unauthorized prescription
Vicodin E.S.	847738	3/7/03		dosage directions changed without authorization

76. During the time Respondent Simon was the Pharmacist-in-charge, she was unaware that Christina Burgos was processing prescriptions, as set forth in Table D, without physician authorization.

The Twelve Thousand Dollar Check

77. On November 20, 2001, Respondent Simon wrote and signed a check from All Med Drugs to herself for $12,256.49. Respondent Simon had the authority to sign checks for All Med Drugs. Sometime thereafter, a co-owner of All Med Drugs questioned Respondent Simon regarding the payment. Respondent Simon explained that she had bought supplies for All Med Drugs by purchasing medical supplies from pharmacies that were closing or going out of business. For unexplained reasons, Respondent Simon purchased the supplies in cash (her own cash), over a period of approximately three to five weeks from a pharmacy called MTC Pharmacy (MTC), in Van Nuys, California.[22] At the time of the purchases, Respondent Simon did not request, or receive, a receipt.

[22] Respondent Simon was the Pharmacist-in-Charge for MTC from December 10, 1999 to January 22, 2000.

Thereafter, and in response to the co-owner's inquiry, Respondent Simon asked for and acquired one invoice from MTC for the various cash purchases. The invoice was dated November 10, 2001, and showed one payment of $12,256.49. The invoice showed no itemized purchases, only stating "Medical Supplies," and in the space reserved for the "bill to" and "ship to" addresses, the word, "Cash," appeared. Upon seeing the invoice, the co-owner accepted Respondent Simon's explanation and his earlier concerns that prompted his inquiry were satisfied. Between November 20, 2001, and the present, the co-owner has never pursued reimbursement from Respondent Simon nor claimed in any way that Respondent Simon owed All Med Drugs any portion of the $12,256.49 check payment.

78. On November 20 and 21, 2000, MTC was broken into and its inventory was stolen. The police theft report showed, almost exclusively, an inventory of medications as the items stolen. About a year later, MTC filed a Discontinuance of Business form with the Board on October 30, 2001, wherein it stated, "inventory lost in theft." The evidence did not conclusively establish whether the inventory stolen left MTC with no medical supplies other than medications. MTC formally disassociated on November 14, 2001.

The Modified Prescription

79. On May 10, 2002, a prescription for patient L.H. (prescription # 827661) for 1,000 tablets of Roxicodone (30 mg.) was processed at All Med Drugs. The auxiliary label[23] had handwriting that read on one part of the label, "P/F," and on another part of the label, "- 100 of 15 mg. strength!"

80. When questioned at hearing about the handwriting, Respondent Simon admitted that the "letter C looks like my C", but stated that the rest of the writing indicated that the prescription "was touched by numerous people." (RT 7/26/07 162:21-25.) She had a "vague recollection of what was happening" with this prescription, but did recall that All Med Drugs experienced a shortage of Roxicodone (30 mg.) tablets during the time this particular prescription was filled. (RT 7/26/07 161:11-14.) Respondent Simon surmised that the handwriting on the label meant that either she or someone at All Med Drugs dispensed 100 tablets of Roxicodone to L.H., in 15-milligram strength instead of the prescribed 30-milligram strength. There was no evidence that L.H.'s prescribing physician authorized any change in prescription strength. In explaining the handwriting, Respondent Simon stated that if indeed she modified and dispensed Roxicodone, she did it because she would have felt compelled to dispense some Roxicodone to L.H., albeit at a different strength, to afford L.H. some pain relief.

The Medication Audit

81. As part of its investigation and inspections, the Board, through its investigator, conducted an audit of invoices, inventory records, and prescription records for the period of February 6, 2002 through March 11, 2003. The audit found that, on March 11, 2003, All Med Drugs had 800 more tablets of Roxicodone (30 mg.) and a shortage of

[23] The auxiliary label is a second label, identical to the one that is placed on the vial provided to the patient.

982 tablets of OxyContin SR (80 mg.) than what could be accounted for in the inventory records. An audit of Dilaudid (8 mg.) tablets found all Dilaudid tablets accounted for at the pharmacy.

82. Respondent Simon first questioned the audit's accuracy, arguing that since the drugs and the records from All Med Drugs were seized during the Board's inspections, she could not reconcile the discrepancies. Further, Respondent Simon explained that the logs at All Med Drugs used to quantify and track the medication inventory were not always updated daily. Depending on the workload, a day or two could pass before the medication logs were updated. Given the quantities of Roxicodone and OxyContin that were dispensed at All Med Drugs, Respondent Simon argued that it was likely the records could be reconciled satisfactorily had she had a chance to review the complete records. The evidence did not prove Respondent Simon's argument. (See Legal Conclusion 35.)

The CURES Data

83. Respondents are required by state law to submit prescription information to the State Controlled Substance Utilization Review and Evaluation System (CURES). CURES is a statewide data base system that collects prescription information for all dispensed Schedule II controlled substances. As part of the Board's investigation, the Board's inspector requested All Med Drugs's CURES reports from the Board, for calendar years 2001, 2002, and 2003. The Inspector requested these reports using pharmacy license numbers 45269 and 19488. License number 19488 was All Med Drugs's previous pharmacy license number under a previous owner. The resultant CURES reports for 2001 and 2002, proffered by Complainant, showed no reporting by All Med Drugs under either pharmacy license number. However, when Respondent Simon's counsel obtained CURES reports from the California Department of Justice's Bureau of Narcotic Enforcement, the CURES reports showed that from January 1, 2001 to June 30, 2001, All Med Drugs did report dispensed Schedule II controlled substances, under license number 19488. The CURES reports for 2003, proffered by Complainant, showed that All Med Drugs did not report any dispensed controlled substances in January, February, March, or April 2003 under license number 45269, but began reporting in May 2003. Complainant did not offer a CURES report for 2003, under pharmacy license number 19488.

84. While the Pharmacist-in-Charge at All Med Drugs, Respondent Simon believed pharmacy staff was submitting CURES data regularly at all times.

The Expired Drugs

85. On March 11, 2003, as part of the Board's investigation, 55 medications were taken from All Med Drugs with varying expiration dates. Two medications had 2001 expiration dates, 26 medications had 2002 expiration dates, and the remaining medications had expiration dates ranging from January to December 2003.

86. On March 11, 2003, the Board's inspector produced an inspection report that directed Respondent Simon to remove all expired drugs from the shelves. When the

Inspector returned two days later, on March 13, 2003, the Inspector still found expired drugs on the shelves. The Inspector then ordered Respondent Simon to remove all expired drugs from the shelves by March 19, 2003; Respondent Simon complied. At hearing, Respondent Simon did not deny the existence of expired drugs, and did not dispute the expiration dates of the 55 medications taken from All Med Drugs on March 11, 2003.

87. Sydejko acknowledged that most pharmacies would likely have some expired drugs on its shelves, but in the case of All Med Drugs, the situation was not like what one would commonly find in most pharmacies due to the ages of the involved drugs. Having such expired medications on the shelves, Sydejko opined, was indicative that pharmacy staff did not execute regular reviews, and was consequently indicative of a more serious problem. At hearing, Respondent argued that the expired drugs remained on the shelves because she understood all medications needed to be in a secured and locked area, and therefore, when uncovered by the Board's inspector, the drugs were kept in the secured area, awaiting removal and destruction.

Complainant's Costs

88. Complainant incurred $34,515 in investigation and inspection costs. Complainant also incurred $103,588.75 in costs to prosecute this matter through the California Department of Justice, Office of the Attorney General.

LEGAL CONCLUSIONS

Expert Testimony

1. Expert testimony is required to establish the standard of care with respect to a profession. See, *Flowers v. Torrance Memorial Hospital Medical Center* (1994) 8 Cal.4th 992, 1001; *Williams v. Prida* (1999) 75 Cal.App.4th 1417, 1424.

2. A profession is a vocation or occupation requiring special and advanced education and skill predominately of an intellectual nature. The practice of pharmacy, like the practice of medicine, is a profession. *Vermont & 110th Medical Arts Pharmacy v. Board of Pharmacy* (1981) 125 Cal.App.3d 19, 25.

3. A witness is qualified to offer an expert opinion if he or she possesses the special knowledge, skill, experience, training or education sufficient to qualify as an expert on the subject to which the testimony relates. (Evidence Code Section 720.)

4. In cases where experts are needed to establish negligence, their testimony sets the standard of care, and is said to be "conclusive." The California Court of Appeal in *Osborn v. Irwin Memorial Blood Bank* (1992) 5 Cal.App.4th 234, 277, quoting from a list of authorities, stated as follows: "Ordinarily, where a professional person is accused of negligence in failing to adhere to accepted standards within his profession the accepted standards must be established only by qualified expert testimony [citations] unless the

standard is a matter of common knowledge. [Citation.] However, when the matter in issue is within the knowledge of experts only and not within common knowledge, expert evidence is conclusive and cannot be disregarded."

The Standard of Proof

5. Complainant must prove her case by clear and convincing evidence to a reasonable certainty. Clear and convincing evidence means the evidence is "so clear as to leave no substantial doubt" and is "sufficiently strong to command the unhesitating assent of every reasonable mind." (*Mathieu v. Norrell Corporation* (2004) 115 Cal.App.4th 1174, 1190 [citing *Mock v. Michigan Millers Mutual Ins. Co.* (1992) 4 Cal.App.4th 306, 332-333].)

Legal Responsibility

6. Business and Professions Code section 4113 states in pertinent part:

[¶] . . .[¶]

(b) 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.

7. "The licensee, if he elects to operate his business through employees must be responsible to the licensing authority for their conduct in the exercise of his license...By virtue of the ownership of a ...license such owner has a responsibility to see to it that the license is not used in violation of the law." *Banks v. Board of Pharmacy* (1984) 161 Cal.App.3d 708, 713, citing *Ford Dealers Assn. v. Department of Motor Vehicles* (1982) 32 Cal.3d 347.

The Sizeable and Copious Prescriptions

8. A licensee may be disciplined on the basis of ordinary negligence when charged with the "clearly excessive furnishing of controlled substances." *Smith v. State Board of Pharmacy* (1997) 37 Cal.App.4th 229, 246-247.

9. Business and Professions Code section 4300 states in pertinent part:

(a) Every license may be suspended or revoked.

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

[¶] . . . [¶]

(2) Placing him or her on probation.

(4) Revoking his or her license.

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

(e) The proceedings under this article shall be conducted in conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

10. Business and Professions Code section 4301 states in pertinent part:

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

[¶] . . . [¶]

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.[24]

11. Health and Safety Code section 11153 states in pertinent part:

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

[24] Complainant alleged in the Accusation that Respondents also violated Section 4301(e) of the Business and Professions Code. However, that Section cross-references Section 11153.5 of the Health and Safety Code, which applies to manufacturers and wholesalers and has no applicability to the facts in this case. As a result, violation of Section 4301(e) was not relied upon in reaching any of the legal conclusions in this case.

12. The Administrative Law Judge in this case found that Respondent Simon's past actions, including contacting the prescribing physician regarding concerns about prescriptions, demonstrated that she acted as a reasonable and prudent pharmacist would when encountering "unconventional" prescriptions. However, the Board disagrees with this assessment for the following reasons. The evidence persuasively showed that Respondent Simon could not establish personal knowledge about the prescriptions, the circumstances surrounding the prescriptions at issue in this case, or that her usual and customary practices regarding the filling of prescriptions were followed in this case. The evidence persuasively showed that Respondent Simon's personal opinions and testimony regarding how a prescription at issue in this case may have been handled at All Med Drugs is speculative and not entitled to any weight. Further, Respondent's contradictory and inconsistent testimony in this case undermines Respondent Simon's credibility in this case. Her selective memory regarding statements she made to law enforcement officials also undermines her credibility.

This conclusion is based upon Factual Findings 10 through 26.

13. The testimony of Complainant's expert Jeb Sydejko – who was the only expert to testify in this case -- established that there was simply no justification for the dispensing of the amounts of Schedule II narcotics listed in Tables A and B. However, the Administrative Law Judge found Sydejko's testimony did not consider the patients' diagnoses, medical histories, or previously attempted drug therapies. Further, in the Administrative Law Judge's opinion, Respondent Simon "took actions that elicited a wide-range of factors" to determine whether a prescription was excessive before dispensing. However, the Board disagrees with this assessment for the reasons stated in Legal Conclusion No. 12. Further, Sydejko's expert testimony in this case established the standard of care for pharmacy practice. Respondent Simon, as a party, does not qualify as an expert in this case. There was no evidence that Sydejko's opinion should be discounted, particularly when reviewing quantities dispensed in this case, simply because he did not know the patients' diagnoses, medical histories, or previously attempted drug therapies. Sydejko established several bases for determining whether a particular prescription for a large quantity was valid and should have been dispensed.

This conclusion is based upon Factual Findings 27, 29-63.

14. Sydejko's testimony established that Respondents excessively furnished prescriptions that went beyond the recommended dose and frequency for prescriptions listed in Table A. In his testimony, Sydejko highlighted the fact that the manufacturer of OxyContin does not intend the drug to be used on an "as needed" basis, though Respondent Simon dispensed it in this manner, pursuant to written prescriptions. However, the Administrative Law Judge found that he could not reconcile Sydejko's opinion with the fact that Schedule II narcotics have "no upper limit" in issued quantity. As a result, the Administrative Law Judge determined that the pharmacy standard for dispensing Schedule II drugs was "elusive." The Board disagrees with this assessment. Such a conclusion would be untenable to the Board because it would mean either that pharmacists are unfettered by any standards when determining whether to dispense or

that pharmacists must defer to the prescriber when dispensing. This is contrary to the standard enunciated by pharmacist expert Sydejko. In Sydejko's opinion, the decision to dispense in a given situation is an individual decision but, an analysis of the appropriateness of the decision takes into consideration objective factors that include a history of early fills of these and other drugs, the manufacturer's recommendations for dosage, consultation with the prescribing physician and patient to obtain the rationales for their pain therapy and recommended alternatives, documentation of consultations with the patient or prescriber, an awareness of other drugs being concurrently dispensed and a review of the prescribing patterns of the physician (Factual Findings 31-63). As Respondents could not demonstrate that the foregoing were considered with respect to the prescriptions listed in Tables A and B, Respondents' dispensing of the prescriptions fell below the standard of care.

15. With the exception of Prescription No. 836842 for Patient K.B., Complainant established, by clear and convincing evidence to a reasonable certainty, that the prescriptions in Tables A and B were clearly excessive and that dispensing those prescriptions by Respondents was below the standard of care. Complainant specifically alleged that the prescriptions in Table A were beyond the recommended dose and dosing frequencies, and that the prescriptions in Table B were for excessively large quantities. It was undisputed that the dosages in the Table A prescriptions were large and frequent, and that the Table B prescriptions were for large quantities. It was also established by clear and convincing evidence that Respondents excessively furnished controlled substances to a patient when a prescription was dispensed prior to the consumption of the previous prescription for T.M.. Complainant also established by clear and convincing evidence that Respondents actions in dispensing to D.S. multiple controlled substances concurrently fell below the standard of care. Respondent Simon knew or should have known based on the facts presented that said prescriptions were not issued for legitimate medical purposes.

This conclusion is based upon Factual Findings 6 through 63, and on Legal Conclusions 1-14.

16. Cause exists to revoke or suspend Respondent Simon's pharmacist license, for unprofessional conduct, for the excessive furnishing of controlled substances, or the improper dispensing of prescriptions, pursuant to Business and Professions Code section 4301, subdivision (d), and Health and Safety Code section 11153, as set forth in Factual Findings 1-2, 4-63, and Legal Conclusions 1-15.

17. Cause exists to discipline Respondent TOT's pharmacy license, for unprofessional conduct, for the excessive furnishing of controlled substances,[25] by Respondent Simon or its employees pursuant to Business and Professions Code section 4301, subdivision (d), and Health and Safety Code section 11153, as set forth in Factual Findings 1-2, 4-63, and Legal Conclusions 1-5, 7-15.

[25] Respondent TOT was not charged in the Second Cause for discipline. As a result, it was not found in violation of the Second Cause for discipline alleged in the Accusation. (State's Ex. 1.)

Patient Consultations

18. Business and Professions Code section 4301 states in pertinent part:

> The Board shall take action against any holder of a license who is guilty of unprofessional conduct . . . . Unprofessional conduct shall include, but is not limited to, any of the following:
>
> [¶] . . . [¶]
>
> (b) Incompetence.

19. Incompetence is a relative term that indicates an absence of qualification, ability, or fitness to perform a prescribed duty or function. According to the California Court of Appeal in *Pollack v. Kinder* (1978) 85 Cal.App.3d 833, 837, "It is commonly defined to mean a general lack of present ability to perform a given duty as distinguished from inability to perform such duty as a result of mere neglect or omission."

20. Complainant alleged that Respondent Simon's failure to document her consultations with either patients or physicians, in the cases of those patients and prescriptions set forth in Tables A and B, constituted incompetence. Sydejko opined that a reasonable and prudent pharmacist would document patient consultations due to the quantity and dosage of narcotic medications, and the failure to do so was incompetence. However, Sydejko did not explain why he thought Respondent Simon was not "capable" of performing that duty. Respondent Simon testified that she consulted with patients as to the prescriptions that concerned her and that she consulted with Dr. Michael Huff, the prescribing physician when questions arose. (Factual Findings 10 through 13.) The evidence did not establish that Respondent Simon was not capable of documenting her consultations, only that Respondent Simon failed to do so for the prescriptions in Tables A and B. As a result, Complainant did not establish by clear and convincing evidence that Respondent Simon acted incompetently with respect to the prescriptions listed in Tables A and B.

21. Cause does not exist to revoke or suspend Respondent Simon's pharmacist license, for incompetence, for failing to document patient and physician consultations, pursuant to Business and Professions Code section 4301, subdivision (b), as set forth in Factual Findings 1, 4-13, 30, and Legal Conclusions 1-5, and 18-20.[26]

Deviating from Prescription Requirements

22. Business and Professions Code section 4301 states in pertinent part:

---

[26] Respondent TOT was not charged in the Third Cause for discipline listed in the Accusation.

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

[¶] . . . [¶]

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

23. California Code of Regulations, title 16, section 1716 states:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

24. Respondent Simon, or someone under her supervision at All Med Drugs, modified patient L.H.'s prescription, by filling and dispensing Roxicodone (15 mg.) instead of Roxicodone (30 mg.). (Factual Finding 79.) The evidence did not establish the change was authorized by the prescribing physician. (Factual Finding 80.) Respondent Simon's explanation, that the pharmacy was likely out of the appropriate strength medication, does not justify the pharmacy's unilateral and unauthorized action, even if her intention was to provide patient L.H. with medication to relieve pain. Therefore, Respondent Simon violated Business and Professions Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1716.

25. Cause exists to revoke or suspend Respondent Simon's pharmacy license, for unprofessional conduct, for Respondent Simon's or someone under her supervision's deviation from the requirements of a prescription, pursuant to Business and Professions Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1716, as set forth in Factual Findings 1-2, 4, 5, 27-30, 38, 79, 80 and Legal Conclusions 1-7, 22-25, and 73-74.[27]

Reviewing Patient Profiles

26. Business and Professions Code section 4301, subdivision (o) is set forth in pertinent part, in Legal Conclusion 22, *ante*.

27. California Code of Regulations, title 16, section 1707.3 states:

Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is

[27] Respondent TOT was not charged in the Fourth Cause for discipline listed in the Accusation.

delivered. The review shall include screening for severe potential drug therapy problems.

28. The Administrative Law Judge found Respondent Simon testified credibly that she reviewed patient profiles before dispensing the medications.[28] He found that, during her testimony, Respondent Simon never feigned a lack of knowledge as to the quantities, dosages, or frequent dispensing of the medications prescribed. Notwithstanding the Board's findings to the contrary regarding Respondent Simon's testimony (Factual Findings 10-26 and Legal Conclusion 12), the evidence did not establish by clear and convincing evidence that either Respondent Simon or another pharmacist at All Med Drugs actually failed to review patient profiles.

29. Cause does not exist to revoke or suspend Respondent Simon's pharmacist license, for unprofessional conduct, for failing to review patient profiles, pursuant to Business and Professions Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1707.3, as set forth in Factual Findings 1, 10-12, 30, 38 and Legal Conclusions 5, and 26-28.

30. Cause does not exist to revoke or suspend Respondent TOT's pharmacy license, for unprofessional conduct, for Respondent Simon's failure to review patient profiles, pursuant to Business and Professions Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1707.3, as set forth in Factual Findings 1, 10-12, and Legal Conclusions 5, and 26-28.

Failure to Maintain Accurate Accountability

31. Business and Professions Code section 4301 states in pertinent part:

> The Board shall take action against any holder of a license who is guilty of unprofessional conduct . . . . Unprofessional conduct shall include, but is not limited to, any of the following:
>
> [¶] . . . [¶]
>
> (j) The violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs.

32. Business and Professions Code section 4081 states in pertinent part:

---

[28] Government Code section 11425.50(b) states, in pertinent part, "If the factual basis for the decision includes a determination based substantially on the credibility of a witness, the statement shall identify any specific evidence of the observed demeanor, manner, or attitude of the witness that supports the determination, and on judicial review the court shall give great weight to the determination to the extent the determination identifies the observed demeanor, manner, or attitude of the witness that supports it." Other findings of credibility did not contain any observations of demeanor or attitude of Respondent Simon.

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs . . . shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every . . . pharmacy . . . holding a currently valid and unrevoked certificate, license, permit, [or] registration . . . who maintains a stock of dangerous drugs . . . .

(b) The owner, officer, and partner of any pharmacy . . . shall be jointly responsible, with the pharmacist-in-charge . . . for maintaining the records and inventory described in this section.

33. Health and Safety Code section 11208 states:

In a prosecution under this division, proof that a defendant received or has had in his possession at any time a greater amount of controlled substances than is accounted for by any record required by law or that the amount of controlled substances possessed by the defendant is a lesser amount than is accounted for by any record required by law is prima facie evidence of guilt.

34. California Code of Regulations, title 16, section 1718 states in pertinent part:

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

35. The Board's audit established discrepancies in the number of Roxicodone and OxyContin tablets. (Factual Finding 82.) While it is possible, as Respondent argued, that given the number of Roxicodone and OxyContin tablets that the pharmacy regularly dispensed, the inventory was simply not reconciled at the time the pharmacy's records were seized by the Board, the evidence did not prove that argument. Moreover, the audit of Dilaudid tablets found no such discrepancy. (*Ibid.*) Therefore, the evidence established that Respondent Simon failed to maintain an accurate accounting of Roxicodone and OxyContin, in violation of Business and Professions Code sections 4301, subdivision (j), 4081, subdivision (a), Health and Safety Code section 11208, and California Code of Regulations, title 16, section 1718.

36. Cause exists to revoke or suspend Respondent Simon's pharmacist license, for unprofessional conduct, for failing to maintain accurate accountability, pursuant to Business and Professions Code sections 4301, subdivision (j), 4081, subdivision (a), Health and Safety Code section 11208, and California Code of Regulations, title 16, section 1718, as set forth in Factual Findings 1, 2, 4, 5, 9, 30, 38, 81, 82, and Legal Conclusions 1-7, 31-35, and 73-74.

37. Cause exists to discipline Respondent TOT's pharmacy license, for

unprofessional conduct, for Respondent Simon's failure to maintain accurate accountability, pursuant to Business and Professions Code sections 4301, subdivision (j), 4081, subdivisions (a) and (b), and California Code of Regulations, title 16, section 1718, as set forth in Factual Findings 1, 2, 4, 5, 9, 30, 38, 81, 82, and Legal Conclusions 1-5, 7, 31-35, and 73-75.

The CURES Reporting

38. Business and Professions Code section 4301, subdivision (j) is set forth in pertinent part, in Legal Conclusion 31, *ante*.

39. Business and Professions Code section 4301, subdivision (o) is set forth in pertinent part, in Legal Conclusion 22, *ante*.

40. Business and Professions Code section 4113 states in pertinent part:

> [¶] . . .[¶]
>
> (b) 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.

41. Health and Safety Code section 11165 states in pertinent part:

> (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II controlled substances, and for statistical analysis, education, and research, the Department of Justice shall . . . establish the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

42. California Code of Regulations, title 16, section 1715.5 states in pertinent part:

> The collection of information authorized by Health and Safety Code section 11165 shall be provided as follows:
>
> (a) For each prescription for a Schedule II controlled substance, the dispensing pharmacy shall provide the following information: the full name and address of the patient; the gender and date of birth of the patient; the DEA (Drug Enforcement Administration) number of the prescriber; the triplicate prescription number; the pharmacy prescription number; the pharmacy license number; the NDC (National Drug Code) number and the quantity of the controlled substance; the ICD-9 (diagnosis code), if available; the date of issue of the prescription, the

date of dispensing of the prescription, and the state medical license number of any prescriber using the DEA number of a government exempt facility.

43. The CURES reports were unreliable and thus could not establish Complainant's allegation that Respondents failed to submit CURES data between 2001 and 2003. While Complainant's evidence (from the Board of Pharmacy) showed no submissions by All Med Drugs in 2001 (under license # 45269 or license # 19488), Respondent's evidence (from the Department of Justice's Bureau of Narcotic Enforcement) showed regular submissions from January to June 2001 (under license # 19488). The evidence did not draw a distinction between the two sources of CURES reports. Furthermore, whether by oversight or design, Complainant failed to proffer evidence of CURES reporting (or the lack thereof), in 2003, under license number 19488. (Factual Finding 83.) Given that the previous license number (19488) elicited proper reporting in the first half of 2001, the evidence offered could not establish Respondents' failure to submit data to CURES in 2003, possibly under the previous license number. The evidence of Respondent Simon's CURES reporting did not establish conclusive violations of state reporting requirements.

44. Cause does not exist to revoke or suspend Respondent Simon's pharmacist license, for unprofessional conduct, for failing to submit CURES data, pursuant to Business and Professions Code sections 4301, subdivisions (j) and (o), 4113, subdivision (b), Health and Safety Code section 11165, and California Code of Regulations, title 16, section 1715.5, as set forth in Factual Findings 1, 4, 5, 83, 84, and Legal Conclusions 5 and 38-43.

45. Cause does not exist to revoke or suspend Respondent TOT's pharmacy license, for unprofessional conduct, for Respondent Simon's failure to submit CURES data, pursuant to Business and Professions Code sections 4301, subdivision (j) and (o), 4113, subdivision (b), Health and Safety Code section 11165, and California Code of Regulations, title 16, section 1715.5, as set forth in Factual Findings 1, 4, 5, 83, 84, and Legal Conclusions 5 and 38-43.

Dispensing Prescriptions to Patient R.S. without a Prescription

46. Business and Professions Code section 4301 states in pertinent part:

> The Board shall take action against any holder of a license who is guilty of unprofessional conduct . . . . Unprofessional conduct shall include, but is not limited to, any of the following:
>
> [¶] . . . [¶]
>
> (e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances

furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

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

47. Business and Professions Code section 4059 states in pertinent part:

(a) A person may not furnish any dangerous drugs, except upon the prescription, except upon the prescription of a physician [or] dentist. . . .

Business and Professions Code section 4063 states in pertinent part:

No prescription for any dangerous drug . . . may be refilled except upon authorization of the prescriber.

48. The parties stipulated that Respondents filled and dispensed Lortab (10-500 mg.) to patient R.S. without a valid prescription. (Factual Finding 68.) The manner in which patient R.S. obtained the Lortab from All Med Drugs was not established, but any allegations made by patient R.S. in this proceeding carried little to no weight due to her admitted history of obtaining pain medications by fraudulent means.[29] The Board inspector's failure to consider patient R.S.'s credibility (Factual Finding 66) weakened Complainant's case as to R.S.'s allegations. As Section 4301(e) is not applicable to the Respondents in this case, it was not considered in reaching this decision (see discussion at fn. 24). The evidence further failed to establish by clear and convincing evidence that the dispensing of R.S.'s fraudulent prescriptions by Respondent Simon were dishonest. Thus, while the parties' stipulation established violations of Business and Professions Code sections 4059 and 4063, the evidence failed to prove violations of Business and Professions Code section 4301, subdivision (f).

49. Cause exists to revoke or suspend Respondent Simon's pharmacist license, for unprofessional conduct, for furnishing controlled substances without a prescription, pursuant to Business and Professions Code sections 4059, and 4063, as set forth in Factual Findings 1, 2, 4, 5, 27-30, 38, 64-70, and Legal Conclusions 1-7, 46-48, and 73-74.

50. Cause exists to discipline Respondent TOT's pharmacy license, for unprofessional conduct, for Respondent Simon's furnishing of controlled substances without a prescription, pursuant to Business and Professions Code sections 4059, and

[29] With little if any credibility given to R.S.'s testimony, her allegation, that Respondent Simon attempted to solicit R.S. to illegally acquire prescription narcotics for cash payments, was not established. (See Factual Finding 23, *ante*.)

4063, as set forth in Factual Findings 1, 2, 4, 5, 27-30, 38, 64-70, and Legal Conclusions 1-5, 7, 46-48, and 73-75.

51. Cause does not exist to revoke or suspend Respondent Simon's pharmacist license or Respondent TOT's pharmacy license, for unprofessional conduct, for Respondent Simon's furnishing of controlled substances without a prescription, pursuant to Business and Professions Code sections 4301, subdivisions (e) and (f), as set forth in Factual Findings 1, 4, 5, 64-69 and Legal Conclusions 5 and 46-48.

Dispensing Early Refills to Patient R.S.

52. Business and Professions Code section 4301 states in pertinent part:

> The Board shall take action against any holder of a license who is guilty of unprofessional conduct . . . . Unprofessional conduct shall include, but is not limited to, any of the following:
>
> [¶] . . . [¶]
>
> (c) Gross negligence.

53. Gross negligence is defined as "the want of even scant care or an extreme departure from the ordinary standard of conduct." (*Eastburn v. Regional Fire Protection Authority* (2003) 31 Cal.4th 1175, 1185-1186.)

54. Of the 14 prescriptions in Table C (Factual Finding 72), two of those prescriptions were not improper early refills (prescription # 828982 on June 19, 2002, and prescription # 831578 on July 15, 2002), despite Sydejko's opinion to the contrary. While these two prescriptions indeed constituted early refills, they were early by just a few days, similar to those other refills Sydejko found appropriate. (Factual Finding 73.) As to the remaining 12 prescriptions in Table C, and in concert with Sydejko's opinion, the pattern of consistently early refills throughout May and July 2002 should have raised a concern for Respondent Simon, sufficient to have prompted, pursuant to her corresponding responsibility, some inquiry on her part with either patient R.S. or the prescribing physician. Respondent Simon failed to establish that she consulted with the prescribing physician or with patient R.S. regarding the pattern of early refills. These refills were, in all cases, significantly early refills. For example, patient R.S. was dispensed a refill of Hydrocodone (10-500 mg.) on March 8, 2002, just two days after a seven day supply was dispensed; on May 10, 2002, she received a refill just three days after a 15 day supply had been dispensed; and on July 19, 2002, she received a refill just one day after a 10 day supply had been dispensed. (Factual Finding 72.) With no evidence that Respondent Simon took any effort to consult with either patient R.S. or her prescribing physician, the refills showed the want of even scant care in dispensing refills of Hydrocodone, a Schedule III controlled substance. Therefore, Respondent Simon's filling and dispensing of such early refills constituted gross negligence, in violation of Business and Professions Code section 4301, subdivision (c).

55. Cause exists to revoke or suspend Respondent Simon's pharmacist license, for unprofessional conduct, gross negligence, for dispensing early refills to Patient R.S., pursuant to Business and Professions Code section 4301, subdivision (c), as set forth in Factual Findings 1-2, 4, 5, 27-30, 38, 71-73, and Legal Conclusions 1-7, 52-54, and 73, 74.[30]

Failing to Remove Expired Medications

56. Business and Professions Code section 4301 states in pertinent part:

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

57. Business and Professions Code section 4342 states in pertinent part:

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

58. California Code of Regulations, title 16, section 1716.2 states in pertinent part:

> (a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:
>
> [¶] . . .[¶]
>
> (3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

59. Respondent Simon did not contest the existence of the 55 expired medications at All Med Drugs. (Factual Finding 86.) The evidence proved 55 medications were expired or had such close expiration dates as to render those medications expired in effect. Her argument that the expired drugs nonetheless needed to be secured and thus

[30] Respondent TOT was not charged in the Ninth Cause for discipline listed in the Accusation.

remain on the shelves explained their placement in a secured area, but it did not explain why at least 28 medications had 2001 and 2002 expiration dates and had not been removed before March 11, 2003. Therefore, Respondent Simon was in violation of Business and Professions Code sections 4301, 4342, subdivision (a), and California Code of Regulations, title 16, section 1716.2, subdivision (a)(3).

60. Cause exists to revoke or suspend Respondent Simon's pharmacist license, for unprofessional conduct, for failing to remove expired drugs, pursuant to Business and Professions Code sections 4301, 4342, subdivision (a), and California Code of Regulations, title 16, section 1716.2, subdivision (a)(3), as set forth in Factual Findings 1, 2, 4, 5, 27-30, 85-87, and Legal Conclusions 1-7, 56-59, and 73, 74.

61. Cause exists to discipline Respondent TOT's pharmacy license, for unprofessional conduct, for Respondent Simon's failure to remove expired drugs, pursuant to Business and Professions Code sections 4301, 4342, subdivision (a), and California Code of Regulations, title 16, section 1716.2, subdivision (a)(3), as set forth in Factual Findings 1, 2, 4, 5, 27-30, 38, 85-87, and Legal Conclusions 1-5, 7, 56-59, and 73-75, 78.

The Unauthorized Actions of the Pharmacy Technician

62. Business and Professions Code section 4301 is set forth in pertinent part in Legal Conclusion 56, *ante*.

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

> [¶] . . .[¶]
>
> (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.
>
> [¶] . . .[¶]
>
> (d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

64. Respondent Simon acknowledged that Pharmacy Technician Christina Burgos had filled prescriptions for family members while a pharmacy technician at All Med Drugs, actions that are not in violation of any law. However, the parties stipulated that Burgos processed prescriptions and refills for family members, changing the quantity and refill availability on those prescriptions, without the authorization of the prescribing

physician. (Factual Findings 74 and 75.) Those actions violate Business and Professions Code section 4301, and California Code of Regulations, title 16, section 1714, subdivisions (b) and (d). Respondent Simon argued that Burgos acted surreptitiously, and thus, despite Respondent Simon's efforts to supervise and monitor pharmacy activity, Burgos acted without Respondent Simon's knowledge. The evidence did not prove Burgos acted with Respondent Simon's knowledge, but, as the Pharmacist-in-Charge, the responsibility for Burgos's actions falls to Respondent Simon as well as to Burgos.

65. Cause exists to revoke or suspend Respondent Simon's pharmacist license, for unprofessional conduct, for failing to maintain adequate security of its drugs, pursuant to Business and Professions Code section 4301, and California Code of Regulations, title 16, section 1714, subdivisions (b) and (d), as set forth in Factual Findings 1, 2, 4, 5, 27-30, 38, 74-76, and Legal Conclusions 1-7, 62-64, 73, 74.

66. Cause exists to discipline Respondent TOT's pharmacy license, for unprofessional conduct, for Respondent Simon's failure to maintain adequate security of its drugs, pursuant to Business and Professions Code section 4301, and California Code of Regulations, title 16, section 1714, subdivisions (b) and (d), as set forth in Factual Findings 1,2, 4, 5, 27-30, 38, 74-76, and Legal Conclusions 1-5, 7, 62-64, and 73-75, 78.

The Twelve Thousand Dollar Check

67. Business and Professions Code section 4301 states in pertinent part:

> The Board shall take action against any holder of a license who is guilty of unprofessional conduct . . . . Unprofessional conduct shall include, but is not limited to, any of the following:
>
> [¶] . . . [¶]
>
> (g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

68. Complainant failed to prove that Respondent Simon knowingly made and signed the $12,256.49 check to herself under false pretenses. While it was undoubtedly odd for Respondent Simon to buy pharmacy equipment in excess of $12,000, with her own cash and not obtain receipts, the evidence did not establish that Respondent Simon stole the money or otherwise improperly paid herself with the approximately $12,000 check. The co-owner did not allege theft or fraud to the authorities or to Respondent Simon directly. There was no law enforcement investigation. Moreover, once the co-owner was aware of the check at issue, he would have reasonably attempted to claim the full sum at some time in the ensuing six years. The co-owner testified at hearing that, upon seeing the MTC invoice, he was satisfied with Respondent Simon's explanation of the check. Had the check been a source of concern regarding theft or fraud, the co-owner would have taken steps to pursue the substantial amount of money; furthermore, he would

have stated at hearing that the check raised such a concern. He did neither, and the absence of any action left sufficient doubt as to whether Respondent Simon made and signed the check under false pretenses. The fact that MTC was burglarized approximately one year before Respondent Simon's purchases (November 2000) did not establish that MTC was left with no pharmacy equipment to sell, since the theft report showed an almost exclusive list of medications stolen. It stands to reason that other medical supplies may have withstood the burglary of MTC and were available for sale after MTC discontinued as a business, in October 2001. (Factual Finding 78.)

69. Cause does not exist to revoke or suspend Respondent Simon's pharmacist license, for unprofessional conduct, for making or signing a false document, pursuant to Business and Professions Code section 4301, subdivision (g), as set forth in Factual Findings 1, 4, 5, 77, 78, and Legal Conclusions 5, 67, and 68.[31]

Complainant's Costs

70. Business and Professions Code section 125.3 states in pertinent part:

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

71. The Board must exercise its discretion to reduce or eliminate cost awards in a manner that will ensure the award does not deter licensees with potentially meritorious claims or defenses from exercising their right to a hearing. (*Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.App.4th 32, 45" "[T]he Board may not assess the full costs of investigation and prosecution when to do so will unfairly penalize a [licenesee] who has committed some misconduct, but who has used the hearing process to obtain dismissal of other charges or a reduction in the severity of the discipline imposed." (Id.) The Board in imposing costs in such situations must consider the licensee's subjective good faith belief in the merits of his or her position and the Board must consider whether or not the licensee has raised colorable claim. The Board must consider the licensee's ability to make payment. Finally, the Board "may not assess the full costs of investigation

[31] Respondent TOT was not charged in the Twelfth Cause for discipline listed in the Accusation.

and prosecution when it has conducted a disproportionately large investigation and prosecution to prove that a [licensee] engaged in relatively innocuous conduct." (Id., footnote omitted.) The evidence established cause for disciplining Respondent Simon's pharmacist license in eight of 12 causes for discipline alleged in the Accusations. The evidence established cause for disciplining Respondent TOT's pharmacy permit in five out of 7 causes for discipline alleged in the Accusations. While it cannot be said that the charges that were not sustained were not of concern to the Board, the charges that were sustained against both Respondents were extremely serious. In particular, the excessive furnishing of controlled substances, furnishing controlled substances without a prescription and failure to maintain accurate inventory and security of controlled substances are very serious charges that were sustained against Respondents. Respondent Simon did not proffer evidence of her ability or inability to pay the costs being sought. The Administrative Law Judge found that it was appropriate to award one-third of the full costs of investigation ($11,505), and one third of the costs of prosecution and enforcement ($34,529). Pursuant to Business and Professions Code section 125.3(d), this finding is not reviewable by the Board to increase the cost award. Complainant is entitled to a total of $46,034. Respondents are jointly and severally liable. (See Legal Conclusions 6, 7.)

72. Cause exists to award Complainant costs, pursuant to Business and Professions Code section 125.3, as set forth in Factual Findings 1-88, and the Legal Conclusions.

Factors Considered for the Appropriate Measure of Discipline

73. In order to determine the appropriate measure of discipline, it is necessary to weigh and balance Respondents' violations of law as well as factors in justification, aggravation, or mitigation. Protection of the public is the Board's highest priority. The Board fulfills its public mandate by, among other things, imposing discipline. It is very important that the Board's licensees are aware of and abide by the standards of pharmacy practice and applicable pharmacy laws. The eight causes for discipline proven demonstrate that Respondent Simon is either unaware of or refuses to abide by those standards and laws. Respondents provided shockingly large quantities of controlled substances and at doses and frequencies that fell below the standard of care. As the record establishes, these drugs were dispensed to these patients without regard for patient health and safety or public safety. In addition, Respondents could not demonstrate that during this time period the pharmacy: maintained adequate security of controlled substances, accounted for its drug inventory, furnished controlled substances with valid prescriptions or authorizations, did not deviate from the requirements of a prescription, did not dispense inappropriately early fills of prescriptions for controlled substances, or removed expired drugs from its shelves. The wide-spread and serious nature of these violations indicates Respondents do not have systems in place to protect patients and dispense prescriptions in a safe and effective manner.

74. Further, Respondent Simon's evasive and inconsistent responses regarding her statements and practices are of concern to the Board. Respondent Simon's admission that she had a practice of signing off on prescriptions for controlled substances

that were filled by other pharmacists and sending that false information to the Drug Enforcement Administration is also of concern to the Board. The public is protected when pharmacists are knowledgeable about their responsibilities and discharge those duties in an honest manner. Respondent Simon's denial that her pharmacy practice in this case fell below the standard of care in the face of clear and convincing evidence to the contrary is also of concern to the Board. These denials, her lack of understanding of her responsibilities, and her lack of remorse demonstrate that Respondent Simon is not able to practice with safety to the public.

75. The five causes for discipline proven against Respondent TOT prove that it has taken no responsibility for monitoring persons that manage the pharmacy and no responsibility for compliance with the laws governing pharmacies. The argument that Respondent Simon was responsible for the failures in this case does not absolve Respondent TOT of its own responsibility to ensure that its agents comply with applicable laws. As a result, public protection requires monitoring to ensure that TOT pharmacy pays close attention to the pharmacy's operations and practices in the future. However, the Board considered the fact that Respondent TOT cooperated in the investigation of these matters and has since disassociated itself from Respondent Simon, who is no longer an owner of the pharmacy.

76. Complainant did not establish the factor alleged in aggravation in this case. In mitigation, Respondents had no previous record of discipline.

77. For the reasons set forth in Legal Conclusions 73 and 74, the public will be protected by outright revocation of Respondent Simon's license.

78. For the reasons set forth in Legal Conclusion 75, the public will be protected by the imposition of stayed revocation and five years' probation with standard terms and conditions on Respondent TOT's pharmacy permit. Five years' probation is the minimum necessary for the Board to monitor Respondent TOT's conduct with respect to the issues in this case. The imposition of discipline will produce a positive effect for Respondent TOT and the public, in that discipline will encourage on-going assessment of pharmacy operations, places the public on notice that such conduct is significant, and serves the public by having a fully-informed, educated and rehabilitated licensee. The Board has determined that the following terms and conditions of probation for Respondent TOT are sufficient to meet the goal of rehabilitation in this case.

ORDERS

Regarding Respondent Simon

1. License number RPH 41523, issued to Respondent Carol Zalez-Simon is REVOKED.

2. Respondent Carol Zalez-Simon and Respondent TOT Pharmacy are ordered to pay the Board of Pharmacy $46,034.

Regarding Respondent TOT

3. Permit number PHY 45269, issued to Respondent TOT Pharmacy is REVOKED; however, the revocation is STAYED and Respondent TOT is placed on PROBATION for five years upon the following terms and conditions (where "Respondent TOT" is mentioned in this Order, any and all owners of TOT pharmacy, doing business as All Med Drugs, is intended to be included):

(a) Obey All Laws

Respondent TOT shall obey all state and federal laws and regulations substantially related to or governing the practice of pharmacy.

Respondent TOT shall report any of the following occurrences to the Board, in writing, within 72 hours of such occurrence:

1) an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;

2) a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment;

3) a conviction of any crime;

4) discipline, citation, or other administrative action filed by any state and federal agency which involves respondent TOT's pharmacy license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

(b) Reporting to the Board

Respondent TOT shall report to the Board quarterly. The report shall be made either in person or in writing, as directed. Respondent TOT shall state under penalty of perjury whether there has been compliance with all the terms and conditions of probation. If the final probation report is not made as directed, probation shall be extended automatically until such time as the final report is made and accepted by the Board.

(c) Interview with the Board

Upon receipt of reasonable notice, Respondent TOT shall appear in person, for interviews with the Board, upon request at various intervals at a location to be determined by the Board. Failure to appear for a scheduled interview without prior notification to Board staff shall be considered a violation of probation.

(d) Cooperation with Board Staff

Respondent TOT shall cooperate with the Board's inspectional program and in the Board's monitoring and investigation of Respondent TOT's compliance with the terms and conditions of its probation. Failure to comply shall be considered a violation of probation.

(e) Reimbursement of Board Costs

Respondent TOT shall pay to the Board its costs of investigation and prosecution in the amount of $46,034. Respondent TOT shall make said payments as determined by the Board. Respondent TOT and Respondent Simon are jointly and severally liable.

The filing of bankruptcy by Respondent TOT shall not relieve Respondent TOT of its responsibility to reimburse the Board its costs of investigation and prosecution.

(f) Probation Monitoring Costs

Respondent TOT shall pay the costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board at the end of each year of probation. Failure to pay such costs shall be considered a violation of probation.

(g) Status of License

Respondent TOT shall, at all times while on probation, maintain a current license with the Board. If Respondent TOT submits an application to the Board, and the application is approved, for a change of location, change of permit or change of ownership, the Board shall retain continuing jurisdiction over the license, and Respondent TOT shall remain on probation as determined by the Board.

(h) License Surrender while on Probation

Following the effective date of this decision, should Respondent TOT cease practice due to retirement or health of its owners, or be otherwise unable to satisfy the terms and conditions of probation, Respondent TOT may tender its license to the Board for surrender. The Board shall have the discretion whether to grant the

request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent TOT will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, Respondent TOT shall relinquish its pocket license to the Board within 10 days of notification by the Board that the surrender is accepted. Respondent TOT may not reapply for any license from the Board for three years from the effective date of the surrender. Respondent TOT shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board.

(i) Notice to Employees

Respondent TOT shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent TOT shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions by posting a notice, circulating a notice, or both.

"Employees" as used in this provision includes all full-time, part-time, temporary and relief employees and independent contractors employed or hired at any time during probation.

(j) Owners and Officers: Knowledge of the Law

Respondent TOT shall provide, within 30 days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of 10% or more of the interest in Respondent TOT or Respondent TOT's stock, and any officer, stating said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy.

(k) Violation of Probation

If Respondent TOT violates probation in any respect, the Board, after giving Respondent TOT notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order which was stayed. If a petition to revoke probation or an accusation is filed against Respondent TOT during probation, the Board shall have continuing jurisdiction and the period of probation shall be extended, until the petition to revoke probation or accusation is heard and decided.

If Respondent TOT has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent TOT, and probation shall automatically be extended until all terms and conditions have been satisfied or

the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty which was stayed.

(l) Completion of Probation

Upon successful completion of probation, Respondent TOT's license will be fully restored.

This Decision shall become effective on August 18, 2008.

IT IS SO ORDERED this 17th day of July 2008.

Kenneth H. Schell

Kenneth H. Schell
President, Board of Pharmacy
Department of Consumer Affairs

BILL LOCKYER, Attorney General
of the State of California
GLORIA A. BARRIOS,
Supervising Deputy Attorney General
MICHEL W. VALENTINE, State Bar No. 153078
Deputy Attorney General
California Department of Justice
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-1034
Facsimile: (213) 897-2804

Attorneys for Complainant

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

In the Matter of the Accusation Against: TOT PHARMACY, INC. dba ALL MED DRUGS 442 N. Moorpark Road Thousand Oaks, California 91360 CAROL ZALEZ-SIMON, Pharmacist-in-Charge (From 7/27/01 to 6/30/03) Pharmacy Permit No. PHY 45269 and CAROL MARIE ZALEZ-SIMON 16161 Ventura Blvd., Suite 487 Encino, California 91436 Pharmacist No. RPH 41523 Respondents.	Case No. 2683 OAH No. L-2003120195 **FIRST AMENDED AND SUPPLEMENTAL ACCUSATION**

Complainant alleges:

PARTIES

Virginia K. Herold, (Complainant) brings this First Amended and Supplemental Accusation solely in her official capacity as the Acting Executive Officer of the Board of Pharmacy, Department of Consumer Affairs and supplements the Accusation filed on

///

October 21, 2003 and the First Supplemental Accusation filed on August 2, 2006, in this matter, and for cause for discipline further alleges:

52. Paragraphs two (2) through fifty one (51), inclusive, are incorporated herein by reference, as if fully set forth.

53. Section 4301 states:

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

. . . .

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

54. California Code of Regulations, title 16, section 1714, states:

. . . .

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

. . . .

"(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist."

55. <u>CONTROLLED SUBSTANCES</u>

A. "Vicodin ES 7.5mg./750mg.," is the brand name for Hydrocodone with Acetaminophen. It is a Schedule III controlled substance as designated by Health and Safety

///

Code section 11056, subdivision (e)(4) and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.

B. "Vicodin HP 10mg./660mg.," is the brand name for Hydrocodone with Acetaminophen. It is a Schedule III controlled substance as designated by Health and Safety Code section 11056, subdivision (e)(4) and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.

C. "Valium," is the brand name for Diazepam. It is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(9) and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.

56. DANGEROUS DRUGS

A. "Lasix" is the brand name for Furosemide and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.

B. "Zestril," is the brand name for Lisinopril and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.

C. "Naprosyn," is the brand name for Naproxen and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.

D. "Glucotrol," is the brand name for Metformin and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate Security of Controlled Substances and Dangerous Drugs)

57. Respondents Pharmacy and Zalez-Simon are subject to disciplinary action under sections 4300 and 4301, on the grounds of unprofessional conduct, for violating California Code of Regulations, title 16, section 1714, subdivisions (b) and (d), in that Respondents failed to maintain adequate security of controlled substances and dangerous drugs, by allowing staff to process their own prescriptions and prescriptions for family members, which resulted in the dispensing of prescriptions and prescription refills unauthorized by the prescriber, with changes in quantities, increase in the number of refills, and changes in directions, without obtaining a new

///

prescription. More Specifically, Respondents allowed Pharmacy Technician, C.B. to process unauthorized prescriptions for her family members, including but not limited to:

a. Prescription no. 844083 for #60 tablets of Naproxen 250mg. was dispensed on January 2, 2003 and refilled on April 8, 2003 for #100 tablets of Naproxen 250mg., which was not authorized by Dr. Scarborough for C.M., the aunt of C.B.

b. Prescription no. 844333 for #30 tablets of Lisinopril 10mg. was dispensed on January 6, 2003 and refilled on February 3, 2003 for #30 tablets, March 7, 2003 for #30 tablets, and April 3, 2003 for #100 tablets, which was not authorized by Dr. Baghoumian for patient C.M., the aunt of C.B.

c. Prescription no. 852471 for #100 tablets of Metformin 500mg. was dispensed on April 29, 2003 and refilled on June 21, 2003,.which was not authorized by Dr. Baghoumian for patient C.M., the aunt of C.B.

d. Prescription no. 844506 for #30 tablets of Lasix 20mg., with 4 refills, a possible total of 150 tablets was dispensed on January 8, 2003 for #60 tablets, refilled on April 3, 2003, July 23, 2003, and October 17, 2003, each for #100 tablets. A total of 360 tablets were dispensed of which 210 were not authorized by Dr. Wong for patient C.M., the aunt of C.B.

e. Prescription no. 850914 for #30 tablets of Lisinopril 1mg., with 5 refills, a possible total of #180 tablets was dispensed on July 14, 2003 for #100 tablets, refilled on September 24, 2003, and January 12, 2004, each for #100 tablets. A total of #300 tablets were dispensed of which 120 tablets were not authorized by Dr. Wong for C.M., the aunt of C.B.

f. Prescription no. 855939 for #60 tablets of Metformin 500mg., with 4 refills, a possible total of #300 tablets was dispensed on July 23, 2003 for #100 tablets and refilled on September 24, 2003, November 11, 2003, and January 12, 2004, each for #100 tablets. A total of #400 tablets were dispensed of which #100 tablets were not authorized by Dr. Wong for patient C.M., the aunt of C.B.

g. Prescription no. 872252 for #60 tablets of Metformin 500mg., with 5 refills, a possible total of #360 tablets was dispensed on February 16, 2004 for #120 tablets,

///

refilled on May 5, 2004, July 8, 2004, and September 8, 2004. A total of #480 tablets were dispensed of which #120 tablets were not authorized by Dr. Wong for patient C.M., the aunt of C.B.

h. Prescription no. 846718 for Vicodin HP was dispensed on February 21, 2003 for #40 tablets, then refilled on March 12, 2003 for #40 tablets, March 26, 2003 for #40 tablets, June 26, 2003 for #100 tablets, and July 22, 2003 for #100 tablets. Prescription 846718 was renewed as Prescription no. 859159 on July 22, 2003 for two (2) refills. Prescription 846718 was dispensed on August 13, 2003 for #100 tablets, then refilled on September 11, 2003 for #100 tablets, October 9, 2003 for #100 tablets, October 29, 2003 for #100 tablets, and December 3, 2003 for #100 tablets. Prescription 859159 was renewed as Prescription 868000 for one (1) refill. Prescription 868000 was dispensed on December 19, 2003 for #100 tablets, then refilled on January 20, 2004 for #100 tablets, February 4, 2004 for #100 tablets, April 8, 2004 for #100 tablets, and April 28, 2004 for #100 tablets.

i. Prescription no. 845198 was written as a telephone order for #60 tablets of Vicodin ES with directions to take 1 tablet, twice daily, as needed for pain. The prescription was dispensed on January 16, 2003, refilled on February 4, 2003, renewed on February 20, 2003, and processed as prescription no. 847738 for #360 tablets, with one refill on March 7, 2003. There was a change of directions to take 2 tablets every 4 to 6 hours, as needed for pain, without a verbal order taken by a pharmacist or written order by Dr. Darakjian for R.C., the stepfather of C.B.

TWELFTH CAUSE FOR DISCIPLINE

(Knowingly Made or Signed A False Certificate or Other Document)

58. Respondent Zalez-Simon is subject to disciplinary action under section 4300 and 4301, subdivision (g), on the grounds of unprofessional conduct, in that on or about November 20, 2001, Respondent knowingly wrote a check to herself for $12,256.49, to pay for a false invoice, dated November 10, 2001, for the purchase of medical supplies from MTC Pharmacy, when MTC Pharmacy was no longer conducting business, effective March 2001.

///

///

PRAYER

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

1. Revoking or suspending Original Pharmacy Permit No. PHY 45259, issued to Tot Pharmacy, doing business as, All Med Drugs;

2. Revoking or suspending Original Pharmacist No. RPH 41523, issued to Carol Marie Zalez-Simon;

3. Ordering Tot Pharmacy and Carol Marie Zalez-Simon to pay the Pharmacy Board the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

DATED: 12/22/06

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

LA2003600653
60179480.wpd
jz (11/21/06)

BILL LOCKYER, Attorney General
of the State of California
MICHEL W. VALENTINE, State Bar No. 153078
Deputy Attorney General
California Department of Justice
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-1034
Facsimile: (213) 897-2804

Attorneys for Complainant

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

In the Matter of the Accusation Against: TOT PHARMACY, INC. dba ALL MED DRUGS 442 N. Moorpark Road Thousand Oaks, California 91360 CAROL ZALEZ-SIMON, Pharmacist-in-Charge (From 7/27/01 to 6/30/03) JOHN LEE, Pharmacist-in-Charge (From 7/14/03) Pharmacy Permit No. PHY 45269 and CAROL MARIE ZALEZ-SIMON 16161 Ventura Blvd., Suite 487 Encino, California 91436 Pharmacist No. RPH 41523 Respondents.	Case No. 2683 OAH No. L-2003120195 **FIRST SUPPLEMENTAL ACCUSATION**

Complainant alleges:

PARTIES

Virginia K. Herold (Complainant) brings this First Supplemental Accusation solely in her official capacity as the Interim Executive Officer of the Board of Pharmacy, Department of Consumer Affairs and supplements the accusation filed on October 21, 2003, in this matter, and for cause for discipline further alleges:

///

52. Paragraphs two (2) through fifty one (51), inclusive, are incorporated herein by reference, as if fully set forth.

53. California Code of Regulations, title 16, section 1714, states:

. . . .

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

. . . .

"(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist."

54. CONTROLLED SUBSTANCES

A. "Vicodin ES 7.5mg./750mg.," is the brand name for Hydrocodone with Acetaminophen. It is a Schedule III controlled substance as designated by Health and Safety Code section 11056, subdivision (e)(4) and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.

B. "Vicodin HP 10mg./660mg.," is the brand name for Hydrocodone with Acetaminophen. It is a Schedule III controlled substance as designated by Health and Safety Code section 11056, subdivision (e)(4) and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.

C. "Valium," is the brand name for Diazepam. It is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(9) and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.

///

///

55. DANGEROUS DRUGS

A. "Lasix" is the brand name for Furosemide and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.

B. "Zestril," is the brand name for Lisinopril and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.

C. "Naprosyn," is the brand name for Naproxen and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.

D. "Glucotrol," is the brand name for Metformin and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate Security of Controlled Substances and Dangerous Drugs)

56. Respondents Pharmacy and Zalez-Simon are subject to disciplinary action under sections 4300 and 4301, on the grounds of unprofessional conduct, for violating California Code of Regulations, title 16, section 1714, subdivisions (b) and (d), in that Respondents failed to maintain adequate security of controlled substances and dangerous drugs, by allowing staff to process their own prescriptions and prescriptions for family members, which resulted in the dispensing of prescriptions and prescription refills unauthorized by the prescriber, with changes in quantities, increase in the number of refills, and changes in directions, without obtaining a new prescription. More Specifically, Respondents allowed Pharmacy Technician, C.B. to process unauthorized prescriptions for her family members, including but not limited to:

a. Prescription no. 844083 for #60 tablets of Naproxen 250mg. was dispensed on January 2, 2003 and refilled on April 8, 2003 for #100 tablets of Naproxen 250mg., which was not authorized by Dr. Scarborough for C.M., the aunt of C.B.

b. Prescription no. 844333 for #30 tablets of Lisinopril 10mg. was dispensed on January 6, 2003 and refilled on February 3, 2003 for #30 tablets, March 7, 2003 for #30 tablets, and April 3, 2003 for #100 tablets, which was not authorized by Dr. Baghoumian for patient C.M., the aunt of C.B.

///

c. Prescription no. 852471 for #100 tablets of Metformin 500mg. was dispensed on April 29, 2003 and refilled on June 21, 2003, which was not authorized by Dr. Baghoumian for patient C.M., the aunt of C.B.

d. Prescription no. 844506 for #30 tablets of Lasix 20mg., with 4 refills, a possible total of 150 tablets was dispensed on January 8, 2003 for #60 tablets, refilled on April 3, 2003, July 23, 2003, and October 17, 2003, each for #100 tablets. A total of 360 tablets were dispensed of which 210 were not authorized by Dr. Wong for patient C.M., the aunt of C.B.

e. Prescription no. 850914 for #30 tablets of Lisinopril 1mg., with 5 refills, a possible total of #180 tablets was dispensed on July 14, 2003 for #100 tablets, refilled on September 24, 2003, and January 12, 2004, each for #100 tablets. A total of #300 tablets were dispensed of which 120 tablets were not authorized by Dr. Wong for C.M., the aunt of C.B.

f. Prescription no. 855939 for #60 tablets of Metformin 500mg., with 4 refills, a possible total of #300 tablets was dispensed on July 23, 2003 for #100 tablets and refilled on September 24, 2003, November 11, 2003, and January 12, 2004, each for #100 tablets. A total of #400 tablets were dispensed of which #100 tablets were not authorized by Dr. Wong for patient C.M., the aunt of C.B.

g. Prescription no. 872252 for #60 tablets of Metformin 500mg., with 5 refills, a possible total of #360 tablets was dispensed on February 16, 2004 for #120 tablets, refilled on May 5, 2004, July 8, 2004, and September 8, 2004. A total of #480 tablets were dispensed of which #120 tablets were not authorized by Dr. Wong for patient C.M., the aunt of C.B.

h. Prescription no. 846718 for Vicodin HP was dispensed on February 21, 2003 for #40 tablets, then refilled on March 12, 2003 for #40 tablets, March 26, 2003 for #40 tablets, June 26, 2003 for #100 tablets, and July 22, 2003 for #100 tablets. Prescription 846718 was renewed as Prescription no. 859159 on July 22, 2003 for two (2) refills. Prescription 846718 was dispensed on August 13, 2003 for #100 tablets, then refilled on September 11, 2003 for #100 tablets, October 9, 2003 for #100 tablets, October 29, 2003 for #100 tablets, and December 3, 2003 for #100 tablets. Prescription 859159 was renewed as Prescription 868000 for one (1) refill.

Prescription 868000 was dispensed on December 19, 2003 for #100 tablets, then refilled on January 20, 2004 for #100 tablets, February 4, 2004 for #100 tablets, April 8, 2004 for #100 tablets, and April 28, 2004 for #100 tablets.

i. Prescription no. 845198 was written as a telephone order for #60 tablets of Vicodin ES with directions to take 1 tablet, twice daily, as needed for pain. The prescription was dispensed on January 16, 2003, refilled on February 4, 2003, renewed on February 20, 2003, and processed as prescription no. 847738 for #360 tablets, with one refill on March 7, 2003. There was a change of directions to take 2 tablets every 4 to 6 hours, as needed for pain, without a verbal order taken by a pharmacist or written order by Dr. Darakjian for R.C., the stepfather of C.B.

PRAYER

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

1. Revoking or suspending Original Pharmacy Permit No. PHY 45259, issued to Tot Pharmacy, doing business as, All Med Drugs;

2. Revoking or suspending Original Pharmacist No. RPH 41523, issued to Carol Marie Zalez-Simon;

3. Ordering Tot Pharmacy and Carol Marie Zalez-Simon to pay the Pharmacy Board the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

DATED: 8/2/06

Michael W. Valente DAG for

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

LA2003600653
60147701.wpd
jz (8/2/06)

BILL LOCKYER, Attorney General
of the State of California
MICHEL W. VALENTINE, State Bar No. 153078
Deputy Attorney General
California Department of Justice
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-1034
Facsimile: (213) 897-2804

Attorneys for Complainant

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

In the Matter of the Accusation Against: TOT PHARMACY dba ALL MED DRUGS 442 N. Moorpark Road Thousand Oaks, California 91360 CAROL ZALEZ-SIMON Pharmacist-in-Charge Pharmacy Permit No. PHY 45269 and CAROL MARIE ZALEZ-SIMON 16161 Ventura Blvd., Suite 487 Encino, California 91436 Pharmacist No. RPH 41523 Respondents.	Case No. 2683 **ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about July 27, 2001, the Board of Pharmacy issued Original Pharmacy Permit No. PHY 45269 to Tot Pharmacy, dba All Med Drugs (Respondent

Pharmacy). From July 27, 2001 through June 30, 2003, Carol Marie Zalez-Simon was the Pharmacist-in-Charge. Since July 14, 2003, John Lee, RPH 41523, has been the Pharmacist-in-Charge. The Permit was in full force and effect at all times relevant to the charges brought herein and will expire on July 1, 2004, unless renewed.

3. On or about April 23, 1988, the Board of Pharmacy issued Pharmacist Number RPH 41523 to Carol Marie Zalez-Simon (Respondent Zalez-Simon). The permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2005, unless renewed.

JURISDICTION

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

5. Section 4300 permits the Board to take disciplinary action to suspend or revoke a license or permit.

6. Section 118(b) states the suspension, expiration, or forfeiture by operation of law of a license issued by a Board in the department, or its suspension, forfeiture, or cancellation by order of the Board or by order of a court of law, or its surrender without the written consent of the Board, shall not, during any period in which it may be renewed, restored, reissued (Section 4096), or reinstated, deprive the Board of its authority to institute or continue a disciplinary proceeding against the licensee.

7. Section 4301 states that the Board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

"(b) Incompetence.

"(c) Gross negligence.

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

1 "(e) The clearly excessive furnishing of controlled substances in violation of
2 subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in
3 determining whether the furnishing of controlled substances is clearly excessive shall include,
4 but not be limited to, the amount of controlled substances furnished, the previous ordering
5 pattern of the customer (including size and frequency of orders), the type and size of the
6 customer, and where and to whom the customer distributes its product.
7 "(f) The commission of any act involving moral turpitude, dishonesty, fraud,
8 deceit, or corruption, whether the act is committed in the course of relations as a licensee or
9 otherwise, and whether the act is a felony or misdemeanor or not.
10 "(j) The violation of any of the statutes of this state or of the United States
11 regulating controlled substances and dangerous drugs.
12 "(o) Violating or attempting to violate, directly or indirectly, or assisting in or
13 abetting the violation of or conspiring to violate any provision or term of this chapter or of the
14 applicable federal and state laws and regulations governing pharmacy, including regulations
15 established by the board.
16 8. Section 4022 defines "Dangerous Drugs" as any drug that is unsafe for
17 self-medication and which by federal or state law can be lawfully dispensed only on prescription.
18 9. Section 4059(a) states, in pertinent part, that no person shall furnish any
19 dangerous drug, except on the prescription of a physician.
20 10. Section 4063 provides that no prescription for any dangerous drug or
21 dangerous device may be refilled except on authorization of the prescriber. The authorization
22 may be given orally or at the time of giving the original prescription. No prescription for any
23 dangerous drug that is a controlled substance may be designated refillable as needed.
24 11. Section 4081(a) states, in pertinent part, that records of manufacture and of
25 sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times
26 during business hours open to inspection by authorized officers of the law, and shall be preserved
27 for at least three years from the date of making. A current inventory shall be kept by every
28 ///

pharmacy, or establishment holding a currently valid and unrevoked certificate, license, permit, registration who maintains a stock of dangerous drugs or dangerous devices.

12. Section 4081(b) states, in pertinent part, that the owner, officer, and partner of any pharmacy shall be jointly responsible, with the pharmacist-in-charge or exemptee, for maintaining the records and inventory described in this section.

13. Section 4113(b) states that 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.

14. Section 4342(a) states, in pertinent part, that the Board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary.

15. Health and Safety Code section 11153(a), states in part 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. 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.

16. Health and Safety Code section 11165(a), states, in pertinent part, that to assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, and the Osteopathic Medical Board of California Contingent Fund, establish the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

17. Health & Safety Code section 11208 provides, in pertinent part, that an individual received or has had in his possession at any time a greater amount of controlled substances than is accounted for by any record required by law or that the amount of controlled substances possessed by the individual is a lesser amount than is accounted for by law is prima facie evidence of guilt.

18. California Code of Regulations, title 16, section 1707.3, states a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems.

19. California Code of Regulations, title 16, section 1715.5(a) states, in pertinent part, that each prescription for a Schedule II controlled substance, the dispensing pharmacy shall provide the following information: the full name and address of the patient; the gender and date of birth of the patient; the DEA (Drug Enforcement Administration) number of the prescriber; the triplicate prescription number; the pharmacy prescription number; the pharmacy license number; the NDC (National Drug Code) number and the quantity of the controlled substance; the ICD-9 (diagnosis code), if available; the date of issue of the prescription, the date of dispensing of the prescription, and the state medical license number of any prescriber using the DEA number of a government exempt facility.

20. California Code of Regulations, title 16, section 1716 states, in pertinent part, that Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with section 4047.6.

21. California Code of Regulations, title 16, section 1716.2(a) states, in pertinent part, that for the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

(3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber.

///

Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

22. California Code of Regulations, title 16, section 1718, states "Current Inventory" shall be considered to include complete accountability for all dangerous drugs handled by every licensee.

23. Section 125.3 states, 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.

CONTROLLED SUBSTANCES

24. Actiq (generic - Fentanyl) which is a dangerous drug as defined in section 4022 and a Schedule II controlled substance under Health and Safety Code section 11055(c)(8). It is used in the treatment of break-through cancer pain in patients with malignancies.

25. Dilaudid (generic - Hydromorphone) which is a dangerous drug as defined in section 4022 and a Schedule II controlled substance under Health and Safety Code section 11055(b)(1)(K). It is used in the treatment of moderate to severe pain.

26. Lortab (generic - Hydrocodone 7.5 with acetaminophen [APAP] 500 mg) which is a dangerous drug as defined by section 4022 and a controlled substance Schedule III as listed in Health and Safety Code Section 11056(e)(3). It is a narcotic analgesic combination.

27. Methadone (generic - Methadone) which is a dangerous drug as defined in section 4022 and a Schedule II controlled substance under Health and Safety Code section 11055(c)(14). It is used in the treatment of severe pain and detoxification.

28. OxyContin (generic - Oxycodone) which is a dangerous drug as defined in section 4022 and a Schedule II controlled substance under Health and Safety Code section 11055(b)(1)(N). It is used in the treatment of moderate to severe pain.

///

///

29. Roxicodone (generic - Oxycodone) which is a dangerous drug as defined in section 4022 and a Schedule II controlled substance under Health and Safety Code section 11055(b)(1)(N). It is used in the treatment of moderate to severe pain.

FIRST CAUSE FOR DISCIPLINE

(Excessive Furnishing of Controlled Substances)

30. Respondents Pharmacy and Zalez-Simon have subjected their licenses to discipline pursuant to section 4301 for unprofessional conduct as defined in sections 4301(d) and (e) in that Respondents clearly furnished excessive amounts of controlled substances by reason of the following facts:

Patient B.B.

31. On or about August 28, 2002, Respondents filled prescription 835221 for OxyContin 80mg to Patient B.B. which was beyond the recommended dose and dosing frequency.

Patient K.B.

32. From September 20, 2002 to October 29, 2002, Respondents filled prescriptions 836842, 839522, and 841553 for large quantities of Roxicodone 30mg. to Patient K.B.

Patient T.M.

33. On or about February 13, 2003, Respondents filled prescription 847302 for OxyContin 80mg to Patient T.M. which was beyond the recommended dose and dosing frequency. On or about January 31, 2003, Respondents filled prescription 846241 for OxyContin 80mg to Patient T.M. which was beyond the recommended dose and dosing frequency. On or about January 6, 2002, Respondents filled prescription 844299 for OxyContin 80mg to Patient T.M. which was beyond the recommended dose and dosing frequency. On or about December 12, 2002, Respondents failed to properly dispense prescription 842666 for Patient T.M. in that they dispensed it prior to the consumption of the previous prescription.

///

///

Patient J.R.

34. On or about September 10, 2002, Respondents filled prescription 836087 for OxyContin 80mg to Patient J.R. which was beyond the recommended dose and dosing frequency. From August 26, 2002 to October 28, 2002, Respondents filled large quantities of OxyContin 80mg for prescriptions 835044, 836087, 837624, and 839323.

35. From February 6, 2002 to March 11, 2003, Respondents filled prescription 842671 for Dilaudid 8mg to Patient J.R. which was beyond the recommended dose and dosing frequency. Respondents filled large quantities of Dilaudid 8mg. for prescription 835671.

36. From February 6, 2002 to March 11, 2003, Respondents filled large quantities of Roxicodone 30mg for prescriptions 834513, 835045, 836089, 837029, and 842670 to Patient J.R.

Patient C.S.

37. From August 21, 2002 to February 10, 2003, Respondents filled prescriptions 836420, 838347, 840637, 843319, 845289, 847020 for large quantities of OxyContin 80mg to Patient C.S. In addition, Respondents filled prescriptions 834787, 836419, 838346, 840636, 843317, 843987, 845287 and 847022 for large quantities of Roxicodone 30mg to Patient C.S.

Patient D.S.

38. From February 6, 2002 to March 11, 2003, Respondents filled prescriptions for Actiq 1600 mcg to Patient D.S. which was beyond the recommended dose and dosing frequency. Respondents filled large quantities of 360 Actiq 1600mcg lozenges for prescriptions 821016, 824507, 833274, 833855, 835399, 837795, 839696, 841656, 842511 and 844496 to Patient D.S. Actiq is only prescribed for the management of breakthrough cancer pain in patients with malignancies. Patient D.S. did not have cancer nor did she have a history of cancer.

39. From February 6, 2002 to March 11, 2003, Respondents filled prescription 833275 for OxyContin 80mg to Patient D.S. which was beyond the recommended dose and dosing frequency. Respondents filled large quantities of OxyContin for prescriptions

821977, 824509, 832350, 833275, 833857, 835400, 837796, 841656, 842572, 843535, and 844495 to Patient D.S.

40. From February 6, 2002 to March 11, 2003, Respondents failed to properly fill controlled substance prescriptions when they dispensed large qualitites of concurrently multiple controlled substances to Patient D.S. During this period, she had a combination of Actiq 1600 mcg, OxyContin 80mg and Methadone 10mg.

Patient L.T.

41. On or about March 6, 2003, Respondents filled prescription 848840 for large quantities of Dilaudid 8mg to Patient L.T.

SECOND CAUSE FOR DISCIPLINE

(Failure to Properly Dispense Prescriptions)

42. Respondent Zalez-Simon has subjected her license to discipline pursuant to section 4301 for unprofessional conduct as defined in section 4301(d) and in conjunction with Health and Safety Code section 11153 as set forth hereinabove at paragraphs 30 through 41 in that Respondents knew or had reason to know that the prescriptions were not for legitimate medical purposes.

THIRD CAUSE FOR DISCIPLINE

(Incompetence)

43. Respondent Zalez-Simon has subjected her license to discipline pursuant to section 4301 for unprofessional conduct as defined in section 4301(b) for incompetence in that Respondent Zalez-Simon failed to document that she consulted with either the patients or physician as to the increase in the prescriptions as set forth hereinabove at paragraphs 30 through 41.

FOURTH CAUSE FOR DISCIPLINE

(Deviating from the Requirements of a Prescription)

44. Respondent Zalez-Simon has subjected her license to discipline pursuant to section 4301 for unprofessional conduct as defined in section 4301(o) and in conjunction with California Code of Regulations, title 16, section 1716, in that on May 10, 2002, when

Respondent Zalez-Simon filled prescription 827661, she changed the dosage and strength of the prescription without the prior consent of the prescriber.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Review Patient Profiles)

45. Respondents Pharmacy and Zalez-Simon have subjected their licenses to discipline pursuant to section 4301 for unprofessional conduct as defined in section 4301(o) and in conjunction with California Code of Regulations, title 16, section 1707.3 in that Respondents did not review patients medication profile before furnishing medication. A review of the refills dispensed revealed frequent visits by patients to Respondent Pharmacy to obtain more narcotic type controlled substances as set forth hereinabove at paragraphs 31 through 41. Respondents knew or had objective reasons to know that said refills were not issued for legitimate medical purposes and that the quantities dispensed did not constitute a reasonable amount sufficient to maintain the patient until the prescriber could be contacted.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Accurate Accountability)

46. Respondents Pharmacy and Zalez-Simon have subjected their licenses to discipline pursuant to section 4301for unprofessional conduct as defined in section 4301(j) and in violation of sections 4081(a) and (b) in conjunction with California Code of Regulations, title 16, section 1718 and Health and Safety Code section 11208 in that Respondents failed to maintain compliance and control over drug inventory and failed to maintain accurate records of acquisitions and disposition of controlled substances. An audit was conducted for the time period of February 6, 2002 through March 11, 2003. The audit revealed that Respondents did not maintain accurate records of acquisition and disposition of controlled substances as follows:

a. An overage of 800 tablets of Roxicodone 30mg.

b. A shortage of 982 tablets OxyContin SR 80mg.

///

///

///

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Submit Prescription Information)

47. Respondents Pharmacy and Zalez-Simon have subjected their licenses to discipline pursuant to section 4301 for unprofessional conduct as defined in sections 4301(j) and (o) in violation of section 4113(b) and in conjunction with California Code of Regulations, title 16, section 1715.5(a) and Health and Safety Code section 11165 in that from July 2001 to March 11, 2003, Respondents failed to submit prescription information for all Scheduled II controlled substances to the Controlled Substance Utilization Review and Evaluation System as required by law.

EIGHTH CAUSE FOR DISCIPLINE

(Furnishing Controlled Substances without a Prescription)

48. Respondents Pharmacy and Zalez-Simon have subjected their licenses to discipline pursuant to section 4301 as defined in sections 4301(e) and (f) for unprofessional conduct and in violation of section 4059 by filling prescriptions for Patient R.S. without a prescription and/or authorization of the prescriber in violation of section 4063 as follows:

a. On July 29, 2002, August 14, 2002, August 29, 2002, September 9, 2002, September 13, 2002 and October 11, 2002, Respondents filled prescription 833105 for Lortab 10mg/500mg without a prescription.

b. On June 19, 2002, and July 24, 2002, Respondents refilled prescription 828982 for Lortab 10mg/500mg without obtaining authorization from the prescriber.

NINTH CAUSE FOR DISCIPLINE

(Gross Negligence)

49. Respondent Zalez-Simon has subjected her license to discipline pursuant to section 4301 as defined in section 4301(c) for gross negligence in that Respondent, without proper documentation, made early refills of prescriptions for Patient R.S. as follows:

Prescription No.	Early Dispensing Date
822513	March 8, 2002
822513	April 5, 2002

827367	May 10, 2002
828982	May 29, 2002
828982	May 31, 2002
828982	June 19, 2002
828982	June 24, 2002
828982	June 27, 2002
828982	July 1, 2002
831578	July 5, 2002
831578	July 8, 2002
831578	July 15, 2002
831578	July 18, 2002
831578	July 19, 2002
831578	July 22, 2002
836415	September 13, 2002

TENTH CAUSE FOR DISCIPLINE

(Failure to Remove Expired Drugs)

50. Respondents Pharmacy and Zalez-Simon have subjected their licenses to discipline pursuant to section 4301 for unprofessional conduct in violation of section 4342(a) and in conjunction with California Code of Regulations, title 16, section 1716.2(a)(3) in that Respondents failed to remove expired dangerous drugs from their inventory that contained an expiration date greater than180 days for compound dangerous drugs as follows:

a. On March 11, 2003, during an inspection at Respondent Pharmacy, Board inspectors found numerous bottles and vials of compound drugs bearing expiration dates beyond the permissible 180 day period.

AGGRAVATING CIRCUMSTANCES

51. To determine the degree of discipline, if any, to be imposed on Respondent Zalez-Simon, Complainant further alleges by way of aggravation that Respondent Zalez-Simon offered Patient R.S. money if she could get a doctor to write prescriptions for drugs.

Respondent Zalez-Simon told Patient R.S. that she knew of a doctor who would write these prescriptions for her.

PRAYER

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

1. Revoking or suspending Original Pharmacy Number Permit No. PHY 45269, issued to Tot Pharmacy, dba All Med Drugs;

2. Revoking or suspending Pharmacist Number RPH 41523, issued to Carol Marie Zalez-Simon;

3. Ordering Tot Pharmacy and Carol Marie Zalez-Simon to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

DATED: 10/21/03

PATRICIA F. HARRIS
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

03583110-LA2003600653
lbf