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3 **BEFORE THE**
4 **BOARD OF PHARMACY**
5 **DEPARTMENT OF CONSUMER AFFAIRS**
6 **STATE OF CALIFORNIA**

7 In the Matter of the Accusation Against:

Case No. 2216

8 STEPHEN GEORGE MILLER
9 1680 Morningsun Drive
10 Redding, California 96002

**ORDER DENYING PETITION
FOR RECONSIDERATION**

11 Certificate No. RPH 28932

12 SHASTA PHARMACY
13 4460 Westside Road
14 Redding, California 96001

15 Permit No. PHY 39684

16 Respondents

17 **ORDER DENYING RECONSIDERATION**

18 The Board of Pharmacy having read and considered respondent's petition for reconsideration of the
19 board's decision initially effective February 27, 2005 and thereafter stayed to March 10, 2005 to permit the board
20 to consider the petition, NOW THEREFORE IT IS ORDERED that the petition for reconsideration is denied.

21 The materials submitted along with the petition were considered by the board for the sole purpose of
22 deciding whether or not to grant the petition and have not been admitted into the administrative record for any
23 other purpose. The originals of said materials are being returned to the petitioner with this order.

24 IT IS SO ORDERED this 10th day of March 2005.

25 BOARD OF PHARMACY
26 DEPARTMENT OF CONSUMER AFFAIRS
27 STATE OF CALIFORNIA

28 By



STANLEY W. GOLDENBERG
Board President

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7 In the Matter of the Accusation Against:

Case No. 2216

8 STEPHEN GEORGE MILLER
9 1680 Morningsun Drive
10 Redding, California 96002

OAH No. N2000060411

11 Certificate No. RPH 28932

12 SHASTA PHARMACY
13 4460 Westside Road
14 Redding, California 96001

15 Permit No. PHY 39684

16 **STAY ORDER**

17 A stay of execution of the Board of Pharmacy's decision effective February 27, 2005 (Sunday),
18 is hereby ordered until March 10, 2005.

19 The decision in this matter is stayed to permit the board to consider a petition for reconsideration
20 filed by the petitioner and received by the board on February 28, 2005.

21 It is so ORDERED on March 3, 2005.

22
23 BOARD OF PHARMACY
24 DEPARTMENT OF CONSUMER AFFAIRS
25 STATE OF CALIFORNIA

26 

27 By _____
28 STANLEY W. GOLDENBERG
Board President

BEFORE THE
BOARD OF PHARMACY
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

STEPHEN GEORGE MILLER
2645 Howard Drive
Redding, California 96001

Certificate No. RPH 28932

SHASTA PHARMACY
4460 Westside Road
Redding, California 96001

Permit No. PHY 39684

Respondents.

Case No. 2216

OAH No. N2000060411

PROPOSED DECISION

This matter was heard before Ann Elizabeth Sarli, Administrative Law Judge, State of California, Office of Administrative Hearings, in Redding, California. The hearing commenced May 10, 2004, and continued for 14 days through July 1, 2004.¹

Complainant was represented by Joel S. Primes, Deputy Attorney General.

Stephen George Miller represented himself and Shasta Pharmacy, with the assistance of Mrs. Miller, through June 6, 2004. On June 7, 2004, Janice L. Mackey, Attorney at Law, filed a Substitution of Attorney and thereafter represented Mr. Miller and Shasta Pharmacy.

Complainant made an oral closing argument at hearing. Respondents requested the opportunity to file a written closing brief and to file certain documents related to Controlled Utilization Review and Evaluation System (CURES) registration. Respondents were given until September 30, 2004, to file said documents. Respondents' written closing argument was filed on October 4, 2004, and was marked for identification as Exhibit AAA. No CURES documents were filed. Complainant's reply closing argument was filed on November 5, 2004, and was marked for identification as Exhibit 76. The matter was submitted and the record closed on November 5, 2004.

¹ The dates of hearing were as follows; May 10, May 11, May 12, May 13, May 18, June 7, June 8, June 9, June 10, June 11, June 24, June 25, June 30 and July 1.

FACTUAL FINDINGS

1. On July 17, 1974, the Board of Pharmacy issued Pharmacist Certificate Number RHP 28932 to Stephen George Miller. The certificate was in full force and effect at all times pertinent herein. The certificate was suspended pursuant to an Interim Suspension Order issued by the Superior Court of Shasta County effective May 21, 2001. The certificate expired on May 31, 2003, and was not renewed.

2. On February 22, 1994, the Board of Pharmacy (Board) issued Pharmacy Permit Number PHY 39684 to Stephen George Miller, Sole Owner, to do business as Shasta Pharmacy. The permit was in full force and effect at all times pertinent herein and was renewed through February 1, 2000. The pharmacy discontinued business and closed on February 18, 1999.

3. On March 29, 2000, complainant, Patricia F. Harris made and filed an Accusation² against Mr. Miller and Shasta Pharmacy in her official capacity as Executive Officer of the Board. The Accusation alleges that Mr. Miller and Shasta Pharmacy violated numerous sections of the Business and Professions Code, which regulate the practice of pharmacy.

4. Respondents timely filed a Notice of Defense to the Accusation, pursuant to Government Code sections 11505 and 11509. The matter was set for an evidentiary hearing before an Administrative Law Judge of the Office of Administrative Hearings, an independent adjudicative agency of the State of California, pursuant to Government Code section 11500, et.seq.

5. The hearing of this matter was stayed by the Superior Court of Shasta County pending the resolution of criminal charges against Mr. Miller, his wife Madeline Miller, and Frank Fisher, M.D. The criminal matter was dismissed and this hearing was set.

Respondents' Pharmacy Practice

6. Mr. Miller attended Shasta Community College for two years before enrolling in the five-year pharmacy program at Oregon State College. After graduation, he obtained a pharmacist license in Oregon and moved to California. In 1986 he bought the Shasta Pharmacy, which was located in a Holiday Market store in Anderson. He worked as the sole pharmacist, but employed a series of pharmacy technicians and clerks.

² The Accusation was amended at hearing to reflect amendments to statutes since the time the Accusation was filed. The following changes were made on page 4 of the Accusation; on line 12, Health and Safety Code section 11057 (d) (9) was amended by replacing (9) with (11), on line 16, Health and Safety Code section 11057 (d) (12) was amended by replacing (12) with (14), on line 19, Health and Safety Code section 11057 (d) (8) was amended by replacing (8) with (9).

Mr. Miller employed Charleen Meek as a pharmacy clerk in the early 1990s. She received her Pharmacy Technician license while in Mr. Miller's employ. Mr. Miller employed other pharmacy clerks who, after about three months of training in the pharmacy operations, were permitted to use the computer to print labels for prescriptions.

7. The pharmacy's customary method for filling prescriptions was this: When a new patient came into the pharmacy presenting a prescription, the clerks or the pharmacy technician would take the prescription and ask for the patient's name, address, date of birth and phone number, and inquire about allergic reactions. The clerk would record this information on the front of the prescription. If the patient was unknown to the pharmacy and presented a prescription for a controlled substance, the clerk would call the prescribing physician's office to verify that he or she issued the prescription.

After taking the patient's information, the clerk would prepare the label for the prescription bottle using the McKesson computer and software system. The clerk would enter the prescription information: dosing schedule, name of medication, prescribing physician, expiration date and number of refills, if any, into the program and print out a label for the container. The system also printed out the manufacturer's fact sheet containing information about the drug, such as interactions and contra-indications. The clerk would band together the empty prescription container, the unattached label and the manufacturer's information and place the bundle at Mr. Miller's counter. There, Mr. Miller would verify that the label matched the information on the prescription. If the information matched, he attached the label to the bottle.

Mr. Miller would then go to the shelf containing bulk medications, count out the number of pills or the dose required to fill the prescription, fill the container and band it with the manufacturer's fact sheet. If he felt it necessary to consult with the patient, he would write "see Steve" on the manufacturer's fact sheet, so that the clerk ringing up the purchase would be certain to get him for a consult when the patient picked up the prescription. The staff then filed the original prescription form by its number.

When the clerk entered a new patient's name, identifying information and prescription information, the McKesson system created a file accessible by the patient's name. When an existing patient requested a refill, the clerk would access the patient file and check whether a refill was available. If so, the clerk would note in the computer that the prescription was being refilled. When a patient presented with a new prescription (rather than a request for a refill) the new prescription information was entered into the patient's computer file.

Pharmacists are required to perform a Drug Utilization Review (DUR) to avoid potential drug interactions among a patient's prescriptions, and to alert the pharmacist to situations where the patient exceeds the daily dosage and requests an early refill. The McKesson system alerted the staff to these situations. The system also allowed the staff to override these DUR alerts by entering a code. Mr. Miller provided his clerks with the override code and instructed them to override the DUR alerts so that prescriptions could be

filled.

8. During the first years of his practice at Shasta Pharmacy, Mr. Miller often worked alongside the clerks, inputting prescription data and printing labels. Of the fewer than 70 prescriptions Shasta Pharmacy filled a day, few if any were for controlled substances.

9. The number of prescriptions Shasta Pharmacy filled increased dramatically in 1997, when Madeline Spencer began working in the pharmacy. In the early 1990s, Ms. Spencer owned and operated a restaurant located next to Shasta Pharmacy, and she began visiting Mr. Miller at the pharmacy. Around 1995 they started dating, and she began working at the pharmacy a half-day on Saturdays. In February of 1997, Ms. Spencer closed her restaurant and became the full-time manager at Shasta Pharmacy, but never drew a salary for that employment. Ms. Spencer and Mr. Miller married on April 19, 1997, and Ms. Spencer began using the name Madeline Miller.

10. After Mrs. Miller began working at Shasta Pharmacy, an increasing number of patients began presenting with prescriptions for Schedule II controlled substances. Mr. Miller started ordering large quantities of controlled substances from wholesalers, primarily McKesson Drug Company, in order to have the stock necessary to fill these prescriptions. By February of 1999, Shasta Pharmacy had become one of the largest purchasers of controlled substances in the United States and the largest purchaser of Oxycodone products in California. Between July 8, 1998, and February 18, 1999, Shasta Pharmacy dispensed 619,575 dosage units of Schedule II controlled substances.³

³ Schedule II controlled substances are drugs that are classified by the California Health and Safety Code and the California Business and Professions Code as dangerous drugs. The following Schedule II controlled substances are involved in this proceeding:

Oxycodone (Roxicodone, Oxycontin, Oxycodone/APAP, Endocet, Percodan, Percocet) is a Schedule II narcotic controlled substance as defined in Health and Safety Code section 11055, subdivision (b)(1)(N), and is categorized as a dangerous drug pursuant to Business and Professions Code, section 4022. This drug is indicated for treatment of moderate to moderate severe pain.

Codeine is a Schedule II narcotic controlled substance as defined in Health and Safety Code section 11055, subdivision (b)(1)(H), and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022. The drug is indicated for treatment of mild to moderate pain.

Morphine (MS Contin, Oramorph, morphine soluble tablets) is a Schedule II narcotic controlled substance as defined in Health and Safety Code section 11055, subdivision (b)(1)(M), and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022. The drug is indicated for treatment of moderate to moderate severe pain and severe pain.

Hydromorphone (Dilaudid) is a Schedule II narcotic controlled substance as defined in Health and Safety Code section 11055, subdivision (b)(1)(K), and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022. The drug is indicated for treatment of severe pain.

Meperidine (Demerol) is a Schedule II narcotic controlled substance as defined in Health and Safety Code section 11055, subdivision (c)(17), and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022. The drug is indicated for treatment of moderate to severe pain.

Codeine/Acetaminophen (Tylenol #3, Tylenol #4, APAP #3, APAP #4) is a Schedule III narcotic controlled substance as defined in Health and Safety Code section 11056, subdivision (e)(2), and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022. The drug is indicated for treatment of pain.

Hydrocodone/Acetaminophen (Vicodin, Vicodin ES, Vicodin HP, Norco, Lortab 7.5, Lortab 10) is a Schedule III narcotic controlled substance as defined in Health and Safety Code section 11056, subdivision (e)(4), and is

11. The average number of prescriptions Shasta Pharmacy filled each business day increased rapidly. In November and December of 1997, Shasta Pharmacy filled an average of 111 prescriptions per business day.

In the first quarter of 1998, Shasta Pharmacy filled an average of 135 prescriptions per business day. In the second quarter of 1998, Shasta Pharmacy filled an average of 153 prescriptions per business day. In the last half of 1998, Shasta Pharmacy filled an average of 165 prescriptions per business day.

On January 4, 1999, Shasta Pharmacy filled 330 prescriptions. On January 11, 1999, Shasta Pharmacy filled 289 prescriptions and on January 25, 1999, Shasta Pharmacy filled 342 prescriptions.

Between February 1, 1999, and February 17, 1999, when the pharmacy closed, Shasta Pharmacy filled an average of 218 prescriptions per business day. On February 15, 1999, Shasta Pharmacy filled 319 prescriptions and on February 16, 1999, it filled 286 prescriptions. On February 17, 1999, Shasta Pharmacy filled 290 prescriptions.

12. Shasta Pharmacy's rapid growth in prescription business was due to prescriptions written by Frank Fisher, M.D. Dr. Fisher was treating Mrs. Miller for chronic intractable pain (CIP) when she started working in the pharmacy. Dr. Fisher was the sole proprietor of Westwood Walk-In Clinic, a community care clinic located in Redding. Westwood Walk-In Clinic served primarily the poor and those insured through Medi-Cal. Dr. Fisher's practice emphasized pain management and treatment. He classified approximately 80 percent of his patients as CIP patients. Approximately 80 percent of the

categorized as a dangerous drug pursuant to Business and Professions Code section 4022. The drug is indicated for treatment of pain.

Hydrocodone/Aspirin (Damason-P) is a Schedule III narcotic controlled substance as defined in Health and Safety Code section 11056, subdivision (e)(4), and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022. The drug is indicated for treatment of pain.

Ethchlorvynol (Placidyl) is a Schedule IV depressant controlled substance as defined in Health and Safety Code section 11057, subdivision (d) (11), and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022. The drug is indicated for sleep.

Fluazepam (Dalmane) is a Schedule IV depressant controlled substance as defined in Health and Safety Code section 11057, subdivision (d) (14), and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022. The drug is indicated for sleep.

Diazepam (Valium) is a Schedule IV depressant controlled substance as defined in Health and Safety Code section 11057, subdivision (d) (9), and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022. This drug is a benzodiazepine used in the treatment of anxiety disorders and muscle relaxation.

Alprazolam (Xanax) is a Schedule IV depressant controlled substance as defined in Health and Safety Code section 11057, subdivision (d) (1), and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022. This drug is a benzodiazepine used in the treatment of anxiety disorders and muscle relaxation.

Phenergan with Codeine is a Schedule V antitussive controlled substance as defined by Health and Safety Code section 11058, subdivision (c) (1), and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022. The drug is indicated for cough.

Carisoprodol (Soma) 350 mg. is categorized as a dangerous drug pursuant to Business and Professions Code section 4022. The drug is a skeletal muscle relaxant used in the treatment of painful musculoskeletal conditions.

CIP patients were Medi-Cal beneficiaries. Dr. Fisher wrote approximately 77 percent of the prescriptions Shasta Pharmacy filled for controlled substances.

13. Dr. Fisher and the Millers began working in concert in early 1997, with the goal of providing services to patients who suffered chronic intractable pain. The "Chronic Intractable Pain Act" (Business and Professions Code section 2241.5⁴) and the "Pain Patient Bill of Rights" (Health and Safety Code sections 124960 and 124961⁵) had been

⁴ Business and Professions Code section 2241.5 provides:

Administration of controlled substances to person experiencing "intractable pain."

(a) Notwithstanding any other provision of law, a physician and surgeon may prescribe or administer controlled substances to a person in the course of the physician and surgeon's treatment of that person for a diagnosed condition causing intractable pain.

(b) "Intractable pain," as used in this section, means a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain.

(c) No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain.

(d) This section shall not apply to those persons being treated by the physician and surgeon for chemical dependency because of their use of drugs or controlled substances.

(e) This section shall not authorize a physician and surgeon to prescribe or administer controlled substances to a person the physician and surgeon knows to be using drugs or substances for non-therapeutic purposes.

(f) This section shall not affect the power of the board to deny, revoke, or suspend the license of any physician and surgeon who does any of the following:

(1) Prescribes or administers a controlled substance or treatment that is nontherapeutic in nature or nontherapeutic in the manner the controlled substance or treatment is administered or prescribed or is for a nontherapeutic purpose in a non-therapeutic manner.

(2) Fails to keep complete and accurate records of purchases and disposals of substances listed in the California Controlled Substances Act, or of controlled substances scheduled in, or pursuant to, the federal Comprehensive Drug Abuse Prevention and Control Act of 1970. A physician and surgeon shall keep records of his or her purchases and disposals of these drugs, including the date of purchase, the date and records of the sale or disposal of the drugs by the physician and surgeon, the name and address of the person receiving the drugs, and the reason for the disposal of or the dispensing of the drugs to the person and shall otherwise comply with all state record keeping requirements for controlled substances.

(3) Writes false or fictitious prescriptions for controlled substances listed in the California Controlled Substances Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

(4) Prescribes, administers, or dispenses in a manner not consistent with public health and welfare controlled substances listed in the California Controlled Substance Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

(5) Prescribes, administers, or dispenses in violation of either Chapter 4 (commencing with Section 11150) or Chapter 5 (commencing with Section 11210) of Division 10 of the Health and Safety Code or this chapter.

(g) Nothing in this section shall be construed to prohibit the governing body of a hospital from taking disciplinary actions against a physician and surgeon, as authorized pursuant to Sections 809.05, 809.4, and 809.5.

⁵ Health and Safety Code section 124960 provides in pertinent part:

The Legislature finds and declares all of the following:

(a) The state has a right and duty to control the illegal use of opiate drugs.

(b) Inadequate treatment of acute and chronic pain originating from cancer or noncancerous conditions is a significant health problem.

(c) For some patients, pain management is the single most important treatment a physician can provide.

(d) A patient suffering from severe chronic intractable pain should have access to proper treatment of his or her pain.

(e) Due to the complexity of their problems, many patients suffering from severe chronic intractable pain may

enacted in 1990 and 1997 respectively. These statutes recognize the serious problem of untreated or under-treated intractable pain and permit physicians to prescribe or administer controlled substances in treating intractable pain patients.

14. Dr. Fisher and the Millers attended a course, sponsored by the drug manufacturer Purdue, on treatment of CIP patients with opioid therapy. Mr. Miller gained some additional information about CIP treatment from speaking with sales representatives

require referral to a physician with expertise in the treatment of severe chronic intractable pain. In some cases, severe chronic intractable pain is best treated by a team of clinicians in order to address the associated physical, psychological, social, and vocational issues.

(f) In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute and severe chronic intractable pain can be safe.

(g) Opiates can be an accepted treatment for patients in severe chronic intractable pain who have not obtained relief from any other means of treatment.

(h) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities to relieve his or her severe chronic intractable pain.

(i) A physician treating a patient who suffers from severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve severe chronic intractable pain as long as the prescribing is in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(j) A patient who suffers from severe chronic intractable pain has the option to choose opiate medication for the treatment of the severe chronic intractable pain as long as the prescribing is in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(k) The patient's physician may refuse to prescribe opiate medication for a patient who requests the treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates.

Health and Safety Code section 124961 provides in pertinent part:

Effect on Intractable Pain Treatment Act; Bill of Rights

Nothing in this section shall be construed to alter any of the provisions set forth in the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code. This section shall be known as the Pain Patient's Bill of Rights.

(a) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities in order to relieve his or her severe chronic intractable pain.

(b) A patient who suffers from severe chronic intractable pain has the option to choose opiate medications to relieve severe chronic intractable pain without first having to submit to an invasive medical procedure, which is defined as surgery, destruction of a nerve or other body tissue by manipulation, or the implantation of a drug delivery system or device, as long as the prescribing physician acts in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(c) The patient's physician may refuse to prescribe opiate medication for the patient who requests a treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates.

(d) A physician who uses opiate therapy to relieve severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve severe chronic intractable pain, as long as that prescribing is in conformance with the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(e) A patient may voluntarily request that his or her physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification.

(f) Nothing in this section shall do either of the following:

(1) Limit any reporting or disciplinary provisions applicable to licensed physicians and surgeons who violate prescribing practices or other provisions set forth in the Medical Practice Act, Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code, or the regulations adopted thereunder.

(2) Limit the applicability of any federal statute or federal regulation or any of the other statutes or regulations of this state that regulate dangerous drugs or controlled substances.

of Purdue.

15. Mr. Miller did not have previous experience with dispensing controlled substances for the CIP patient population. After attending the course, speaking with Dr. Fisher and observing his wife's progress on opioid therapy, he felt knowledgeable enough to dispense large quantities of opioids to CIP patients. Additionally, Mr. Miller was influenced by Mrs. Miller's and Dr. Fisher's views that the Chronic Intractable Pain Act and the Pain Patient Bill of Rights vested full and unquestionable discretion in the prescribing physician and the patient to determine the types and levels of opioids prescribed.

16. Mr. Miller's practice changed dramatically with the influx of Dr. Fisher's prescriptions and the installation of Mrs. Miller as the pharmacy's manager. Within the first few months of 1997, Mr. Miller changed the focus of his pharmacy from a small general community pharmacy to one that focused on filling the numerous prescriptions for hundreds of doses of controlled substances, which Dr. Fisher routinely wrote for his CIP patients. Despite the change in focus and volume of business, Mr. Miller made few changes in the manner in which the pharmacy was run. He remained the sole pharmacist and retained one full-time pharmacy technician. However, he did not permit the technician to count out medications, limiting the scope of the technician's responsibilities so that she functioned primarily as a clerk. Mr. Miller purchased a pill counting machine in late November of 1998. The pill counting machine made it possible for him to count medications more quickly than by hand.

17. As the volume of prescriptions increased, Mr. Miller did little but fill prescription bottles. He did not review the information in the patients' computer files to conduct DURs. He relied upon his clerks and his wife to alert him to the computer system's notifications of drug interactions, contra-indications or early refills. He relied upon his wife to communicate with Dr. Fisher's office regarding questions on patient prescriptions.

Dr. Fisher routinely wrote prescriptions for two or more medications on one prescription form. Because controlled substances cannot be refilled without a new prescription, each prescription should have been entered in the computer's patient's profile as a new prescription. In order to save the time involved in entering all of the new prescriptions in the patient's profile, Mr. Miller directed the clerks to enter only one prescription as the new prescription and to record the remaining as refills of existing prescriptions.

18. The Millers often took three-day weekends off from the pharmacy. When they did so, Mr. Miller hired one of two substitute pharmacists to work on Monday. The substitute pharmacists were overwhelmed by the number of prescriptions and had no time to do anything but fill them. Both pharmacists felt extremely uncomfortable filling Dr. Fisher's prescriptions for controlled substances, as the number of doses was often far greater than they believed was appropriate.

One relief pharmacist, Errol Vrh, testified persuasively that the volume of prescriptions was so high that there was no opportunity to evaluate prescriptions. He was filling up to 200 prescriptions a day in August of 1998. There was no pharmacy documentation on the background of the patients or their clinical evaluation. Mr. Vrh was uncomfortable with the number of controlled substances dispensed and the strengths and dosages of the controlled substances dispensed. He once asked Mr. Miller if the prescribing physician was "legitimate," but Mr. Miller did not reply.

19. Mrs. Miller's role in the pharmacy expanded in response to the influx of Dr. Fisher's patients. Mrs. Miller worked 40 to 60 hours a week managing all aspects of the pharmacy's operations. She worked with the pharmacy technician, Charleen Meek, and the pharmacy clerks in taking in prescriptions, typing information from the prescriptions into the pharmacy computer and preparing labels for prescription bottles. She managed the finances and bookkeeping, ordered medications and supplies, supervised the pharmacy technician and clerks, and sought payment from Medi-Cal for patient prescriptions.

20. Mrs. Miller spent a considerable amount of her working hours preparing treatment authorization requests (TARs). The Medi-Cal program required that a TAR be completed before Medi-Cal would pay for certain non-formulary drugs or refills over a designated number. The Millers took on the task of preparing TARs for Dr. Fisher's Medi-Cal patients.

21. Mr. Miller ordinarily would fill prescriptions for Medi-Cal patients while a TAR was pending. Often Medi-Cal denied payment or took over two weeks to pay the pharmacy for the prescription. Dr. Fisher agreed to reimburse the Millers for prescriptions that Medi-Cal denied. Pharmacy staff maintained a binder known as "the Dr. Fisher book." The binder was labeled "TARS PENDING DR. FISHER NOT PAID YET." It was organized by patient name and contained copies of the labels and charges for Dr. Fisher's prescriptions. The staff made handwritten notations on the prescription copies concerning the status of the TAR (i.e., "TAR Pending"), and payment by Dr. Fisher (i.e., "Fisher pay").

22. Mrs. Miller either filled out the TARs herself or directed the pharmacy technician and clerks in filling out TARs. The TARs required information on the drugs prescribed and their dosages, a description of the patient's diagnosis and the medical justification for the prescription. The TARs also required an attestation from the physician or provider who signed the TAR that "to the best of my knowledge, the information is true, accurate and complete and the requested services are medically indicated and necessary to the health of the patient." Mrs. Miller repeatedly signed the TAR attestations on the signature line entitled "physician or provider," and included her title as "Manager." Mrs. Miller also routinely signed the name "Dr. Fisher," and inserted his phone number after the portion of the TAR entitled "Medical Justification."

23. Mrs. Miller functioned as a liaison between Dr. Fisher and Shasta Pharmacy, not just by completing TARs for his patients, but also in conveying information to Mr. Miller about Dr. Fisher's prescriptions. Mrs. Miller and Dr. Fisher conversed repeatedly throughout the day. Dr. Fisher rarely spoke with Mr. Miller directly. Mr. Miller told the pharmacy technician and clerks that Mrs. Miller and Dr. Fisher were friends and that calls to and from his office should go through her.

24. The Millers and Dr. Fisher denied at hearing that Mrs. Miller functioned as the intermediary between Dr. Fisher and Mr. Miller. They were impeached by prior admissions and by the testimony of pharmacy staff. On February 18, 1999, Mr. Miller had admitted to police officers that Mrs. Miller and the clerks called Dr. Fisher for him. Mr. Miller admitted that he had discussed his concerns about Dr. Fisher's prescriptions with Mrs. Miller, but that she had said it was "OK" to fill the prescriptions. Mr. Miller also admitted that he probably had Mrs. Miller call Dr. Fisher regarding whether it was "OK" to fill a codeine cough syrup prescription for over sixteen ounces a week. Additionally, Mr. Miller used the expression "we called Dr. Fisher's office" repeatedly during his testimony when referring to contacts only a pharmacist was authorized to make.

On February 18, 1999, Mrs. Miller had admitted to police officers that she verified almost all of the prescriptions from Dr. Fisher. She then amended her statement and said that if she knew they were Dr. Fisher's CIP patients, she would not bother to call Dr. Fisher.

On February 18, 1999, Nikki Miralles, a pharmacy clerk, told police officers that Mrs. Miller "definitely ran the show," and communicated "a lot" throughout the day with Dr. Fisher.

On February 18, 1999, pharmacy technician Charleen Meek told police officers that Mrs. Miller contacted Dr. Fisher repeatedly throughout the day. Mrs. Miller had told her that the pharmacy would honor Dr. Fisher's prescriptions because they were "covered by some law."⁶ Ms. Meek observed that Mr. Miller regularly consulted with his wife when he had concerns about whether they should fill a prescription from Dr. Fisher. Mrs. Miller advised Ms. Meek and all of the staff that if Dr. Fisher said a patient needed a prescription, they would fill it.

Ms. Meek witnessed several occasions where Mrs. Miller called Dr. Fisher when patients presented with early refills in an intoxicated state. Patient K.B. called for an early refill of Soma and Ms. Meek noticed had slurred speech. Ms. Meek told Mrs. Miller, who called Dr. Fisher for approval to fill the prescription. Mrs. Miller told the staff that she would make all calls to Dr. Fisher if there were any problems with a patient's behavior or demeanor.

⁶ Ms. Meek confirmed this information at the instant hearing and in sworn testimony during the preliminary hearing in the criminal matter.

On one occasion, Ms. Meek grew concerned when Patient E.N. presented with a prescription for Phenadrine and Codeine. Ms. Meek checked the patient's profile and added up the pints of these drugs that had been dispensed to E.N. and to E.N.'s family. The patient and her family were receiving pints of these medications two to three times a week. Ms. Meek expressed her concern to Mrs. Miller, who responded that if Dr. Fisher said E.N. needed the medications he was "the last word." Ms. Meek then told Mr. Miller about the amount of Phenadrine and Codeine that had already been dispensed to this patient and her family. Mr. Miller spoke with his wife about E.N.'s prescription. In Ms. Meek's presence, Mrs. Miller told Mr. Miller that Dr. Fisher "has the say" in what he prescribes and that he monitors his patients' usage. Mrs. Miller told Mr. Miller that if Dr. Fisher wrote a dose down they should fill it. Mr. Miller filled the prescription.

Wendy Imboden, a pharmacy clerk who was employed for five months at Shasta Pharmacy, heard Mrs. Miller call Dr. Fisher for authorization of an early refill of Phenergan with Codeine cough syrup. The patient claimed his dog drank the syrup dispensed earlier.⁷ Ms. Imboden questioned Mrs. Miller regarding why they were filling Dr. Fisher's prescriptions. Mrs. Miller responded that the law allowed it and someone had to make the money. Mrs. Miller did not allow her to ask Mr. Miller questions about prescriptions.

Gordon Nielsen, a pharmacist who had done relief work for Mr. Miller in February of 1999, told the Millers that he was uncomfortable filling Dr. Fisher's prescriptions for large quantities of narcotics. Mr. Miller did not reply; but Mrs. Miller answered that there was nothing wrong with Dr. Fisher's prescriptions. Mr. Nielsen got the impression from this and other conversations with the Millers that Mrs. Miller was making the decisions at the pharmacy.

25. Documentary evidence confirmed that Mr. Miller allowed his wife to function as the liaison between Dr. Fisher and Shasta Pharmacy. Mrs. Miller filled out the great majority of the TARs, including the diagnoses and medical justifications, and signed her name and Dr. Fisher's names. Mrs. Miller corresponded with Medi-Cal authorities as to what documentation was necessary to support the TARs. She often obtained the necessary patient information from Dr. Fisher or the patient. For instance, on a TAR for patient C.H. dated 9-4-98, Mrs. Miller responded to Medi-Cal's request to "consider a less costly alternative" with the following statement:

Pt. tried Zanex-made her jittery Made her feel ill pt. has been on this med for approx 3 years-works well for her...patient and MD do not want her to change this med. at this time."

On another TAR for C.H. dated 12-15-98, Mrs. Miller wrote in the "medical justification" section that the patient was fully informed of the risks and benefits of exceeding 4 grams of acetaminophen per day.

⁷ Ms. Imboden did not testify at this hearing. A copy of her sworn testimony from the preliminary hearing was admitted in evidence.

For a time, Ms. Imboden assisted Mrs. Miller with filling out TARS. Mrs. Miller would dictate to her what to write in the diagnosis and medical justifications sections. They routinely wrote "chronic intractable pain" or "lower back pain" in these sections.

26. The record contained correspondence from physicians addressed to Mrs. Miller or to Mrs. and Mr. Miller. The physicians provided medical information in answer to medical questions regarding drugs prescribed to patients. Dr. Fisher wrote to "Shasta Pharmacy Steve/Madeline" to advise that Soma (or Carisporal) is non-toxic to organ systems and can be dispensed in excess of 20 per day when the patient is properly monitored. Elisabeth Neumann, M.D., of Wallace Laboratories, wrote to Mrs. Miller answering her request for information on liver toxicity and increased liver function test results for persons taking Soma. These letters support the testimony of pharmacy staff that Mr. Miller allowed his wife free rein in communicating with physicians regarding prescriptions.

27. Dr. Fisher actively discouraged pharmacists from questioning his prescriptions. Two area pharmacists, Daryl Odegard and Errol Vrh, unsuccessfully attempted to question Dr. Fisher about his prescribing practices when they were filling his patients' prescriptions. Dr. Fisher was not cooperative or forthcoming with information. When Mr. Odegard received prescriptions containing acetaminophen (APAP) in toxic amounts, he asked Dr. Fisher for live lab values so that he could determine whether the patients' livers were performing normally. Dr. Fisher was at first agreeable to providing these but then "acted like he could not be bothered." Dr. Fisher ultimately told Mr. Odegard that he was a Harvard-trained physician and that Mr. Odegard should not question his orders. Mr. Odegard stopped filling prescriptions because of the excessive amounts of acetaminophen and the excessive number of pills prescribed.

28. In addition to allowing Mrs. Miller to contact Dr. Fisher about filling patient prescriptions, Mr. Miller allowed Mrs. Miller to count pills. Although the Millers denied that Mrs. Miller counted pills, Ms. Meek's testimony to the contrary was more persuasive and she was a far more credible witness. Her hearing testimony was consistent with several prior statements, and her testimony was generally supported by documentation. A statement of another pharmacy clerk, Debi Moore, supported Ms. Meek's testimony that Debi Moore had been permitted to count out pills on one occasion. A hearsay statement of clerk Nicki Miralles also supported Ms. Meek's testimony. Ms. Miralles stated that Mr. Miller allowed clerk Amy Edwards to count medications. Mr. Miller admitted at hearing that he allowed Amy Edwards to count out Ibuprofen in bottles of 100 once, but only to demonstrate that counting medications "is harder than it looks."

29. Mr. Miller also followed his wife's dictates when he dispensed medications to her. When the authorities searched Shasta Pharmacy, on February 18, 1999, they found a heavily taped box on the top shelf in the pharmacy bathroom. The box contained prescription medications labeled with three names: Madeline Miller, Madeline Spencer and Madeline Ciulla. The medications all bore Mrs. Miller's former address. The labeled

medications were Lortab 10 (approximately 100 pills), Endocet (approximately 800 pills), and Meperidine 100 mg. (approximately 1,200 pills). The box contained unlabeled Dexedrine 5 mg. tablets (approximately 1000 pills) and Dexedrine 15 mg. spansules (approximately 250 count). The box contained a packet of Zig Zag cigarette papers and \$28,800 cash in \$100 bills wrapped in a "Claritan" wrapper. One of the Endocet bottles had a piece of paper taped to the side with a running inventory of the drugs in the box.

Mr. Miller had furnished all of the medications in the taped box to Mrs. Miller while she legally held the name Miller and while she resided at a different address from the one appearing on the label.

Mr. Miller admitted at hearing that all of the prescriptions he filled for Mrs. Miller were written by Dr. Fisher to Mrs. Miller under the name Madeline Miller. He maintained that there was nothing improper in using her maiden name (Chula) and her former married name (Spencer) on prescription bottle labels. He maintained that there was nothing improper about using her former address, as that was the address on her driver's license. The Millers testified that he used her former names to conceal Mrs. Miller's prescription history from Ms. Meek. They were not credible.

Ms. Meek admitted that she looked at computer records to see what medications Mrs. Miller was taking. However, she was familiar with both of Mrs. Miller's former names, having known her when she used these names, and she looked up Mrs. Miller's prescriptions under the name "Spencer."

The evidence was persuasive that Mr. Miller allowed Ms. Miller to use incorrect names and addresses when she typed labels for her own prescriptions. Mr. Miller had a duty to ensure only correct patient names and addresses appear on pharmacy labels. He violated this duty when he allowed his wife to use multiple names to suit her purposes. Mrs. Miller's motives, innocent or not, in concealing her identity do not excuse Mr. Miller from this duty.

Standards of Pharmacy Practice

30. The standard of pharmacy practice was established through the testimony of several expert witnesses. Complainant called Daryl Odegard, Errol Vrh and Gordon Nielsen as expert witnesses and as percipient witnesses. Mr. Odegard has been a licensed pharmacist since 1971, and works in a clinic in Redding. Mr. Vrh has been a licensed pharmacist since 1964. Both worked as relief pharmacists at Shasta Pharmacy. Gordon Nielsen has been a licensed pharmacist since 1967.

Complainant called Jeb Sydeko, a licensed pharmacist in practice since 1985, and Brenda Barnard, a pharmacist in practice since 1975, now employed by the Board as an inspector. Ms. Barnard testified as a percipient witness and expert on the standard of practice.

Respondents called Kathryn Hahn, a licensed pharmacist since 1980. Ms. Hahn has significant experience in pharmacy pain management services. Respondent called Frank Fisher, M.D., who testified as a percipient witness and as an expert witness in the area of medical pain management.

Additionally, upon respondents' motion, a transcript of the sworn preliminary hearing testimony of John H. Eisele, M.D., was admitted in evidence. Dr. Eisele has been licensed as a physician and surgeon for over 35 years. He specializes in pain medicine, teaches pain management at U.C. Davis Medical School and started a pain clinic in the early 1990s. Dr. Eisele works part time at the clinic, teaches and serves as a consultant in pain management issues.

A written evaluation by Barth Wilsey, M.D., was admitted in evidence. The evaluation was prepared for the Board and summarized Dr. Fisher's prescription practices for patients L.B., V.B. and G.D.

Doctors Fisher, Eisele and Wilsey offered opinions on proper prescribing by physicians, rather than opinion on the standards of pharmacy practice.

31. The expert witnesses agreed on the standards of pharmacy practice applicable to Mr. Miller and Shasta Pharmacy. The standards today are the same standards that were in place when Shasta Pharmacy was operating.

The expert witnesses established that the duties of a pharmacist may not be delegated to anyone other than a licensed pharmacist. The pharmacist has an independent and corresponding duty with the prescribing physician to ensure that a prescription is appropriate for a patient. The pharmacist must verify the validity of each patient prescription. Verification of a prescription requires the pharmacist to verify the identity of the patient and prescribing physician, accurately read the dosage and medication designated, and follow up with the prescribing physician on any questions related to these areas. The pharmacist must be aware of the condition for which the medication is prescribed and must be reasonably certain that the medication is prescribed for treating a legitimate medical condition. The pharmacist may not dispense the medication without first clearing up doubts about the purpose for the prescription.

The pharmacist must be knowledgeable of all aspects of the medication prescribed, including the composition of the medication, recommended and toxic doses, if any, appropriate dosing schedules, potential contra-indications and interactions with other medications. The pharmacist must be familiar with the side effects of medications.

The pharmacist is required to counsel patients on dosages, dosing schedule, contra-indications and side effects when dispensing any drug the patient has not previously taken. The pharmacist must counsel patients when the dosages or dosing schedule of a medication changes. The pharmacist is required to offer to counsel patients any time a prescription is filled. This is particularly important with patients receiving opioids.

The pharmacist must be familiar with a patient's history of prescriptions, at least those filled in that pharmacy. The pharmacist is required to perform "drug utilization reviews" (DUR) of the pharmacy's prescriptions for a patient. The DUR is conducted to determine whether the patient is in compliance with dosing schedules; is presenting for an early refill; is taking other medications which would interact with or are contra-indicated by a new prescription, or by the patient's disease state; and whether the drug therapy is appropriate. The pharmacist must evaluate any alert raised by DUR software, and may not delegate this duty to staff. The pharmacist has a duty to recognize an early refill of medications. The pharmacist should be able to calculate from the DUR when a prescription was last dispensed and the number of days before the prescription may be refilled.

In the event a patient presents with a prescription form with two or more medications listed, the pharmacist must treat each medication as a new prescription, and issue a new prescription number for each. This creates a patient profile which accurately reflects the prescriptions dispensed and prevents the pharmacist from overlooking new information such as a change in dosage, quantity or instructions for use. Pharmacists may not process a new prescription as a refill of an existing prescription, even when the prescriptions are identical.

When a pharmacist begins to take on a specialty within the practice of pharmacy, such as pain management, it is the standard of practice for that pharmacist to become educated within that specialty field. The expert witnesses agreed that the pharmacist who serves chronic pain patients must meet additional standards for this specialized practice. Such pharmacists must work closely with the prescribing doctor and must know the doctor's screening and prescribing procedures. Kathryn Hahn, respondent's expert witness, testified that as a pharmacist serving approximately 25 patients with chronic intractable pain, she communicates with the prescribing doctors 10 to 20 times a day.

The pharmacist who dispenses controlled substances to chronic pain patients has an ongoing duty to monitor and document the patient's response to that therapy. The pharmacist should require that the patient's prescriptions always contain a diagnosis, and the pharmacist should maintain medical files for these patients. While it is not required that the files "shadow" the patient's medical file, they should contain notes on the pharmacist's interactions with the patient, including an initial interview encompassing the patient's history. The pharmacist should maintain notes on how the patient is feeling, therapeutic goals, work and family status, assessments and a plan. It is also the duty of the pharmacist to document changes in the functioning of the chronic pain patient.

The pharmacist has the duty to observe patients presenting with prescriptions and to recognize if patients are in an impaired condition. The pharmacist has a duty to refuse to dispense medications to those whose mental states are not clear, and to notify the prescribing physician.

In dispensing medications above recommended dosages the pharmacist has a duty to alert the prescribing physician that a dosage is in excess of recommended doses or can be

toxic. The pharmacist has a duty to suggest alternatives to the prescribed medication. If the physician refuses to consider alternatives, the pharmacist must evaluate the physician's rationale and any documentation, such as current liver function tests, supporting the physician's prescribed dosages.

The pharmacist has a duty to investigate prescriptions containing dosages of acetaminophen in excess of 4 grams per day because such doses may cause liver damage. A pharmacist dispensing acetaminophen in excess of 4 grams per day has the duty to talk to the prescribing physician to determine whether recent liver function tests were performed and to get copies of the tests to determine whether the liver is functioning normally.

A pharmacist has a duty to investigate prescriptions for controlled substances where the dosages are doubling and tripling. The pharmacist should talk to both the doctor and patient to identify what plan is in place for the patient's treatment, and document the patient's need for such dosages. It is also the pharmacist's responsibility to consider and guard against the possibility of diversion of medications, particularly controlled substances with a high street demand.

In sum, the pharmacist does not function as a mere instrument of the physician, automatically filling prescriptions. The pharmacist has an independent duty to protect the patient and work in concert with the prescribing physician to ensure the optimum medical outcome for the patient.

Respondents' Dispensing Practices

Patient A. (A.T.)

32. Patient A was a CIP patient, treated by Dr. Fisher for lower back pain. His first prescription at Shasta Pharmacy was filled on March 27, 1998. Initially, Mr. Miller filled two sets of prescriptions each month, approximately fifteen days apart. Set one consisted of Hydrocodone 10/650 #90 (90 tablets) and Carisoprodol 350 mg. #100. Set two consisted of Hydrocodone 10/650 #90, and Carisoprodol 350 mg. #100. On April 10, 1998, Oxycontin (Oxycodone Hydrochloride-controlled release) 80 mg. #360 was added. Mr. Miller continued to dispense these drugs in this pattern until July 7, 1998, when Patient A received an early refill of Hydrocodone 10/650 #90. On July 30, 1998, Patient A received MS Contin (morphine sulphate-controlled release) 100 mg. #90. Twelve days later he received Meperidine 100 mg. #90.

During the time MS Contin and Meperidine were added to his prescriptions, Patient A continued to receive the two sets of prescriptions for Hydrocodone and Carisoprodol as well as the Oxycontin. The number of Oxycontin tablets prescribed increased to 420 tablets per month in July and September, and to 900 tablets in October and December.

33. Dr. Fisher's prescriptions for Patient A did not contain dosing schedules. Rather, the Hydrocodone and Carisoprodol prescriptions were written in the quantity

prescribed (e.g., #100 or #900) with the expression “prn” (as needed) and “Q.I.D” (four times a day). The Oxycontin prescriptions were written with a dosing schedule of 80 mg. 5-7 tablets, but the frequency was not clearly identified. It appears that the frequency was either Q 24 or Q 12 hours. Mr. Miller testified that this reference was to 4 times every twelve hours.

34. Mr. Miller dispensed Patient A’s Hydrocodone and Carisoprodol medications without ascertaining a dosing schedule. Mr. Miller did not consult with Dr. Fisher about dosing schedules. Mr. Miller did not consult with Dr. Fisher about the quantities of medications prescribed for Patient A.

35. Mr. Miller testified that he consulted with Dr. Fisher about Patient A’s prescriptions, as he did with all Dr. Fisher’s patients. He testified that he kept records of his consults with Dr. Fisher on the pharmacy computer and that he was aware of early refills and reasons therefore. He testified that he could not produce records of his consults because drug enforcement officials seized his computer. When it was returned, there was something wrong with the computer and he could not access the notes he kept on the patient consults.

Although Mr. Miller may have had some difficulty accessing complete computer files⁸, it was not credible that these files would demonstrate he made inquiries of Dr. Fisher or kept records of consultations with Dr. Fisher. The volume of prescriptions Mr. Miller filled daily shows that he would have little or no time to consult with Dr. Fisher. The pharmacy staff inputted prescription data in the computer and they, particularly Mrs. Miller, were the computer gatekeepers. They were responsible for alerting Mr. Miller to potential problems with early refills and over prescribing. They had no training or qualifications for detecting these problems. Moreover, Mrs. Miller believed that anything Dr. Fisher prescribed should not be questioned and she so instructed the staff. With that philosophy institutionalized and with Mr. Miller’s direction to override alerts, the clerks would communicate few if any problems or concerns to Mr. Miller.

Mr. Miller also testified that he kept information on Patient A and his refills “in his head.” He testified that he knew Patient A was progressing because he hired him to clean the pharmacy and he could talk with and observe him. It was not credible that Mr. Miller could or did keep prescription and other patient information in his head when he filled thousands of prescriptions for hundreds of patients.

⁸ Mr. Miller argued at hearing that he had numerous difficulties securing his pharmacy files from the Attorney General’s Office after they were seized on February 18, 1999. Respondents’ attorney did not secure all of the pharmacy records until close to the time of the administrative hearing. However, Mr. Miller had access to all of the pharmacy files during the four year period when the Accusation was pending. Mr. Miller’s attorney acknowledged during the preliminary hearing in the criminal trial, in April of 1999, that he had the charts of the patients at issue in that matter. Mrs. Miller’s attorney testified in the instant hearing that he had access to the pharmacy files during the three-year pendency of the criminal trial. Moreover, the evidence was persuasive that the pharmacy did not keep records of consultations with Dr. Fisher on the computer files for the patients.

36. Mr. Miller continued to dispense excessive quantities of acetaminophen to Patient A after he was provided information that Patient A had elevated liver enzymes and had a chance of having hepatitis C. On Oct. 30, 1998, Dr. Fisher wrote on a prescription form for Patient A, "please do Tar for elevated LFT chance Hep C." The TAR was prepared so that Patient A could get Medi-Cal reimbursement for a prescription for Norco, which contained less acetaminophen than the Lorcet the patient was taking. Ms. Meek incorporated Dr. Fisher's language into the TAR request for Norco, and Mr. Miller began filling prescriptions for Norco containing 325 mg. of APAP, #100.

In November of 1998, Mr. Miller was dispensing to Patient A almost twenty times the 4 gram maximum dosage for APAP. The dosage of APAP increased significantly and on Feb. 15, 1999, Mr. Miller dispensed 100 tablets, followed by 100 tablets the following day. Between Nov. 11, 1998 and Feb. 16, 1998, Mr. Miller was dispensing massive and unsafe doses of APAP to Patient A when he knew the patient had increased liver function and might be developing hepatitis C.

37. Although Patient A's prescriptions did not contain a dosing schedule, if Mr. Miller had reviewed the patient's drug history and calculated the patient's approximate days supply, he would have found multiple instances where the patient was taking excessive amounts of medications. Mr. Miller dispensed Carisoprodol (Soma) 350 mg., 100 tablets, 4 times a day Q.I.D. as needed on Nov. 9, 1998. The usual dosage for Carisoprodol is one 350 mg. tablet three times daily and at bed time. Just four days later, Mr. Miller dispensed another 100 tablets of 350 mg. Carisoprodol 350 mg. Q.I.D. to Patient A. Patient A would have to consume twenty-five 350 mg. tablets of Carisoprodol daily (a total of 8,650 mg.) to require a refill after four days. Nevertheless, there was no pharmacy record justifying a refill just four days after the prior prescription was filled.

Nine days later, on Dec. 3, 1998, Mr. Miller dispensed another 100 tablets. Twelve days after that, he dispensed another 100 tablets. He continued dispensing 100 tablets of Carisoprodol to Patient A in short intervals. On Jan. 4, 1999, he dispensed 100 tablets. Four days later he dispensed another 100 tablets. On Feb. 15, 1999, he dispensed 100 tablets, and the next day dispensed another 100 tablets. Mr. Miller had no documentation in his pharmacy records to justify filling prescriptions for Carisoprodol for Patient A with such frequency.

38. Mr. Miller dispensed Hydrocodone (Norco) 10/6325 beginning Oct. 30, 1998, to Patient A at a rate of 100 tablets approximately every two weeks. On Nov. 20, 1998, he dispensed 100 tablets. Five days later he dispensed another 100 tablets. Nine days after that he dispensed another 100 tablets. On Dec 31, 1998, he dispensed 100 tablets. Five days later he dispensed 100 tablets. Four days after that, on Jan. 8, 1999, he dispensed another 100 tablets. On Feb. 15, 1999, he dispensed 100 tablets, and another 100 tablets the following day.

39. Dr. Fisher's prescription of Feb. 10, 1999, included both Soma and Norco and stated that Patient A should be given 100 tablets of each and "one refill now." Mr. Miller

had no documentation in his pharmacy records to justify dispensing Hydrocodone and Soma to Patient A with such frequency. Mr. Miller dispensed the refills without obtaining justification for immediate refills.

40. The Accusation alleges that Mr. Miller dispensed Meperidine when Patient A's customary usage was exceeded. However, there is a record of only one dispensing of this drug, on Aug. 12, 1998. This allegation is not supported by the evidence.

41. Mr. Miller dispensed large quantities of Oxycontin (Oxycodone Hydrochloride-controlled release) to Patient A over short periods of time, without investigating and documenting the reasons for the large quantities. Mr. Miller dispensed 360 to 420 tablets of Oxycontin 80 mg. to Patient A approximately every thirty days between April and December of 1998. This provided a dosage of approximately 12 tablets per day. On July 15, 1998, he dispensed 420 tablets of Oxycontin 80 mg. to Patient A. Fifteen days later he dispensed 90 tablets of 100 mg. MS Contin. Mr. Miller had no documentation in his pharmacy records to justify dispensing MS Contin to Patient A when he had recently dispensed 420 tablets of Oxycontin. On Oct. 15, 1998, and on Dec. 15, 1998, Mr. Miller dispensed 900 tablets of Oxycontin 80 mg. to Patient A. On Dec. 15, 1998, he also dispensed 100 tablets of Norco.

42. The manufacturer of Oxycontin cautions that 80 mg. doses should only be dispensed to patients who are opioid tolerant. Patient A was opioid tolerant when he was placed on 80 mg. doses of Oxycontin. There is no established "maximum dose" for Oxycontin. However, the number of doses - 900 in October and 900 more sixty days later - should have raised concerns to a pharmacist, particularly with a patient who was concurrently taking Hydrocodone/Norco in large quantities. Those concerns include the potential risks from an overdose or the diversion of the controlled substances. Mr. Miller did not consult with Dr. Fisher or with the patient about these high doses. In fact, Mr. Miller admitted to police officers that he was shocked when he saw Oxycontin prescribed in such a high quantity. At hearing he admitted he was shocked, but qualified the statement by saying that he was shocked at the expense involved in supplying 900 tablets of Oxycontin to one patient.

Patient B. (L.A.)

43. Patient B was a CIP Patient, being treated by Dr. Fisher for HIV/Acquired Immune Deficiency Syndrome and related illnesses. Patient B had been a heroin addict.

Mr. Miller began dispensing Dilaudid to Patient B on May 8, 1998. He filled prescriptions for 360 tablets of Dilaudid 4 mg. approximately every two weeks. Patient B was taking approximately 20 tablets of Dilaudid per day. There was no record that Mr. Miller checked to determine whether Patient B had previously taken opiate/opioids and thus was opiate/opioid tolerant before he was placed on 20 daily tablets of Dilaudid 4 mg. As with most opioids, the starting dose of Dilaudid should be based on prior opiate/opioid usage. In instances where initial doses are as high as those prescribed by Dr. Fisher, Mr. Miller

should have confirmed that the patient was opiate/opioid tolerant by contacting the pharmacists or physicians who had prescribed and dispensed earlier opiate/opioid treatment.

44. On July 23, 1998, Dr. Fisher increased the quantity to 600 tablets of Dilaudid 4 mg. Mr. Miller filled this prescription approximately every two weeks until Sept. 16, 1998, when the number of tablets prescribed was raised to 900 every two weeks. On Oct. 21, 1998 and on Nov. 16, 1998, Mr. Miller dispensed 1,500 tablets of Dilaudid 4 mg. to Patient B. On Jan. 21, 1999 and Feb. 3, 1999, Mr. Miller dispensed 900 tablets of Dilaudid 4 mg. to Patient B. These prescriptions increased Patient B's daily dosage to 60 to 70 tablets per day. Mr. Miller had no documentation in his pharmacy records to justify filling prescriptions for Dilaudid for Patient B with such frequency and in such quantities. Mr. Miller did not contact Dr. Fisher or otherwise document the reasons for this increase in dosage.

45. At the time that Mr. Miller was dispensing Dilaudid to Patient B, he was also dispensing Dr. Fisher's prescriptions for immediate release (IR) morphine 30 mg., water-soluble. IR morphine water-soluble is susceptible to abuse because it can be easily diluted and injected. Generally, Patient B's prescriptions for morphine and Dilaudid were written and filled on the same dates. As the prescription dosages for Dilaudid increased, so did the doses of morphine, from approximately 30 tablets per day to up to 70 tablets per day. Once, on Sept. 14, 1998, Mr. Miller dispensed morphine in a dosage of over 100 tablets per day. Mr. Miller did not contact Dr. Fisher or otherwise document the reasons for this increase in dosage of morphine. He did not document any reasons why the doctor chose to prescribe two short acting opiate/opioids for Patient B. There was no documentation that Mr. Miller counseled the patient on the use of these medications.

46. Between July 8, 1998 and February 18, 1999, Mr. Miller dispensed 22,820 dosage units of Schedule II controlled substances to Patient B. There is no pharmacy documentation that Mr. Miller noted the increases in prescribing that occurred with Patient B, or that he contacted Dr. Fisher to recommend alternatives to safeguard the patient from becoming tolerant, addicted or otherwise harmed. There is no pharmacy documentation that Mr. Miller consulted with the Patient B about the dangers of overdose and dependency, particularly with the patient's history of opioid addiction.

47. Patient B's December 24, 1998, prescription was written for 100 tablets of Oramorph 100 mg. However, Mr. Miller dispensed 600 tablets of 100 mg. MS Contin on that date. Patient B's January, 1999, prescriptions for Schedule II controlled substances were written with the Health and Safety Code section 11159.2 exemption for persons with less than a year to live. In violation of that section, Mr. Miller dispensed three controlled substances written on one prescription blank. This prescription was not dated, nor did it bear the "11159.2 exemption" certification, as required.

Patient C (V.B.)

48. Patient C was treated by Dr. Fisher for chronic intractable pain from rheumatoid arthritis. She presented to Shasta Pharmacy for the first time on July 17, 1998, with a prescription for 450 tablets of immediate release morphine sulfate (MSIR) 30 mg., 2 to 4 tablets per day. Mr. Miller did not inquire of the patient or Dr. Fisher about Patient C's drug utilization history or her opiate tolerance.

Patient C presented to Shasta Pharmacy seven days later with a prescription for MS Contin 60 mg., 420 tablets, 5 to 7 per day. Mr. Miller filled this prescription. Patient C was thus taking daily up to 120 mg. short acting/immediate release morphine sulphate and up to 240 mg. morphine sulfate in the long acting/controlled release MS Contin. Morphine sulfate in excess of 200 mg. is indicated only for opiate tolerant patients. A week later, on Aug. 4, 1998, Mr. Miller filled a new prescription for MSIR 30 mg. at an increased dosage of 3 to 5 tablets per day, with an increased quantity of 600 tablets. Three days later, on Aug. 10, 1998, he filled a prescription for MS Contin 60 mg. at an increased dosage of 7 to 10 tablets per day, in a quantity of 600.

There were no directions on the prescriptions as to how the patient was to use the short acting morphine sulphate in conjunction with the longer acting morphine. Mr. Miller dispensed the medications without this direction and without consulting with the patient. Mr. Miller did not consult with Dr. Fisher or obtain patient medical records to substantiate the need for the increasing doses or the combination of medications.

49. Between July 8, 1998, and Dec. 31, 1998, Patient C's average daily usage of morphine derivatives increased from 18 to 25 tablets per day to 44 to 50 tablets per day. At the same time, Mr. Miller dispensed large quantities of Carisoprodol 350 mg. to Patient C. In total, Mr. Miller dispensed 18,270 doses of Schedule II controlled substance to Patient C. There was no medical documentation of the need for these increases over a five-month period. No other analgesic alternatives were attempted.

50. On several occasions, Mr. Miller dispensed early refills to Patient C. On Aug. 19, 1998, he dispensed 600 tablets of MSIR, 8 to 10 per day, a 60-day supply. Seven days later he dispensed 600 more tablets. On Oct. 1, 1998, Mr. Miller filled a prescription for 900 tablets of MSIR, eight to 10 tablets per day, a 90-day supply. Twenty days later he dispensed 900 more tablets. On Nov. 22, 1998, Mr. Miller filled a prescription for 1,500 tablets of MSIR, two to five tablets per day, a 300-day supply. Twenty-eight days later, he dispensed 1,500 more tablets. In total, in the four-month period between Aug. 19 and Dec. 17, 1998, Mr. Miller dispensed 6,000 tablets of MSIR to Patient C, an average of 50 tablets per day.

51. On Nov. 3, 1998, Mr. Miller filled two prescriptions for Patient C for MS Contin: One for 1,500 tablets, 100 mg., to be taken 10 to 12 every twelve hours; and one for 1,500 tablets, 60 mg., to be taken 10 to 12 every twelve hours. The prescription was for MS Contin, but Mr. Miller filled it with Oramorph. The patient left the pharmacy with 3000 doses of Oramorph. Even assuming it was appropriate for the patient to be taking the maximum dosage of 24 tablets a day of *each* prescription (48 tablets every 24 hours), the prescriptions would provide a 62-day supply. However, 30 days later on Dec. 2, 1998, Patient C presented with another prescription for MS Contin 100 mg., 1,500 tablets, to be taken 10 to 12 every 12 hours as needed. Mr. Miller filled this prescription without obtaining information from the physician and the patient on the need for such large doses of this controlled substance. Mr. Miller did not counsel the patient regarding the differing strengths of the two prescriptions or the manner in which the patient was to take them.

52. On Dec. 17, 1998, only 45 days after filling the MS Contin 60 mg., 1,500-tablet prescription, the patient presented with another prescription for MS Contin 60 mg., 1,500 tablets. Mr. Miller filled this prescription without obtaining information from the physician and the patient on the need for such large doses of this controlled substance. He did not counsel the patient regarding the differing strengths of the two MS Contin prescriptions. There was no documentation as to the reasons for filling this prescription.

53. Dr. Eisele, testified that Patient C went from 450 mg. daily of short acting morphine to 1,500 mg., a nearly four-fold increase. At the same time, Patient C was taking a long acting morphine, starting at 300 mg. a day and rising to 6000 mg. a day. Dr. Eisele testified that the "absolute number" of milligrams per day did not concern him. He testified that some of his patients require higher doses of morphine. However, he opined that "it is the rate of escalation and the absence of any documentation that the patient had worsening pain, a new pain, or any rationale for bumping the medication up..." that was of concern. Dr. Eisele reviewed Dr. Fisher's medical chart on Patient C⁹ and concluded that she had been doing well, her pain coverage was adequate on the lower doses and there was no justification for escalating the dosages.

54. Mr. Sedeyko testified that Patient C was inappropriately and dramatically increased in her dosages over only a five-month period, and no other analgesics than the three narcotics were attempted.

⁹ During the preliminary hearing, the Judge asked the parties if they had the medical records of the patients at issue in that proceeding. The attorneys for Mr. Miller, Mrs. Miller and Dr. Fisher all responded that they had possession of copies of those records. (Exhibit QQ page 66.) Three of the patients at issue in the criminal matter are at issue in this proceeding (Patients A, C, and H). At the hearing of the instant matter, Mr. Miller and Dr. Fisher both testified that they did not have access to the medical records of the patients at issue herein. That testimony was not credible in light of their attorneys' representations to the contrary.

Patient D. (G.D.)

55. Patient D. was treated by Dr. Fisher for chronic intractable pain due to spinal cord injuries and degeneration of the spine. Between June 2, 1998, and January 29, 1999, Mr. Miller simultaneously filled prescriptions for MS Contin 100 mg. and Oxycontin 80 mg. for Patient D. Both medications are long-acting/controlled release opioid analgesics.

56. Mr. Miller initially filled the Oxycontin prescription for 450 80 mg. tablets, to be taken 6 to 8 tablets every 12 hours, a maximum dose of 16 tablets per day. The dosage increased on Sept. 14, 1998 to 10 to 15 every 12 hours, a maximum dose of 30 tablets per day. Then on Nov. 11, 1998, the dosage decreased to 8 to 10 every 12 hours, a maximum dose of 20 tablets per day.

57. The number of tablets of MS Contin prescribed and the frequency of refills indicated that Patient D was using amounts in excess of those prescribed. On Aug. 6, 1998, Mr. Miller filled a prescription for 600 tablets of MS Contin 100 mg. to be taken 8 to 10 tablets every 12 hours, a 30-day supply at the maximum prescribed dosage. Nineteen days later, on Aug. 25, he filled a prescription with 600 more tablets. On Nov. 11, 1998, Mr. Miller filled a prescription of 1,500 tablets, a 75-day supply. Thirty-six days later, on Dec. 17, he filled a prescription for 1,500 tablets.

58. On Aug. 28, 1998, Mr. Miller filled Patient D's prescription for 600 tablets of Oxycontin 80 mg., 7 to 10 tablets every 12 hours, a 30 day supply at the maximum dosage. Ten days later, on Sept. 4, he filled a prescription for Oxycontin 80 mg. 10 to 15 every 12 hours, with 900 tablets. On Oct. 27, 1998, Mr. Miller filled Patient D's prescription for 900 tablets of Oxycontin 80 mg., 10-15 every 12 hours, a 30-day supply. Sixteen days later, on Nov. 11, 1998, he filled Patient D's prescription for 900 tablets of Oxycontin 80 mg., 8 to 10 every 12 hours.

59. During the period of Aug. 25, 1998 through Jan. 1, 1999, Patient D was also taking Demerol and Dilaudid for pain relief.

60. Mr. Miller filled Patient D's prescriptions without obtaining information from Dr. Fisher and the patient on the need for early refills. Although Patient D testified that he talked with Mr. Miller and Dr. Fisher about the dangers of over-dosages, he also made it clear that neither one expressed concern with the rate of narcotic consumption. He testified that Dr. Fisher told him he could use the medications as he needed and that he could "take a little more" as needed for break through pain. Patient D's pattern of use and consequent early refills should have prompted Mr. Miller to consult with the patient and Dr. Fisher, and to document the need for the quantity of medications apparently consumed by the patient. Mr. Miller did not do this.

61. The Board investigator, Brenda Bernard, discovered that Patient D was receiving the same prescription drugs from another pharmacy at the time Shasta Pharmacy was filling his prescriptions. If Mr. Miller had contacted Dr. Fisher about the patient's early

refills, the fact that Patient D was filling prescriptions at two pharmacies may have come to their attention.

Patient E (L.B.)

62. Patient E was treated by Dr. Fisher for chronic intractable lumbar pain following back surgeries. She also suffered neck and shoulder pain stemming from an automobile accident. Previously, another pharmacy was filling Patient E's prescriptions. Between July 6, 1998, and February 16, 1999, Mr. Miller filled prescriptions for Patient E.

63. Patient E initially presented with prescriptions for Carisoprodol (Soma) 350 mg., Lortab (Hydrocodone / APAP) 10/500, morphine 30 mg. and Oxycontin 80 mg. Mr. Miller dispensed approximately 5.5 grams per day of acetaminophen when filling Patient E's Lortab prescriptions between July 6, 1998 and Sept. 4, 1998. At the same time, Mr. Miller dispensed Patient E's Carisoprodol prescriptions at a rate of approximately 14 tablets per day. This Carisoprodol dosage exceeded the maximum dosage of 8 tablets per day. The combination of Carisoprodol use with Hydrocodone APAP should have alerted Mr. Miller to potential liver damage, as Carisoprodol is metabolized in the liver and excreted by the kidneys.

Mr. Miller continued to dispense these quantities of acetaminophen to Patient E. He did not obtain liver function test results from Dr. Fisher or recommend that the patient be placed on pain medications containing less acetaminophen. Mr. Miller did not counsel Patient E on the dangers of use of acetaminophen in excess of 4 grams per day. There was no pharmacy documentation as to the reasons for filling prescriptions containing dosages of acetaminophen in excess of 4 grams per day.

64. Between July 17, 1998 and Jan. 12, 1998, Mr. Miller dispensed a prescription for morphine 30 mg. to Patient E. On July 17, 1998, the patient Mr. Miller dispensed a prescription for approximately 11 tablets of morphine per day. On August 18, 1998, Mr. Miller dispensed a prescription for approximately 23 tablets of morphine per day. On October 12, 1998, Mr. Miller dispensed a prescription for approximately 36 morphine tablets per day. On November 16, 1998, he dispensed a prescription for 1,500 tablets of morphine, approximately 36 tablets per day, a 42-day supply.

65. On July 21, 1998, Mr. Miller dispensed a prescription for approximately 14 tablets of Oxycontin per day to Patient E. On August 18, 1998, Mr. Miller dispensed a prescription for approximately 16 tablets of Oxycontin per day. On Sept. 15, 1998, Mr. Miller dispensed a prescription for approximately 20 Oxycontin tablets per day. On Oct. 12, 1998, and monthly thereafter, he dispensed prescriptions for 900 tablets of Oxycontin, with a dosage of between 20 and 30 tablets per day.

66. A review of Patient E's drug utilization in September of 1998, would have shown Mr. Miller that Patient E was taking the following daily:

5.5 tablets of Carisoprodol, 350 mg.;
7.5 tablets of Lortab 10/500;
30 tablets of morphine, 30 mg.;
20 tablets of Oxycontin, 80 mg.

67. Mr. Miller continued to dispense these quantities of Carisoprodol, Lortab, Oxycontin and morphine without documenting the reasons for filling these prescriptions, and without counseling the patient on the risks of large dosages of opiate/opioid therapy.

68. Patient E testified that her pain decreased and her functioning increased significantly as a result of her medication regimen. Patient E testified that she talked regularly to Mr. Miller about her progress when she came into the pharmacy to pick up prescriptions. However, the patient's attestation that she was feeling better on a particular drug regimen does not relieve the pharmacist of his responsibilities to make adequate medical inquiries about the drug regimen and provide appropriate warnings to patients.

Patient F (R.C.)

69. Patient F was a cancer patient of Dr. Fisher. Between July 1, 1998 and Feb. 8, 1999, Mr. Miller filled prescriptions for Patient F for Percocet (Oxycodone/APAP). This formulation contained 325 mg. of acetaminophen. Patient F's use of Percocet went from approximately 43 tablets per day to over 60 per day during the months of October and November 1998. The patient's daily dosage of acetaminophen reached a high of 16 or 17 grams a day.

Mr. Miller did not request liver function test results for this patient. He did not suggest alternative medications to reduce acetaminophen usage. He did not document the rationale for this dispensing or consult with Dr. Fisher or the patient about the risks of acetaminophen usage.

Patient G (B.P.)

70. Patient G was a chronic pain patient of Dr. Fisher. Mr. Miller filled prescriptions for Patient G from Oct. 28, 1998 through Feb. 17, 1999. Initially, Dr. Fisher prescribed Oxycodone/APAP. The first prescription Mr. Miller filled consisted of 600 tablets of Oxycodone/APAP, with a daily dosage of approximately 32 tablets per day. Nineteen days after filling the first prescription, Mr. Miller filled another prescription for Oxycodone/APAP for 1,200 tablets. This corresponded to a supply of 57 tablets per day. Mr. Miller subsequently filled prescriptions for Oxycodone/APAP, which furnished Patient G with 43, 71, and 44 tablets per day respectively. These prescriptions provided Patient G with far in excess of the recommended maximum dosage of 4 grams per day of acetaminophen.

71. Mr. Miller did not request liver function test results for Patient G. He did not suggest alternative medications (such as Oxycodone without APAP) to decrease

acetaminophen usage. He did not document the rationale for this dispensing or consult with Dr. Fisher or the patient about the risks of acetaminophen usage.

Patient H (M.M.)

72. Patient H, was a patient of Dr. Fisher, and Mr. Miller's wife. She had a diagnosis of chronic lower back pain. In January of 1998, Mr. Miller began dispensing narcotic pain relievers, Norco 10/325 and Oxycodone/ASA, to Patient H. In March of 1998, he began filling additional prescriptions for Oxycodone/APAP. In April 1998, Mr. Miller began filling two more narcotic prescriptions for Patient H: Demerol 100 mg. and Hydrocodone/APAP 10/500. In February 1999, he filled a prescription for another narcotic, Oxycontin 40 mg. Between April of 1998 and February 18, 1999, Mr. Miller was dispensing at least five narcotics to Patient H.

73. Between January of 1998 and February 18, 1999, Mr. Miller also dispensed to Patient H prescriptions for one muscle relaxant, Carisoprodol/Soma, two sleep medications, Ambien and Placidyl, as well as Dexedrine, a stimulant indicated for narcolepsy or attention deficit disorder.

74. The quantities of medications Mr. Miller dispensed to Patient H were large. Between Jan 10, 1998 and Feb. 4, 1999, Mr. Miller dispensed 4,800 tablets of Carisoprodol 350 mg. Between April 28, 1999 and Nov. 5, 1998, Mr. Miller dispensed 2,895 tablets of Demerol 100 mg. On Nov. 5, 1998, Mr. Miller dispensed 1,500 tablets of Demerol 100 mg.

75. Between Jan. 2, 1998, and Jan 13, 1999, Mr. Miller dispensed 1,288 tablets of Dexedrine 15 mg. SP. to Patient H. On all but one of the dates he filled prescriptions for Dexedrine 15 mg. SP, Mr. Miller also filled prescriptions for Dexedrine 5 mg. Mr. Miller dispensed a total of 5,100 tablets of Dexedrine 5 mg. to Patient H during this period, 1,500 of them on Nov. 24, 1998.

76. Between Sept. 9, 1998 and Nov. 13, 1998, Mr. Miller dispensed 2,010 tablets of Dilaudid 4 mg. to Patient H, 1,500 of them on Nov. 4, 1998.

77. Between April 3, 1998 and Feb 4, 1999, Mr. Miller dispensed 1,310 tablets of Hydrocodone 10/500 to Patient H. Between Jan. 23, 1998 and Feb. 4, 1999, Mr. Miller dispensed 2,720 tablets of Norco 10/325 to Patient H. Patient H received both Norco 10/325 and Hydrocodone 10/500 concurrently. Norco 10/325 and Hydrocodone 10/500 contain acetaminophen in 325 mg. and 500 mg. strengths respectively. Mr. Miller dispensed dosages of acetaminophen far in excess of the recommended maximum dose of 4 grams daily. Mr. Sedeyko testified persuasively that Norco and Hydrocodone were the same medications. By dispensing the two drugs simultaneously, Mr. Miller dispensed duplicative drugs to Patient H.

78. Between March 7, 1998, and Nov. 4, 1998, Mr. Miller dispensed 1,950 tablets of Oxycodone/APAP to Patient H. Between Jan. 10, 1998, and April 2, 1998, he dispensed

750 tablets of Oxycodone/ASA. On Feb 4, 1999, he dispensed 100 tablets of Oxycontin 40 mg.

79. Between Jan. 16, 1998 and Jan. 13, 1999, Mr. Miller dispensed 800 tablets of Placidyl 500 mg. to Patient H. During that period, he also dispensed 860 tablets of Ambien 10 mg.

80. On November 4, 1998, Mr. Miller dispensed 1,500 tablets of Dilaudid and 1,500 tablets of Oxycodone to Patient H. The following day he dispensed 1,500 tablets of Demerol to Patient H. Patient H was also taking Lortab and Norco. Thus, Mr. Miller dispensed five different short-acting narcotic analgesics, and he dispensed approximately 5,000 doses of these medications at the same time. Nineteen days later, on Nov. 25, 1998, he dispensed 1,500 tablets of Dexedrine 5 mg. The testimony of Dr. Eisele established that dispensing over 6,000 doses of these medications within twenty days was excessive.

81. Mr. Miller did not document any explanations or support for dispensing multiple opioids and multiple sleep medications to Patient H. He did not document any rationale for dispensing contradictory drugs (Dexedrine, Ambien and Placidyl) as well as drugs similar in effect (the opioid prescriptions). Nor did Mr. Miller document or explain the need for the quantities dispensed. Mr. Miller did not inquire of Dr. Fisher about the necessity, if any, for repeated prescription of doses of acetaminophen in excess of 4 grams.

Patient I (D.W.)

82. Patient I was a patient of Dr. Fisher. Dr. Fisher's prescriptions noted that Patient I was treated for neck pain. Between July 8, 1998 and February 18, 1999, Mr. Miller dispensed at least 22,470 doses of four different narcotic analgesics: Morphine 30 mg., Norco 10/325, Oramorph 60, and Oxycontin 80 mg. to Patient I.

With each drug, except Norco 10/325, the prescriptions increased in quantity to the point where the patient was taking 50 tablets of Oramorph 60 mg., approximately 44 tablets of morphine 30 mg. sol. and approximately 30 tablets of Oxycontin 80 mg. per day. During this period, Patient I continued to take approximately 23 tablets of Norco 10/325 per day.

83. Mr. Miller continued to dispense the quantities that Dr. Fisher prescribed with no documentation for the need for these doses and without consultations with Dr. Fisher or the patient. He made no suggestions to Dr. Fisher or the patient about decreasing the patient's daily usage of narcotic analgesics or acetaminophen.

Patient J (J.L.)

84. Patient J was a patient of Dr. Fisher. Dr. Fisher indicated on prescriptions that Patient J was a chronic intractable pain patient due to chronic hip pain.

On August 24, 1998, Mr. Miller filled a prescription for 300 tablets of morphine IR 30 mg. tablets for Patient J. The prescription contained a dosing schedule of 7 to 10 QUU PRN. Mr. Miller wrote on the prescription "spoke to Patient/dose up to max!" He emphasized the word "max" by underlining it twice. The 300 tablets lasted the patient 30 days, indicating Patient J was taking the maximum dose of 10 tablets per day.

Mr. Miller filled the morphine IR 30 mg prescription again on Sept. 22, 1998, giving the patient another 300 tablets. Despite Mr. Miller's recognition that the patient was consuming the maximum dosage, Mr. Miller again filled this prescription twenty days later with 900 tablets. The patient would have to consume 15 tablets per day to use up his previous prescription. Mr. Miller again filled this prescription 22 days later, and this time the prescription called for 1,500 tablets. The patient was at this time consuming approximately 40 tablets per day.

In November 1998, Mr. Miller dispensed another 3,500 tablets, and on Dec. 22, 1998, another 2,000 tablets with a dose of 5 to 7 QUU PRN. On Jan 15, 1999, he dispensed 2,500 tablets and on Feb. 15, 1999, he dispensed another 1,700 tablets. These refills increased Patient J's daily consumption of morphine 30 mg. IR to daily doses of approximately 60 tablets and finally to 82 tablets.

85. Mr. Miller failed to document the basis for continuing the short-acting narcotic morphine 30 mg. IR when it was evident that Patient J was increasing his daily dosage beyond the 7 to 10 tablets per day that Mr. Miller had advised the patient was the maximum dose. Mr. Miller did not consult with Dr. Fisher about the use of long-acting pain medications rather than massive doses of short-acting medications. Nor did he discuss with Dr. Fisher the use of alternative short-acting medications.

Patient K (J.K.)

86. Patient K was a patient of Dr. Fisher. On Sept. 28, 1998, Mr. Miller dispensed 600 tablets of Roxicodone 5 with a maximum dosage of 20 tablets per day, per the dosing schedule. A month later, he dispensed another 900 tablets of the same medication with the same dosing schedule. A month later, he dispensed 1,500 tablets of the same medication with the same dosing schedule. The following month, on Dec. 22, 1998, Mr. Miller dispensed 1,500 tablets of Roxicodone 5 mg. with the same maximum dosing schedule. It was clear from the maximum dosage on the prescriptions, the number of tablets dispensed and the frequency with which the patient presented for refills of the prescription that the patient was consuming in excess of 20 tablets per day. Daily usage had increased to 32 tablets and ultimately to 51 tablets per day. There was no documentation as to the reasons Mr. Miller filled these prescriptions, or why such large quantities of a short-acting opioid were prescribed over several months time.

87. Patient K was also taking Oxycontin 80 mg. during the period of time she was taking Roxicodone. Approximately every 28 days Mr. Miller dispensed 900 tablets of 80 mg. Oxycontin. The dosing schedule in the Dec. 22, 1998 prescription indicated a maximum

dosage of 20 tablets per day. Mr. Miller consistently dispensed a dosage of approximately 32 tablets per day. There was no documentation as to the reasons Mr. Miller filled these prescriptions.

Patient L (R.K.)

88. Patient L was a patient of Dr. Fisher. Patient L had the same last name and address as Patient K. Patient L was prescribed Roxicodone 5 mg. and Oxycontin 80 mg. In July of 1998, Patient L was taking 40 mg. of Oxycontin at a rate of 14 tablets per day. This dosage increased on Oct. 16, 1998, to 80 mg. tablets and a maximum of 20 tablets per day. This dosage was again dispensed on Dec. 22, 1998. At the same time, Mr. Miller was dispensing Roxicodone 5 mg. to Patient L. Mr. Miller dispensed 600 tablets of Roxicodone 5 mg. to this patient on Aug. 13, 1998 and on Sept. 10, 1998. Mr. Miller dispensed 900 tablets of Roxicodone on Oct. 6, 1998. The patient presented with a new prescription on 11/5/98, indicating that he had consumed 45 tablets per day rather than the maximum dosage of 20 tablets per day. Mr. Miller dispensed 1500 tablets. Again on 12/22/98 he dispensed 1500 tablets, even though the patient's prior use showed he was consuming 75 tablets per day, far in excess of the maximum dosage. Mr. Miller did not ascertain or document the reasons for these early refills.

Both patients K and L received the same medications, in the same dosages and with similar refill schedules. There was no documentation to explain why these two patients were receiving almost identical drug regimens. There was no documentation for either patient as to the reasons for filling these prescriptions. There was no documentation that these patients were advised not to share their medications.

Additional Patients

89. Mr. Miller regularly dispensed prescriptions for medications containing acetaminophen in excess of 4 grams per day. In addition to filling prescriptions for the patients identified above, he filled these prescriptions during January 1999.

K.B. received 1,008 tablets of Carisoprodol and 1,008 tablets of Hydrocodone/APAP 10 (Hydrocodone APAP 10 has 500 mg. of acetaminophen per tablet.)

G.B. received 540 tablets of Carisoprodol, 360 tablets of Tylenol #3, and 600 tablets of Hydrocodone/APAP 7.5 (Hydrocodone APAP 7.5 has 750 mg. of acetaminophen per tablet.)

E.C. received 400 tablets of Carisoprodol and 800 tablets of Hydrocodone/APAP 10.

J.D. received 300 tablets of Carisoprodol and 375 tablets of Hydrocodone/APAP 7.5.

R.D.1. received 100 tablets of Carisoprodol and 480 tablets of Hydrocodone/APAP 7.5.

R.D.2. received 400 tablets of Carisoprodol and 360 tablets of Hydrocodone/APAP 7.5.
D.K. received 400 tablets of Carisoprodol and 810 tablets of Hydrocodone/APAP 10.
W.L. received 400 tablets of Carisoprodol and 810 tablets of Hydrocodone/APAP 10.
S.M. received 300 tablets of Carisoprodol and 270 tablets of Hydrocodone/APAP 7.5.
E.N. received 270 tablets of Carisoprodol and 270 tablets of Hydrocodone/APAP 7.5.
D.P. received 600 tablets of Carisoprodol and 360 tablets of Hydrocodone/APAP 7.5.
B.R. received 800 tablets of Carisoprodol and 480 tablets of Hydrocodone/APAP 7.5.
D.S. received 400 tablets of Carisoprodol and 360 tablets of Hydrocodone/APAP 7.5.

90. All of these patients received over 4 grams of acetaminophen daily. There is no documentation of the need for dispensing acetaminophen in excess of 4 grams per day. There is no documentation that liver function tests or drug utilization reviews were conducted before dispensing these medications to these patients. There is no documentation that Mr. Miller consulted with these patients before dispensing these medications or that the patients refused consultation.

Failure to Consult On New Prescriptions

91. From July 8, 1998, through February 18, 1999, Mr. Miller filled approximately 15,800 new prescriptions, but consulted with only approximately 20 patients. During 1998, Mr. Miller consulted with new patients 10 times or less.

Dispensing to Impaired Customers

92. At times, patients presented at the pharmacy in an impaired condition and with prescriptions for early refills of controlled substances. On one occasion, Patient E (L.B.) arrived at the pharmacy with a prescription for controlled substances. Ms. Meek observed that Patient E. was "really out of it," and she told Mr. Miller's that Patient E. was slurring her speech and falling asleep. Mrs. Miller called Dr. Fisher's office, and the pharmacy dispensed the medications to Patient E. On another occasion Patient E came in again with slurred speech and difficulty speaking. Mr. Miller observed her and filled her prescriptions.

Patient K.B. called several times for early refills. Ms. Meek observed that on one occasion his speech was slurred and he laughingly told her he had taken Soma. Ms. Meek advised Mrs. Miller of the situation. Mrs. Miller called Dr. Fisher's office, and the pharmacy dispensed K.B.'s early refills. On another occasion, K.B. came into the pharmacy with

slurred speech and with a swaying gait. Ms. Meek told Mr. Miller. Mr. Miller filled K.B.'s prescription later that day.

Failure to Transmit Data

93. During the period of September 18, 1998, through February 18, 1999, Mr. Miller failed to submit data on Schedule II prescriptions filled at Shasta Pharmacy to Atlantic Associates. Atlantic Associates conveys this information to the Department of Justice. Mr. Miller had arranged with McKesson to draw this information from the pharmacy computer system and transfer it to the Department of Justice. Unbeknownst to Mr. Miller, McKesson failed to transmit the data to Atlantic Associates.

Packaging and Storage of Drugs

94. During execution of the search warrant at Shasta Pharmacy on February 18, 1999, Board pharmacy inspectors conducted an audit. Inspectors discovered repackaged and pre-counted controlled substances in containers that were not properly labeled as to the quantity of tablets/capsules contained in the container. Generic Dilaudid 4 mg. had been repackaged in 100-count manufacturer's bottles to contain 200, 300, 400 or 500 tablets. Original containers for many controlled substance Schedule II drugs were missing. The audit revealed numerous pre-counted generic Vicodin ES bottles containing 60, 90 and 120 tablets. These containers were not labeled with any information. There were expired drugs on the pharmacy shelves and dangerous drugs were stored in a taped box in the bathroom and in the refrigerator.

Pharmacy Sanitation

95. During execution of the search warrant, Board pharmacy inspectors found rotten and moldy food stored in a refrigerator interspersed with dangerous drugs and other pharmaceutical inventory. Although Mr. Miller employed regular pest control services and a cleaning service, inspectors found rodent droppings in the pharmacy.

Respondents' Defenses

96. Respondents complained of a conspiracy by Medi-Cal, the Drug Enforcement Agency and the Attorney General's Office. Respondents asserted that Medi-Cal officials were angry with the Millers and Dr. Fisher because they prevailed in a hearing involving a TAR denial for one of Dr. Fisher's patients. Respondents asserted that these three agencies launched the criminal investigation against them because Medi-Cal wanted to avoid paying for patient prescriptions and wanted to discourage the Millers and Dr. Fisher from taking any additional TAR denials to hearing.

The criminal investigation and prosecution against the Millers and Dr. Fisher have no bearing on the instant proceeding. Mr. Miller and Shasta Pharmacy are subject to numerous statutes and regulations governing the practice of pharmacy. Clear and convincing evidence

established that respondents violated these statutes and regulations in the operation of Shasta Pharmacy.

97. Respondents maintain that the Chronic Intractable Pain Act and the Patients' Bill of Rights essentially exempt them from compliance with many pharmacy laws and regulations. They maintain that as long as a patient is a CIP patient and has a contract with the treating doctor, the doctor and patient may dictate the nature and amounts of medications the pharmacist should dispense. In essence, respondents maintain that when a physician deems a patient a CIP patient, the pharmacist no longer has a corresponding duty to question or monitor the patient's drug usage.

This argument is without merit. Neither the Chronic Intractable Pain Act nor the Patients' Bill of Rights mandate or allow a pharmacist to relinquish professional duties.

98. Respondents assert that they had established a relationship of trust with Dr. Fisher, similar to the relationship Ms. Hahn and her fellow pharmacists share with referring physicians. Thus, they argue, there was no need for Mr. Miller to consult with Dr. Fisher about the quantities of opioids he prescribed, the medical reasons for the prescriptions, dosing schedules, early refills or acetaminophen content.

This argument lacks merit. A pharmacist may not neglect the duties of inquiry, verification and documentation because he or she assumes a particular physician has a good reason for a prescription. Moreover, the relationship Ms. Hahn described between her pharmacy and CIP physicians was not the same type of relationship Mr. Miller shared with Dr. Fisher. Ms. Hahn maintained an on-going working relationship with prescribing physicians and forged her own relationship with patients. She made inquiries and suggestions and documented consultations with physicians and patients. She maintained a chart on each CIP patient. Mr. Miller, on the other hand, had very little contact with Dr. Fisher or the patients, and investigated and documented virtually nothing. Ms. Hahn and her pharmacists worked closely as a team with doctors and patients; Mr. Miller removed himself from the physician-patient-pharmacist team and allowed his wife to fill the vacuum.

99. Respondents maintain that the quantities of acetaminophen they dispensed were not toxic. Respondents sought to establish this through the testimony of Dr. Fisher. Dr. Fisher testified that the studies establishing 4 grams as the maximum safe dose are flawed in that the studies were conducted on animals. Dr. Fisher testified that another study by Dr. Harvey Rose showed that acetaminophen consumption in excess of 4 grams per day was safe. Dr. Rose's study ostensibly established that patients did not develop liver toxicity after twenty years or more of acetaminophen consumption in excess of 4 grams.

This argument was not persuasive. All of the expert witnesses except Dr. Fisher, testified that the medical literature established 4 grams as the maximum safe dosage. The manufacturer recommends 4 grams as the maximum dose. (Dr. Fisher claimed that the manufacturer's recommendations were underestimated in order to avoid liability.) Moreover, Dr. Rose's study was not a scientific study, but was observational of his small

sample of patients. Most importantly, Dr. Rose's patients had normal liver function tests. Many of Dr. Fisher's patients had impaired liver function indicated in lab tests. For these reasons and others Dr. Fisher's opinion lacks weight.

100. Dr. Fisher testified that the types and dosages of controlled substances he prescribed were appropriate. Therefore, respondents argue, it follows that Mr. Miller did not violate the standards of pharmacy practice in dispensing these prescriptions. Dr. Fisher testified that there are no maximum dosages for opioids and that once tolerance is established opioids are not toxic to any organ system. He testified that he titrated patient dosages to the desired effect of pain relief and improved functionality. He pointed to medical literature that indicated that dosages of opioids could be doubled every twenty-four hours until the treatment goals are met. He explained that he prescribed multiple short and long acting opioids because there are different types of opioid receptors in the body. Some opioid formulations will only "hit" certain receptors. Dr. Fisher also testified that he prescribed multiple opiate/opioids and large quantities of tablets on a single prescription because he did not want to run out of triplicate prescription forms. At that time, physicians were allocated a maximum of 200 triplicate prescription forms per month.

The expert witnesses confirmed that some of the pain management principles Dr. Fisher espoused were within the standard of care. Ms. Hahn agreed that titration could proceed by doubling dosages. Dr. Eisele testified that the absolute number of pills prescribed did not concern him. Ms. Hahn testified that multiple opioid therapy is a recognized pain management tool.

However, the medical experts, Dr. Eisele and Dr. Wilsey, were in accord that Dr. Fisher's actual pain management practices were not within the standard of care. In general, Dr. Fisher did not properly assess or monitor patient opioid use. His choices of medications were often "unusual" and "unwise." Although he professed to follow titration principles, he titrated excessively and without careful evaluation of patient response to medications or dosages. He titrated dosages within 24 hours of a dosage increase, even though the ability of a given dosage of sustained release opioid to provide improved pain relief cannot be determined within such a short period.

Moreover, the medical experts were in agreement that a physician may not remedy an administrative problem, such as an anticipated shortage of triplicate prescriptions, by sending patients home with 1,500 doses of a controlled substance.

101. Dr. Fisher's testimony that his prescribing was within the standard of pain management practice was not persuasive for additional reasons. He was not an independent witness. He had a clear interest in the outcome of this proceeding. Moreover, Dr. Fisher has professed the belief that opioids should be rescheduled and put out over the counter.¹⁰ It is difficult to believe that an individual with this philosophy, and with the "laissez faire"

¹⁰ Exhibit V pg. 13.

practices Dr. Wilsey and Dr. Eisele identified, would carefully select, control and monitor his patients' usage of opioids.

102. For the above reasons, respondents' argument that they relied upon Dr. Fisher's sound prescribing practices is not persuasive. Further, respondents had an independent duty to confirm the validity and appropriateness of the types and dosages of Dr. Fisher's prescriptions.

103. Mr. Miller maintains that he did in fact conduct drug utilization reviews, counsel patients, and communicated with Dr. Fisher regularly about dosages and drug choices. However, the evidence is persuasive that he did not.

Moreover, Mr. Miller's testimony was equivocal. Many times he stated that he did not have time to do everything required of him. He testified that the clerks brought DUR problems to his attention. Yet he also testified that he had to rely upon them to do so, implying that he did not conduct the DURs himself. He testified that he trusted Dr. Fisher's procedures and recognized him as an expert in pain management, implying that he did not question Dr. Fisher. He testified that he kept notes of consultations on his computer, yet the only notes produced were on hard copies of prescriptions. Mr. Miller made several admissions to the authorities conducting the search and seizure of the pharmacy, and confirmed those admissions at hearing. The admissions substantiate that he was alarmed with Dr. Fisher's prescribing high doses, but that he deferred to Dr. Fisher and to Mrs. Miller and dispensed the prescriptions.

Furthermore, Mr. Miller had accepted the premise that a physician and patient were free under the Patient Bill of Rights and the Chronic Intractable Pain Act to dictate the amounts and types of opiate/opioids prescribed. He accepted the erroneous premise that the pharmacist should defer to the physician and patient. He did not recognize or accept the fact that he had a separate and independent duty to protect the patient and the public. It was not credible that he fulfilled duties which he did not recognize he held.

104. Mrs. Miller's testimony was intended to establish that Mr. Miller did in fact conduct drug utilization reviews, counsel patients, and communicate with Dr. Fisher regularly about dosages and drug choices. She denied that she was the person who communicated with Dr. Fisher. She also attempted to establish that Mr. Miller had justifiable reasons for dispensing medication to her in incorrect names and with an incorrect address. She testified that she and Mr. Miller had to store medications and cash in the pharmacy bathroom because workers were in their home and they were living at an Embassy Suites. She explained that she did not believe in depositing money in banks, and that the \$28,800 found with medications in the bathroom was household cash.

Mrs. Miller was readily impeached. She did have personal monies in a bank account. She had no documentation to support the testimony that the Millers lived at the Embassy Suites for months. She could not explain why she had cash and medications in her home as well as at the pharmacy. Her rationale for using former names on prescriptions was not

credible, as Ms. Meek knew her former names. Further, she testified that she was completely disabled and on Social Security Disability. Yet she testified that she had worked more than full time in the pharmacy for years, while she collected Social Security Disability benefits.

Additionally, Mrs. Miller's demeanor suggested deception. She was mature and straightforward in some of her testimony. Yet, she became coy and adopted a childish and innocent attitude when confronted with the implausibility of her testimony.

Gross Negligence and Incompetence

105. Ms. Barnard and Mr. Sedeyko testified persuasively that the dispensing practices for the patients identified herein constituted gross negligence and incompetence. They testified persuasively that respondent Miller's delegation of duties to his wife constituted gross negligence and incompetence. They testified persuasively that respondent Miller's failure to educate himself on the pain management specialty constituted gross negligence and incompetence. They testified persuasively that respondents' packaging and storage of drugs within the pharmacy constituted gross negligence and incompetence.

Factors in Justification, Mitigation, Aggravation and Rehabilitation

106. In order to determine whether and to what extent it is appropriate to discipline respondents' licenses, it is necessary to weigh and balance respondents' violations of law as well as factors in justification, aggravation, mitigation and rehabilitation. Complainant did not introduce evidence of aggravation except for the fact that respondents' conduct continued for over a year and a half and all indications are it would have continued had the criminal prosecution not intervened.

Respondents implied that their conduct was justified or at least mitigated by their goal of providing pain relief and a good quality of life to suffering persons, particularly the poor. There is evidence that respondents embraced this objective; there is also evidence that respondents made a great deal of money from dispensing large quantities of expensive controlled substances. Even if respondents' goal was purely altruistic, the means they employed were not. Respondents provided massive quantities of opioids and other controlled substances to patients, virtually on demand, and without regard to patient health and safety or public safety. Their purported rationale for doing so is not a factor that can be considered in establishing justification or mitigation.

In mitigation, respondents had no previous record of discipline.

Respondents produced no evidence of rehabilitation, except that Mr. Miller has kept up with his continuing education credits. He placed his license on inactive status when it came up for renewal in 2001. He has not received or read any journals. Mr. Miller maintains that he is being victimized due to his advocacy for chronic pain patients, particularly those receiving Medi-Cal. His loyalty to Mrs. Miller and Dr. Fisher remains strong. There is no evidence that he now understands his duties as a pharmacist. There is no

evidence that Mr. Miller can now abide by his professional obligations when pressured by others to ignore them.

Costs

107. At hearing, the parties were advised that the Administrative Law Judge would take evidence relating to the factors set forth in *Zuckerman v. Board of Chiropractic Examiners* (2002) 29 Cal. 4th 32. The parties were advised that these factors would be considered in determining the reasonableness of costs. These factors include; whether the licensee has been successful at hearing in getting charges dismissed or reduced, the licensee's subjective good faith belief in the merits of his or her position, whether the licensee has raised a colorable challenge to the proposed discipline, the financial ability of the licensee to pay, and whether the scope of the investigation was appropriate to the alleged misconduct.

Complainant established that the reasonable costs of investigation of this matter were \$25,886.25. The reasonable costs of prosecution of this matter were \$25,525.50. Complainant established that the scope of the investigation was appropriate to the alleged misconduct. Complainant prevailed on all of the charges, with the exception of one allegation regarding Patient A's prescriptions for Meperidine. However, the investigative and prosecutorial time employed in pursuing this unsuccessful allegation was negligible and was subsumed in the time necessary to prepare the charges that were substantiated.

Mr. Miller introduced no evidence regarding his ability to pay costs. The only evidence adduced at hearing relating to respondents' financial condition was that in June or July 2004, the Millers received a check for approximately \$440,000 representing assets seized in the criminal matter. Additionally, Mr. Miller testified that more money was seized and he was pursuing return of that money. Mr. Miller testified, without supporting documentation, that he had to pay tax bills and bills to McKessen. He did not testify as to the approximate amounts owed.

LEGAL CONCLUSIONS

1. 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.

2. The standard of proof in an administrative disciplinary action seeking the suspension or revocation of a professional license is "clear and convincing evidence." *Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 583. "Clear and convincing evidence" means evidence of such convincing force that it demonstrates, in contrast to the opposing evidence, a high probability of the truth of the facts for which it is offered as proof. "Clear and convincing evidence" is a higher standard of proof than proof

by a “preponderance of the evidence.” *BAJI* 2.62. “Clear and convincing evidence” requires a finding of high probability. It must be sufficiently strong to command the unhesitating assent of every reasonable mind. *In re David C.* (1984) 152 Cal.App.3d 1189.

Disciplinary Statutes and Regulations

3. Business and Professions Code section 4300, provides that the Board may suspend or revoke any certificate, license, permit, registration, or exemption.

4. Business and Professions Code section 4301, provides that the Board may take action against the holder of any certificate, license, permit, registration, or exemption on the grounds of unprofessional conduct. Unprofessional conduct shall include, but is not limited to;

.....

(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.

.....

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

.....

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

5. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivisions (b), (c), (d), (j), and (o), to discipline respondents’ licenses, in respect to Mr. Miller’s dispensing of prescriptions to Patient A (A.T.).

This conclusion is based on Factual Findings 30 through 42, and 105, and on the Legal Conclusions.

6. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivisions (b), (c), (d), (j), and (o), to discipline respondents’ licenses, in respect to Mr. Miller’s dispensing of prescriptions to Patient B (L.A.).

This conclusion is based on Factual Findings 30 and 31, 43 through 47, and 105, and on the Legal Conclusions.

7. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivisions (b), (c), (d), (j), and (o), to

discipline respondents' licenses, in respect to Mr. Miller's dispensing of prescriptions to Patient C (V.B.).

This conclusion is based on Factual Findings 30 and 31, 48 through 54, and 105, and on the Legal Conclusions.

8. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivisions (d), (j), and (o), to discipline respondents' licenses, in respect to Mr. Miller's dispensing of prescriptions to Patient D (G.D.).

This conclusion is based on Factual Findings 30 and 31, 55 through 61, and 105, and on the Legal Conclusions.

9. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivisions (b), (c), (d), (j), and (o), to discipline respondents' licenses, in respect to Mr. Miller's dispensing of prescriptions to Patient E (L.B.).

This conclusion is based on Factual Findings 30 and 31, 62 through 68, and 105, and on the Legal Conclusions.

10. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivisions (b), (c), (d), (j), and (o), to discipline respondents' licenses, in respect to Mr. Miller's dispensing of prescriptions to Patient F (R.C.).

This conclusion is based on Factual Findings 30 and 31, 69, and 105, and on the Legal Conclusions.

11. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivisions (b), (c), (d), (j), and (o), to discipline respondents' licenses, in respect to Mr. Miller's dispensing of prescriptions to Patient G (B.P.).

This conclusion is based on Factual Findings 30 and 31, 70 and 71, and 105, and on the Legal Conclusions.

12. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivisions (b), (c), (d), (j), and (o), to discipline respondents' licenses, in respect to Mr. Miller's dispensing of prescriptions to Patient H (M.M.).

This conclusion is based on Factual Findings 30 and 31, 72 through 81, and 105, and on the Legal Conclusions.

13. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivisions (b), (c), (d), (j), and (o), to discipline respondents' licenses, in respect to Mr. Miller's dispensing of prescriptions to Patient I (D.W.).

This conclusion is based on Factual Findings 30 and 31, 82 and 83, and 105, and on the Legal Conclusions.

14. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivisions (c), (d), (j), and (o), to discipline respondents' licenses, in respect to Mr. Miller's dispensing of prescriptions to Patient J (J.L.).

This conclusion is based on Factual Findings 30 and 31, 84 and 85, and 105, and on the Legal Conclusions.

15. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivisions (c), (d), (j), and (o), to discipline respondents' licenses, in respect to Mr. Miller's dispensing of prescriptions to Patient K (J.K.).

This conclusion is based on Factual Findings 30 and 31, 86 and 87, and 105, and on the Legal Conclusions.

16. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivisions (c), (d), (j), and (o), to discipline respondents' licenses, in respect to Mr. Miller's dispensing of prescriptions to Patient L (R.K.).

This conclusion is based on Factual Findings 30 and 31, 88, and 105, and on the Legal Conclusions.

17. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivisions (c), (d), (j), and (o), to discipline respondents' licenses, in respect to Mr. Miller's dispensing of prescriptions to patients K.B., G.B., E.C., J.D., R.D.1., R.D.2., D.K., W.L., S.M., E.N., D.P., B.R., and D.S.

This conclusion is based on Factual Findings 30 and 31, 89 and 90, and 105, and on the Legal Conclusions.

18. California Code of Regulations, title 16, section 1707.2, provides in pertinent part that a pharmacist shall provide oral consultation to his patient or the patient's agent in all care settings, upon request, whenever the pharmacist deems it warranted in the exercise of his or her professional judgment, whenever the prescription drug has not previously been

dispensed to a patient; whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

That section further provides that when oral consultation is provided, it shall include at least the following: directions for use and storage and the importance of compliance with directions; and precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

19. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivisions (o), and California Code of Regulations, title 16, section 1707.2, to discipline respondents' licenses, in respect to Mr. Miller's failure to consult on new prescriptions.

This conclusion is based on Factual Findings 6 through 91, and 105, and on the Legal Conclusions.

20. California Code of Regulations, title 16, section 1707.3, provides in pertinent part that a pharmacist has a duty to review drug therapy and patient medication records prior to delivery of a prescription.

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

21. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1707.3, to discipline respondents' licenses, in respect to Mr. Miller's failure to conduct drug utilization reviews when filling prescriptions.

This conclusion is based on Factual Findings 6 through 91, and 105, and on the Legal Conclusions.

22. California Code of Regulations title 16, section 1793, defines a pharmacy technician:

"Pharmacy technician" means an individual who, under the direct supervision and control of a pharmacist, performs packaging, manipulative, repetitive, or other nondiscretionary tasks related to the processing of a prescription in a pharmacy, but who does not perform duties restricted to a pharmacist under section 1793.1.

Business and Professions Code section 4115(e) (1), provides:

No person shall act as a pharmacy technician without first being registered with the board as a pharmacy technician as set forth in Section 4202.

California Code of Regulations title 16, section 1793.1, sets forth the duties of a pharmacist:

Only a pharmacist, or an intern pharmacist acting under the supervision of a pharmacist, may:

- (a) Receive a new prescription order orally from a prescriber or other person authorized by law.
- (b) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a Patient medication record system or patient chart.
- (c) Identify, evaluate and interpret a prescription.
- (d) Interpret the clinical data in a patient medication record system or patient chart.
- (e) Consult with any prescriber, nurse or other health care professional or authorized agent thereof.
- (f) Supervise the packaging of drugs and check the packaging procedure and product upon completion.
- (g) Perform all functions which require professional judgment.

23. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1793.1, subdivision (e), to discipline respondents' licenses, in respect to Mr. Miller's authorizing his wife, Madeline Miller, an unlicensed person, to consult with prescribers regarding patients prescriptions from March 1997 to February 18, 1999.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

24. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1793.1, subdivision (g), to discipline respondents' licenses, in respect to Mr. Miller's abdicating his professional judgment and responsibilities to Mrs. Miller, an unlicensed person.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

25. California Health and Safety Code section 11153 provides 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.

26. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivisions (d) and (o), and California Code of Regulations, title 16, section 1793.1, subdivision (c), and Health and Safety Code section 11153, to discipline respondents' licenses, in respect to Mr. Miller's deferring to Mrs. Miller the judgment to dispense questionable prescriptions.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

27. The standard pharmacy practice prohibits a pharmacist from delegating specific duties to ancillary personnel. It was established by clear and convincing evidence that Mr. Miller's decision to delegate the prescription verification and medical physician communications to an unlicensed person, his wife, constituted gross negligence, an extreme departure from the standards of practice.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

28. The standard pharmacy practice requires the pharmacist to be the liaison between the patient and the healthcare provider to ensure open communication and understanding about prescribed drugs. It was established by clear and convincing evidence that Mr. Miller minimally communicated with Dr. Fisher, delegating most of these contacts to Mrs. Miller. This unlawful delegation of duty is gross negligence, an extreme departure from the pharmacy standards of practice.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

29. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 4301, subdivision (o), as it relates to Business and Professions Code section 4115, subdivision (e) (1), in conjunction with Business and Professions Code section 4202, to discipline respondents' licenses in that Mr. Miller authorized Mrs. Miller to work as a pharmacy technician without being licensed during the period of July 8, 1998 to February 18, 1999.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

30. It was established by clear and convincing evidence that cause exists to discipline respondents' licenses under Business and Professions Code section 4301, subdivisions (d), (j), 4076, 4077; Health and Safety Code sections 11153, 11164, and section 11173 subdivision (d), CFR 1306.05 and Business and Professions Code section 4301, subdivision (j) as it relates to Health and Safety Code section 11173, subdivision (d), in that Mr. Miller failed to correctly affix labels to controlled substances prescriptions for Patient H.

This conclusion is based on Factual Findings 29 through 31, and 72 through 81, and 94, and on the Legal Conclusions.

31. It was established by clear and convincing evidence that cause exists to discipline respondents' licenses under Business and Professions Code section 430, subdivision (j) as it relates to Health and Safety Code section 11164 in conjunction with California Code of Regulations section 1761, subdivision (a), and Code of Federal Regulations section 1306.05, in that Mr. Miller filled controlled substance prescriptions for Patient H. which had the wrong name and or address.

This conclusion is based on Factual Findings 29 through 31, and 72 through 81, and 94, and on the Legal Conclusions.

32. It was established by clear and convincing evidence that cause exists to discipline respondents' licenses under Business and Professions Code section 4301, subdivision (j), as it relates to Health and Safety Code section 11165, in conjunction with California Code of Regulations section 1715.5, by virtue of respondents' failure to transmit data on Schedule II prescriptions dispensed at Shasta as required under the Controlled Substance Utilization Review and Evaluation System.

This conclusion is based on Factual Finding 93 and on the Legal Conclusions.

33. It was established by clear and convincing evidence that cause exists to discipline respondents' licenses under Business and Professions Code section 4301, subdivision (j), as it relates to Health and Safety Code section 11159.2, in that respondents' dispensed controlled substance Schedule II prescriptions where three controlled substance Schedule II prescriptions were written on one prescription blank for Patient B. The prescription was not dated nor did it bear the certification by the prescriber "11159.2 exemption."

This conclusion is based on Factual Finding 47, and on the Legal Conclusions.

34. It was established by clear and convincing evidence that cause exists to discipline respondents' licenses under Business and Professions Code section 4301,

subdivision (o), as it relates to the California Code of Regulations section 1716, in that Respondent Miller dispensed 600 MS Contin 100 mg. (a Schedule II narcotic) instead of 100 Oramorph 100 mg. (a Schedule II narcotic) as indicated on the triplicate prescription.

This conclusion is based on Factual Finding 47, and on the Legal Conclusions.

35. It was established by clear and convincing evidence that cause exists to discipline respondents' licenses under Business and Professions Code section 4301, subdivision (o), as it relates to Business and Professions Code section 4342 in conjunction with the Sherman Food, Drug and Cosmetic Law section 111340, in that Mr. Miller and Shasta Pharmacy repackaged and pre-counted controlled substances and placed them in containers that were not properly labeled as to the quantity of tablets/capsules contained in the container.

This conclusion is based on Factual Findings 94 and 105, and on the Legal Conclusions.

36. It was established by clear and convincing evidence that cause exists to discipline respondents' licenses under Business and Professions Code section 4301, subdivision (o), as it relates to Business and Professions Code section 4342, in conjunction with California Code of Regulations section 1714, in conjunction with Sherman Food, Drug and Cosmetic Law section 111255, in that respondents had hazardous conditions in the pharmacy.

This conclusion is based on Factual Findings 95 and 105, and on the Legal Conclusions.

37. It was established by clear and convincing evidence that cause exists to discipline respondents' licenses in that respondents violated Business and Professions Code section 4301, subdivision (o), as it relates to Health and Safety Code section 11153. On a frequent basis, Respondents filled prescriptions prior to the time period established by the doctor's prescriptions for patients who appeared at the pharmacy in an impaired condition. Respondents repeatedly dispensed prescriptions to patients K.B. and L.B. who appeared impaired when they were in the pharmacy to pick up the drugs or calling to ask for refills.

This conclusion is based on Factual Findings 92 and 105, and on the Legal Conclusions.

Gross Negligence

38. It was established by clear and convincing evidence that Mr. Miller's practices in dispensing controlled substances fell below the standard of practice. Mr. Miller's pharmacy practices were grossly negligent and an extreme departure from the pharmacy standards of practice in the following respects;

A. Mr. Miller failed to understand and learn about the effective use of controlled substances in the practice of pain management. It was his duty in taking on this specialty to become educated within this field of pain management. He lacked education in the pain management field.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

B. Mr. Miller failed to verify the legitimacy of Dr. Fisher's narcotic prescriptions.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

C. Mr. Miller failed to communicate directly with prescribing physician, Dr. Fisher. Mr. Miller's instead unlawfully delegated of this duty to an unlicensed person.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

D. Mr. Miller failed to recognize early refills of controlled substances. It is the pharmacy standard of practice to deny refills for controlled substances based upon the previous prescription and daily usage indicated by the physician. Mr. Miller filled many prescriptions prior to the expected refill dates.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

E. Mr. Miller failed to obtain, retain, and update appropriate information documenting the course of, and need for, on-going opiate therapy. It is the pharmacy standard of practice for the pharmacist to dispense medications when, to do so, is in the patient's best interests. Generally such an event involves communication with either the patient or prescribing physician, or both. Mr. Miller had no documentation whatsoever to explain the ongoing opiate therapy of his patients. Mr. Miller simply filled and dispensed controlled substances at Shasta Pharmacy, without evaluation.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

F. Mr. Miller failed to observe and recognize patients, impaired mental conditions. It is the normal pharmacy standard of practice for a pharmacist to observe his patients prior to filling any controlled substance, specifically narcotic controlled substances. Mr. Miller on different occasions dispensed a controlled substance to patients who appeared intoxicated or under the influence of drugs.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

G. Mr. Miller failed to retain scheduled narcotics in their original stock bottle form.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

H. Mr. Miller failed to properly label prescription bottles containing controlled substances. The standard pharmacy practice requires the pharmacist to properly label containers that contain controlled substances. The containers found in the bathroom area were not properly labeled.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

I. Mr. Miller delegated non-delegable duties to ancillary personnel.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

J. Mr. Miller failed to properly conduct Drug Utilization Reviews for prescriptions filled at Shasta Pharmacy.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

K. Mr. Miller failed to consult on new prescriptions and when a consultation would be justified.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

L. Mr. Miller dispensed large quantities of controlled substances, with the result that patients were ingesting potentially toxic amounts of acetaminophen.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

Incompetence

39. It was established by clear and convincing evidence that Mr. Miller's failure to perform the duties of a pharmacist as outlined in Legal Conclusions paragraph 38, sections A, B, C, E, G, I, J and L, constituted incompetence.

This conclusion is based on Factual Findings 6 through 92, and 105, and on the Legal Conclusions.

Costs

40. Business and Professions Code section 125.3 provides in pertinent part:

(a) Except as otherwise provided by law, in any order issued in resolution of a disciplinary proceeding before the department...the board may request the administrative law judge to direct a licentiate found to have committed a violation...of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case...

(d) The administrative law judge shall make a proposed finding of the amount of reasonable costs of investigation and prosecution of the case when requested pursuant to subdivision (a)..."

41. It was established by clear and convincing evidence that cause exists under Business and Professions Code section 125.3, to direct respondents to pay costs of \$51,411.75.

This conclusion is based on Factual Findings 6 through 107, and on the Legal Conclusions.

ORDER

1. Pharmacist Certificate Number RPH 28932, issued to Stephen George Miller is REVOKED.
2. Pharmacy Permit Number PHY 39684, issued to Shasta Pharmacy is REVOKED.
3. Stephen George Miller and Shasta Pharmacy are ordered to pay the Board of Pharmacy \$51,411.75.

Dated: December 30, 2004



ANN ELIZABETH SARLI
Administrative Law Judge
Office of Administrative Hearings

BEFORE THE
BOARD OF PHARMACY
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

STEPHEN GEORGE MILLER
2645 Howard Drive
Redding, California 96001

Certificate No. RPH 28932

SHASTA PHARMACY
4460 Westside Road
Redding, California 96001

Permit No. PHY 39684

Respondents.

Case No. 2216

OAH No. N2000060411

DECISION

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy as its Decision in the above-entitled matter.

This Decision shall become effective on February 27, 2005.

IT IS SO ORDERED January 28, 2005.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By


STANLEY W. GOLDENBERG
Board President

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8

9

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

10

11

In the Matter of the Accusation Against:

) Case No. 2 2 1 6

12

) STEPHEN GEORGE MILLER
) 2645 Howard Drive
) Redding, California 96001

) ACCUSATION

13

) Certificate No. RPH 28932

14

) SHASTA PHARMACY
) 4460 Westside Road
) Redding, California 96001

15

) Permit No. PHY 39684

16

) Respondents.

17

18

PARTIES

19

Patricia F. Harris, for causes of discipline, alleges:

20

21 Complainant, Patricia F. Harris makes and files this Accusation in her official
22 capacity as Executive Officer, Board of Pharmacy, Department of Consumer Affairs
23 (hereinafter "Board").

24

25 On July 17, 1974, the Board of Pharmacy issued Pharmacist Certificate Number
26 RPH 28932 to Stephen George Miller (hereinafter "Respondent"). The certificate was in full
27 force and effect at all times pertinent herein and has been renewed through May 31, 2001.

28

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1 this chapter or of the applicable federal and state laws and regulating
2 governing pharmacy, including regulations established by the board.

3 5. Business and Professions Code section 4059(a), provides that no person
4 shall furnish any dangerous drug, except upon the prescription of a physician, dentist,
5 podiatrist, or veterinarian. No person shall furnish any dangerous device, except upon the
6 prescription of a physician, dentist, podiatrist, or veterinarian.

7 **DRUG CLASSIFICATIONS**

8 1. Oxycodone (Roxicodone, Oxycontin, Oxycodone/APAP, Endocet,
9 Percodan, Percocet) is Schedule II narcotic controlled substances as defined in Health and
10 Safety Code section 11055(b)(1)(N) and is categorized as a dangerous drug per Business and
11 Professions Code section 4022. The drugs are for moderate to moderate severe pain.

12 2. Codeine is a Schedule II narcotic controlled substance as defined in
13 Health and Safety Code section 11055(b)(1)(H) and is categorized as a dangerous drug per
14 Business and Professions Code section 4022. The drug is indicated for mild to moderate pain.

15 3. Morphine (MS Contin, Oramorph, morphine soluble tablets) is a
16 Schedule II narcotic controlled substance as defined in Health and Safety Code section
17 11055(b)(1)(M) and is categorized as a dangerous drug per Business and Professions Code
18 section 4022. The drug is indicated for moderate to moderate severe pain and severe pain.

19 4. Hydromorphone (Dilaudid) is a Schedule II narcotic controlled substance
20 as defined in Health and Safety Code section 11055(b)(1)(K) and is categorized as a dangerous
21 drug per Business and Professions Code section 4022. The drug is indicated for severe pain.

22 5. Meperidine (Demerol) is a Schedule II narcotic controlled substance as
23 defined in Health and Safety Code section 11055(c)(17) and is categorized as a dangerous drug
24 per Business and Professions Code section 4022. The drug is indicated for moderate to severe
25 pain.

26 6. Codeine/Acetaminophen (Tylenol # 3, Tylenol # 4, APAP #3, APAP #4)
27 is a Schedule III narcotic controlled substance as defined in Health and Safety Code section

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1 11056(e)(2) and is categorized as a dangerous drug per Business and Professions Code section
2 4022. The drug is indicated for pain.

3 7. Hydrocodone /Acetaminophen (Vicodin, Vicodin ES, Vicodin HP,
4 Norco, Lortab 7.5, Lortab 10) is a Schedule III narcotic controlled substance as defined in
5 Health and Safety Code section 11056(e)(4) and is categorized as a dangerous drug per
6 Business and Professions Code section 4022. The drug is indicated for pain.

7 8. Hydrocodone /Aspirin (Damason-P) is a Schedule III narcotic controlled
8 substance as defined in Health and Safety Code section 11056(e)(4) and is categorized as a
9 dangerous drug per Business and Professions Code section 4022. The drug is indicated for
10 pain.

11 9. Ethchlorvynol (Placidyl) is a Schedule IV depressant controlled
12 substance as defined in Health and Safety Code section 11057(d)(9) and is categorized as a
13 dangerous drug per Business and Professions Code section 4022. This drug is indicated for
14 sleep.

15 10. Fluazepam (Dalmane) is a Schedule IV depressant controlled substance
16 as defined in Health and Safety Code section 11057(d)(12) and is categorized as a dangerous
17 drug per Business and Professions Code section 4022. The drug is indicated for sleep.

18 11. Diazepam (Valium) is a Schedule IV depressant controlled substance as
19 defined in Health and Safety Code section 11057(d)(8) and is categorized as a dangerous drug
20 per Business and Professions Code section 4022. This drug is a benzodiazepine used in the
21 treatment of anxiety disorders and muscle relaxation.

22 12. Alprazolam (Xanax) is a Schedule IV depressant controlled substance as
23 defined in Health and Safety Code section 11057(d)(1) and is categorized as a dangerous drug
24 per Business and Professions Code section 4022. This drug is a benzodiazepine used in the
25 treatment of anxiety disorders and muscle relaxation.

26 13. Phenergan with Codeine is a Schedule V Antitussive controlled
27 substance as defined by Health and Safety Code section 11058(c)(1) and is categorized as a

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1 dangerous drug per Business and Professions Code section 4022. The drug is indicated for
2 cough.

3 14. Carisoprodol (Soma) 350 mg is categorized as a dangerous drug per
4 Business and Professions Code section 4022. The drug is a skeletal muscle relaxant used in the
5 treatment of painful musculoskeletal conditions.

6 I.

7 **EXCESSIVE DISPENSING**

8 Respondent Miller violated Business and Professions Code section 4301(d) as it
9 relates to Health and Safety Code section 11153 in conjunction with Title 21 Code of Federal
10 Regulations section 1306.04 in that Respondent Miller filled prescriptions for controlled
11 substances that were for excessive quantities and not for legitimate medical purposes for
12 patients A through L.

13 A Board audit revealed that from July 8, 1998, to February 18, 1999,
14 Respondent Miller and Shasta Pharmacy dispensed 619,858 dosage units of Schedule II
15 Controlled Substances. During the period November through December of 1998, Respondent
16 Miller and Shasta Pharmacy engaged in a pattern of dispensing escalating quantities of
17 controlled substances prescriptions. Respondent Miller and Shasta Pharmacy increasingly
18 dispensed prescriptions from Dr. Fisher. The prescriptions were excessive. Approximately 77
19 % of the Controlled Substance, Schedule II prescriptions were from Dr. Fisher.

20 Prescriptions written by Dr. Fisher were excessive and regularly above
21 recommended levels, however, Respondent Miller routinely dispensed the drugs. Examples are
22 Respondent's dispensing of Dilaudid 4 mg, 2 to 4 tablets every 4 hours, and Oxycontin SA 80
23 mg, 10-15 tablets twice daily. According to Facts and Comparisons, the recommended dosage
24 of Dilaudid is 4 mg every 4 to 6 hours for severe pain and the recommended starting dosage of
25 Oxycontin is 10 mg twice a day. Dosage quantities were often in the range of 360 to 900
26 tablets per prescription. Respondent Miller engaged in unprofessional conduct when he
27 continuously filled these excessive prescriptions without conducting a reasonable inquiry as to
28 the reasonableness of the prescriptions as required by law.

1 The DEA records for Shasta Pharmacy prove that Shasta was one of the largest
2 purchasers of controlled substances in the United States. These records also indicated that
3 Shasta Pharmacy was the largest purchaser of Oxycodone products in California. DEA
4 personnel provided a copy of Shasta's purchases recorded by the DEA for 1998 to demonstrate
5 the amount of purchases. These purchases were excessive when considering that the population
6 of the Redding and Anderson area was approximately 70,000.

7 Respondent Miller knew that numerous prescriptions were not for legitimate
8 medical purposes, a violation of Business and Professions Code section 4301(b)(d), Health and
9 Safety Code section 11153 and Code of Federal Regulations 1306.04.

10 Respondent Miller engaged in excessive dispensing, early repeated medications
11 and/or clearly excessive quantities and/or questionable combinations of drugs as follows:

12 **UNPROFESSIONAL CONDUCT BY PATIENT**

13 **Patient A. (A.T.)**

14 Patient A progressed from Hydrocodone 10/650 and Carisoprodol 350 mg to
15 Oxycontin 80 mg. Oxycontin 80 mg went from a quantity of 360 tables on April 10, 1998, to
16 900 tables on December 15, 1998. The excessive dispensing occurred in 1998. Medi-Cal
17 T.A.R. records indicated a diagnosis of lower back pain.

18 Patient A received two sets of prescriptions monthly, with each set dispensed
19 approximately fifteen days apart. Set one consisted of Hydrocodone 10/650 # 90 and
20 Carisoprodol 350 mg # 100, and the second consisting of Hydrocodone 10/650 # 90,
21 Carisoprodol 350 mg # 100 and Oxycontin 80 mg # 360. This pattern remained consistent until
22 July 6, 1998, when the patient received an early refill for the Hydrocodone 10/650.

23 It was during July, 1998, that Patient A also received MS Contin, and then
24 twelve days later Meperidine. The purpose behind the addition of these two narcotics is
25 unknown. The record is silent. During this period two new narcotics were added to the
26 patient's drug regimen and the patient continued to take Oxycontin as prescribed. Oxycontin
27 80 mg is recommended for opiate tolerant patients, with the normal dose being 10 mg - 30 mg

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1 every four hours and the dosing individualized. Quantities of Oxycontin 80 mg were increased
2 from 360 to 900 tablets. The approximate days supply remained consistent.

3 A review of the patient's drug history and calculating the patient's approximate
4 days supply based on his previous usage there are definite situations where the patient exceeded
5 his customary usage. The following is a listing of those drugs and dates of service:

<u>Soma</u>	<u>Hydrocodone</u>	<u>Meperidine</u>	<u>MS Contin</u>
11/13/98	11/25/98	8/12/98	7/30/98
12/03/98	12/03/98		
12/15/98	01/04/99		
12/22/98	01/08/99		
1/8/99			
02/16/99	02/16/99		

13 There was no documentation as to the reasons for filling the prescriptions
14 outlined herein:

15 Based on the totality of the circumstances surrounding the dispensing of the
16 controlled substances for Patient A, Respondent Miller violated Business and Professions Code
17 section 4301, as follows:

- 18 (b) Incompetence;
- 19 (c) Gross negligence;
- 20 (d) Clearly excessive furnishing of controlled substances in violation of
21 subdivision (a) of Health and Safety Code section 11153;
- 22 (j) The violation of any of the statutes of this state or of the United States
23 regulating controlled substances and dangerous drugs; and,
- 24 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
25 abetting the violation of or conspiring to violate any provision or term of
26 this chapter or of the applicable federal and state laws and regulations
27 governing pharmacy, including regulations established by the board.

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Patient B. (L.A.)

Patient B received 22,820 dosage units of Schedule II Controlled Substances during the period of July 8, 1998, until February 18, 1999. Patient B received soluble morphine tablets increasing the potential strength of the drug. In January of 1999, Patient B's prescriptions for Schedule II Controlled Substances were written with the Health and Safety Code section 11159.2 exemption. The format for those prescriptions violated Health and Safety Code section 11159.2. The December 24, 1998, prescription for MS Contin 100 mg was written for 100 tablets or Oramorph 100 mg and by pharmacy records dispensed as 600 MS Contin 100 mg, a violation of California Code of Regulation 1716. Prescription documents revealed Patient B had HIV and Medi-Cal records indicated heroin detoxification in 1992 and 1993.

Patient B experienced progressive narcotic usage. Initially this patient was using Dilaudid 4 mg approximately 20 tablets per day and Morphine IR 30 mg at approximately 30 tablets per day. No documentation outlined the need for this usage.

Over the next 5 - 6 months, these daily amounts increased to approximately 60 - 70 tables per day for Dilaudid and over 40 and up to 70 tablets per day for Morphine IR. On one occasion, September 14, 1998, Morphine was being used in excess of 100 per day.

Such a progression without any changes and or additions to Patient B's drug regimen constitutes unprofessional conduct. At some point in time Respondent Miller had to either refuse to fill subsequent prescriptions or document his concerns regarding the progression.

Respondent Miller violation California Code of Regulations, Title 16, section 1716, where MS Contin 100 mg, 600 tablets were dispensed instead of Oramorph 100 mg, 100 tablets. Respondent Miller also violated the law by dispensing controlled substances under the Health and Safety Code section 11159.2 exemption on improperly written prescriptions.

There was no documentation as to the reasons for filling the prescriptions outlined herein:

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1 directions to Patient C as to the proper use of short-acting opioid medication for "break-
2 through" pain in combination with long-acting opioid medication as set forth herein constitutes
3 excessive dispensing of clearly excessive quantities and/or questionable combinations of drugs
4 in violation of Business and Professions Code section 4301(b), (d), Health and Safety Code
5 section 11153 and Code of Federal Regulation section 1306.04.

6 Respondent Miller dispensed large quantities and early refills of medications
7 between the period of August and December, 1998 for Patient C. This patient received
8 different strengths and formulations of morphine at the same time as well as large quantities of
9 Carisoprodol 350 mg. (a muscle relaxant). Prescription document No. 165907 provided that the
10 patient had muscle spasms and rheumatoid arthritis. Patient C received 18,270 doses of
11 Schedule II Controlled Substance from July 8, 1998, until December 31, 1998.

12 Patient C was receiving three different narcotic analgesics, each a morphine
13 derivative. Records show that daily usage on the average increased from approximately 18 - 25
14 tablets per day up to approximately 44 - 50 tablets per day. Such a dramatic increase over only
15 a five month period without physician contact and documentation, violates Section 4301 as
16 listed herein. No other analgesic alternatives were ever attempted.

17 On at least seven different occasions, Patient C received early refills, reflecting
18 excessive use, as follows:

<u>Morphine 30 mg</u>	<u>MS Contin 100 mg</u>	<u>Oramorph 60 mg</u>
08/26/98	11/03/98	11/03/98
10/21/98	12/02/98	12/17/98
12/17/98		

23 Each of the above dates and drugs reflect excessive dispensing to Patient C.
24 This excessive furnishing of controlled substances by Respondent Miller was in violation of
25 Business and Professions Code section 4301, as outlined herein.

26 There was no documentation as to the reasons for the fillings of these
27 prescriptions. Based on the totality of the circumstances surrounding the filling of these

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1 prescriptions, Respondent Miller violated Business and Professions Code sections 4301, in
2 dispensing medications for Patient C as outlined herein, as follows:

- 3 (b) Incompetence;
- 4 (c) Gross negligence;
- 5 (d) Clearly excessive furnishing of controlled substances in violation of
6 subdivision (a) of Health and Safety Code section 11153;
- 7 (j) The violation of any of the statutes of this state or of the United States
8 regulating controlled substances and dangerous drugs; and,
- 9 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
10 abetting the violation of or conspiring to violate any provision or term of
11 this chapter or of the applicable federal and state laws and regulations
12 governing pharmacy, including regulations established by the board.

13 **Patient D. (G.D.)**

14 Patient D's medication history reflect both increases and decreases in daily
15 usage for the two major narcotic analgesics utilized, MS Contin 100 mg and Oxycontin 80 mg.
16 For example, MS Contin was being utilized at approximately 13 tablets per day on or about
17 July 8, 1998, increased to 30 tablets per day twenty days later and then leveled off at 30 - 40
18 tablets per day before the end of the year. Oxycontin also increased in a similar behavior but
19 near the end of the year tapered down. Early refills occurred on the following dates:

20 <u>MS Contin 100 mg</u>	20 <u>Oxycontin 80 mg</u>
21 08/25/98	21 09/04/98
22 12/17/98	22 11/11/98

23 Without any corresponding documentation by Respondent Miller to explain such
24 early refills, such dispensing conduct is excessive furnishing of controlled substances in
25 violation of Business and Professions Code section 4301.

26 There was no documentation as to the reasons for filling the prescriptions
27 outlined herein:

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1 Norco 10/325 and Hydrocodone 10/500 both contain acetaminophen in 325 mg
2 and 500 mg strengths respectively. Chronic consumption of acetaminophen in excess of 4
3 grams per day puts the patient at a high risk for developing liver toxicity.

4 Respondent Miller's dispensing pattern of duplicate and inconsistent drugs,
5 violates Business and Professions Code section 4301, as outlined herein. It is an extreme
6 departure from pharmacy standards to dispense the contradictory drugs as well as drugs so
7 similar in effect and in the quantities dispensed. This dispensing pattern is clearly excessive
8 furnishing of controlled substances in violation of Business and Professions Code section 4301.

9 There was no documentation as to the reasons for filling the prescriptions
10 outlined herein:

11 Based on the totality of the circumstances surrounding the dispensing of the
12 controlled substances for Patient H, Respondent Miller violated Business and Professions Code
13 section 4301, as follows:

- 14 (b) Incompetence;
- 15 (c) Gross negligence;
- 16 (d) Clearly excessive furnishing of controlled substances in violation of
17 subdivision (a) of Health and Safety Code section 11153;
- 18 (j) The violation of any of the statutes of this state or of the United States
19 regulating controlled substances and dangerous drugs; and,
- 20 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
21 abetting the violation of or conspiring to violate any provision or term of
22 this chapter or of the applicable federal and state laws and regulations
23 governing pharmacy, including regulations established by the board.

24 **Patient I. (D.W.)**

25 Respondent dispensed quantities of Schedules II and III Controlled Substances
26 to Patient I. During the Board audit from July 8, 1998, to February 18, 1999, this patient
27 received 22,470 doses of narcotic pain relievers. During the same time the patient received

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1 2,610 Norco 10/325 mg Schedule III. Prescription document No. 170068 indicated Patient I
2 had chronic neck pain.

3 Patient I received primarily four different narcotic analgesics: Morphine 30 mg,
4 Norco 10/325, Oramorph 60, and Oxycontin 80 mg. With each drug, except for Norco 10/325,
5 the patient increased her daily usage. During this period, Patient I continued to take Norco
6 10/325 in dosages of approximately 23 tablets per day, with refills on the average every 3 - 5
7 days.

8 Norco 10/325 contains 325 mg of acetaminophen per tablet. Chronic
9 consumption of acetaminophen in excess of 4 grams per day puts the patient at a high risk for
10 developing liver toxicity.

11 At no time were attempts made to decrease the patient's daily usage of narcotic
12 analgesics or acetaminophen. At no time were alternative therapies attempted such as the
13 addition of dermal patches for long acting narcotic therapy. Instead, Respondent Miller
14 continued to dispense the quantities that Dr. Fisher prescribed with no clear documentation and
15 without consultations.

16 There was no documentation as to the reasons for filling the prescriptions
17 outlined herein:

18 Based on the totality of the circumstances surrounding the dispensing of the
19 controlled substances for Patient I, Respondent Miller violated Business and Professions Code
20 section 4301, as follows:

- 21 (b) Incompetence;
- 22 (c) Gross negligence;
- 23 (d) Clearly excessive furnishing of controlled substances in violation of
24 subdivision (a) of Health and Safety Code section 11153;
- 25 (j) The violation of any of the statutes of this state or of the United States
26 regulating controlled substances and dangerous drugs; and,
- 27 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
28 abetting the violation of or conspiring to violate any provision or term of

1 this chapter or of the applicable federal and state laws and regulations
2 governing pharmacy, including regulations established by the board.

3 **Patient J. (J.L.)**

4 On August 24, 1998, a prescription for 300 morphine 30 mg tablets was
5 dispensed. Respondent Miller expressed concern that the patient was at a maximum dose by
6 documenting a discussion on the prescription. The 300 tablets lasted the patient 30 days. This
7 corresponded to an actual usage of 10 tablets per day based upon the subsequent fill on
8 September 22, 1998. The prescriptions filled on October 12, 1998, reflects a 15 tablet per day
9 dosage schedule over a 24-day period. Respondent Miller failed to document the basis for the
10 continuing of the short acting narcotic when it was evident that Patient J was increasing his
11 daily dosage and Respondent Miller's previous consultation indicated that Patient J was at the
12 maximum dose with respect to Morphine 30 mg IR. Subsequent prescriptions for Morphine 30
13 mg on dates 11/3/98, 11/25/98, 12/22/98, 1/15/99 and 2/15/99, correspond to an increase in
14 daily doses of 37, 68, 69 and 83 tablets respectfully. Prescription document No. 177772
15 indicated Patient J had chronic hip pain.

16 There was no documentation as to the reasons for filling the prescriptions
17 outlined herein:

18 Based on the totality of the circumstances surrounding the dispensing of the
19 controlled substances for Patient J, Respondent Miller violated Business and Professions Code
20 section 4301, as follows:

- 21 (c) Gross negligence;
- 22 (d) Clearly excessive furnishing of controlled substances in violation of
23 subdivision (a) of Health and Safety Code section 11153;
- 24 (j) The violation of any of the statutes of this state or of the United States
25 regulating controlled substances and dangerous drugs; and,
- 26 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
27 abetting the violation of or conspiring to violate any provision or term of

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1 this chapter or of the applicable federal and state laws and regulations
2 governing pharmacy, including regulations established by the board.

3 **Patient K. (J.K.)**

4 On September 28, 1998, Respondent Miller dispensed 600 Roxicodone 5 mg
5 with an actual 20 tablets per day dosage schedule. Subsequent prescriptions for the same
6 medication showed an increase in quantities and in daily usage to 32 and 53 tablets per day.
7 Respondent Miller's dispensing pattern regarding Patient K constitutes excessive dispensing of
8 the narcotic Roxicodone.

9 There was no documentation as to the reasons for filling the prescriptions
10 outlined herein:

11 Based on the totality of the circumstances surrounding the dispensing of the
12 controlled substances for Patient K, Respondent Miller violated Business and Professions Code
13 section 4301, as follows:

- 14 (c) Gross negligence;
- 15 (d) Clearly excessive furnishing of controlled substances in violation of
16 subdivision (a) of Health and Safety Code section 11153;
- 17 (j) The violation of any of the statutes of this state or of the United States
18 regulating controlled substances and dangerous drugs; and,
- 19 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
20 abetting the violation of or conspiring to violate any provision or term of
21 this chapter or of the applicable federal and state laws and regulations
22 governing pharmacy, including regulations established by the board.

23 **Patient L. (R.K.)**

24 Patient L has the same last name and resident address as Patient K. Patient
25 consultation and documentation were extremely important in this situation, because both
26 patients were receiving identical narcotic drugs, except for the fact that Patient K received
27 Dilaudid and Morphine. Patient L increased from 14 tablets per day of Oxycontin 80 mg to 22
28 tablets per day upon the following fill date of September 10, 1998 and a subsequent increase up

1 to 33 tablets per day. This increase without any documentation reflecting a valid reason is
2 evidence of excessive furnishing of controlled substances.

3 There was no documentation as to the reasons for filling the prescriptions
4 outlined herein:

5 Based on the totality of the circumstances surrounding the dispensing of the
6 controlled substances for Patient L, Respondent Miller violated Business and Professions Code
7 section 4301, as follows:

- 8 (c) Gross negligence;
- 9 (d) Clearly excessive furnishing of controlled substances in violation of
10 subdivision (a) of Health and Safety Code section 11153;
- 11 (j) The violation of any of the statutes of this state or of the United States
12 regulating controlled substances and dangerous drugs; and,
- 13 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
14 abetting the violation of or conspiring to violate any provision or term of
15 this chapter or of the applicable federal and state laws and regulations
16 governing pharmacy, including regulations established by the board.

17 The patients listed above are examples of excessive dispensing and early refills.
18 Drug Utilization Reviews were not documented or performed. Only one example of
19 consultation documentation existed. This constituted unprofessional conduct per Business and
20 Professions Code section 4301(b)(c)(d), California Code of Regulations 1707.2 and 1707.3 and
21 Health and Safety Code section 11153.

22 Respondent Miller dispensed excessive prescriptions for Carisoprodol and
23 controlled substances in January 1999 as outlined in Table 1.

24 **TABLE 1**

25 **Patients from Shasta Pharmacy Log of Prescriptions for Dr. Fisher's Payment**
26 **Quantity of Tablets Dispensed in January of 1999**

27

PATIENT	Carisoprodol	Hydrocodone /APAP 10	Hydrocodone /APAP 7.5	Tylenol #3	Diagnosis
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1	K.B.	1008	1008			CIP LBP
2	G.B.	540		600	360	CIP H/A
3	L.B.	300	225			CIP LBP
4	E.C.	400	800			CIP LBP
5	J.D.	300		375		LBP
6	R.D.1	100		480		CIP LBP
7	R.D.2	400		720		CIBP
8	D.K.	400		360		CIP Hip
9	W.L.	400	810			CIP LBP
10	S.M.	300		270		CIP LBP
11	E.N.	270		270		Neck Pain
12	D.P.	600		360		CIP Neck
13	B.R.	800		480		CIP Neck
14	D.S.	400		360		CIP MH/A

14 Patients that received CII Controlled Substances in January are K.B., L.B., and R.D.1

15 CIP = Chronic Intractable Pain
 16 LBP = Low Back Pain
 17 H/A = Headache
 18 MH/A = Migraine Headache

19 All patients except L.B. received over 4 grams of acetaminophen daily
 Hydrocodone APAP 10 has 500 mg of acetaminophen per tablet
 Hydrocodone APAP 7.5 has 750 mg of acetaminophen per tablet

20 **II.**

21 **PHARMACY PRACTICE PERFORMED IN AN UNPROFESSIONAL MANNER**

22 Respondent Miller violated Business and Professions Code section 4301(o) as it
 23 relates to California Code of Regulations section 1707.2 and in conjunction with California
 24 Code of Regulations section 1707.3, in that Respondent Miller failed to consult on new
 25 prescriptions as required and failed to review patient's drug therapy and medication record as
 26 required from January of 1997 until February 18, 1999.

27 During the period of July 8, 1998, through February 18, 1999, Respondent
 28 Miller filled approximately 15,800 new prescriptions. However, Respondent Miller only

1 consulted with approximately twenty patients. During 1998, Respondent Miller only consulted
2 with new patients ten times or less.

3 The Shasta Pharmacy records included a computer printout of prescriptions
4 dispensed each day. The printout gave the total number for prescriptions that were new and
5 refills each day. Samples of totals for February of 1999, are as follows:

6 **TABLE 2**

7

Date	Total Rx	New Rx
2/1/1999	252	104
2/2/1999	186	94
2/3/1999	186	75
2/4/1999	170	78
2/5/1999	135	61
2/8/1999	216	87
2/9/1999	240	99
2/15/1999	319	136
2/16/1999	286	139
2/17/1999	187	103

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18 **III.**

19 **UNLICENSED CONSULTATIONS WITH PRESCRIBERS**

20 Respondent Miller violated Business and Professions Code section 4301(o) as it
21 relates to California Code of Regulations section 1793.1(e) by authorizing his wife, Madeline
22 Miller, an unlicensed person, to consult with prescribers, nurses, and their agents regarding
23 patients prescriptions from March 1997 to February 18, 1999.

24 During this period, Respondent Miller did not consult with patients who
25 received new prescriptions. Respondent Miller allowed an unlicensed employee, Madeline
26 Miller, to consult with patients, prescribers and their staff. Respondent Miller engaged in
27 unprofessional conduct when he authorized unlicensed employees to perform duties required of
28 a pharmacist.

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IV.

ABDICATED DUTIES TO UNLICENSED INDIVIDUAL

Respondent Miller violated Business and Professions Code section 4301(o) as it relates to California Code of Regulations section 1793(i) in that Respondent Miller abdicated his professional judgment and responsibilities to Madeline Miller, an unlicensed person.

During the period March, 1997 to February 18, 1999, Respondent Miller authorized Madeline Miller to determine the pharmacy dispensing policies and to directly communicate with Dr. Fisher about patient drug regimens. During this period, Respondent Miller authorized Madeline Miller to contact physician prescribers to verify prescriptions. This function should have been performed by Respondent Miller, the licensed pharmacist in charge of Shasta Pharmacy. Madeline Miller routinely contacted Dr. Fisher who sent patients to Shasta Pharmacy on a regular basis. Initially, Respondent Miller called Dr. Fisher about prescriptions and to determine if they were correct and to confirm patient information. Respondent Miller subsequently unlawfully delegated this function to his wife, Madeline Miller. Ms. Miller performed these tasks for approximately two years. Ms. Miller communicated with the Dr. Fisher and other prescribers and decided to dispense prescriptions. Respondent Miller, the pharmacist, should have performed these duties. Respondent Miller deferred to his wife the judgment to dispense questionable prescriptions in violation of Business and Professions Code section 4301(d), California Code of Regulation section 1793.1(c)(i) and Health and Safety Code section 11153. Respondent Miller failed to exercise his professional judgment to refuse to dispense questionable prescriptions. Instead he delegated this non-delegatable function to his employee-wife.

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V.

FAILURE TO TRANSMIT REQUIRED DATA

During the period September 18, 1998, to February 18, 1999, Respondent Miller violated Business and Professions Code section 4301(j), as it relates to Health and Safety Code section 11165 and in conjunction with California Code of Regulations section 1715.5, when he

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1 prescription blank for Patient B. The prescription was not dated nor did it bear the certification
2 by the prescriber "11159.2 exemption."

3 **VIII.**

4 **FAILURE TO CORRECTLY AFFIX LABELS**

5 Respondent Miller violated Business and Professions Code section 4301(j) as it
6 relates to Health and Safety Code section 11173(d), in that Respondent affixed labels to
7 controlled substance prescription containers for his wife, Patient H, using the names of
8 Madeline Spencer and Madeline Ciulla on the labels as found in the sealed box hidden in the
9 pharmacy bathroom. The taped shut, square box was found on a very high top shelf hidden in
10 the back bathroom area.

11 **IX.**

12 **FAILED TO CORRECTLY LABEL PRESCRIPTIONS**

13 Respondent Miller violated Business and Professions Code section 4301(j) as it
14 relates to Health and Safety Code section 11164 in conjunction with California Code of
15 Regulations section 1761(a) and Code of Federal Regulations section 1306.05, in that
16 Respondent Miller filled controlled substance prescriptions for Madeline Miller that had the
17 wrong name and/or address.

18 **X.**

19 **INCORRECT DISPENSING OF PRESCRIPTION**

20 Respondent Miller violated Business and Professions Code section 4301(o) as it
21 relates to the California Code of Regulations section 1716, in that Respondent Miller dispensed 600
22 MS Contin 100 mg (a Schedule II narcotic) instead of 100 Oramorph 100 mg (a Schedule II
23 narcotic) as indicated on the triplicate prescription.

24 **XI.**

25 **INACCURATE LABELING OF PRESCRIPTION**

26 Respondent Miller violated Business and Professions Code section 4301(o) as it
27 relates to Business and Professions Code section 4342 in conjunction with the Sherman Food,
28 Drug and Cosmetic Law section 111340, in that Respondent Miller and Shasta Pharmacy

1 repackaged and/or pre-counted controlled substances and placed them in containers that were
2 not properly labeled as to the quantity of tablets/capsules contained in the container, as
3 witnessed by Board of Pharmacy inspectors on February 18, 1999. Some of the audited drugs,
4 such as generic Dilaudid 4 mg had been repackaged in 100 count manufacturer's bottles to
5 contain 200, 300, 400 or 500 tablets in violation of Health and Safety Code section 111340 and
6 Business and Professions Code section 4342(a). Original containers for many controlled
7 substance Schedule II drugs were missing. The audit revealed numerous pre-counted generic
8 Vicodin ES bottles containing 60, 90 and 120 tablets. These containers were not labeled with
9 any information, a violation of Business and Professions Code section 4342(a). Respondent
10 Miller represented that he had not sold any drugs to other pharmacies or doctors offices and
11 was not aware of drugs lost to theft.

12 XII.

13 HAZARDOUS USE OF PHARMACY

14 Respondent Miller violated Business and Professions Code section 4301(o) as it
15 relates to Business and Professions Code section 4342 in conjunction with California Code of
16 Regulations section 1714, in conjunction with Sherman Food, Drug and Cosmetic Law section
17 111255, in that Respondent Miller and Shasta Pharmacy permitted rotten and moldy food to be
18 stored in a refrigerator interspersed with dangerous drugs and other pharmaceutical inventory.
19 Some dangerous drugs were stored in the bathroom. There were expired drugs on the
20 pharmacy shelves. Respondent Miller failed to insure that the pharmacy was free of rodents.
21 Rodent droppings were found in the pharmacy during the February 18, 1999 inspection. The
22 pharmacy was located in the corner of an empty warehouse which previously was a market.

23 XIII.

24 UNLICENSED PHARMACY TECHNICIANS

25 Respondent Miller violated Business and Professions Code section 4301(o) as it
26 relates to Business and Professions Code section 4115(e)(1) in conjunction with Business and
27 Professions Code section 4202, in that Respondent Miller authorized Amy Edwards and

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1 Madeline Miller to work as pharmacy technicians without being licensed during the period of
2 July 8, 1998 to February 18, 1999.

3 **XIV.**

4 **DISPENSED PRESCRIPTIONS TO IMPAIRED CUSTOMERS**

5 Respondent Miller violated Business and Professions Code section 4301(o) as it
6 relates to Health and Safety Code section 11153 in that Respondent Miller on a frequent basis,
7 filled prescriptions prior to the time period established by the doctor's prescription and for
8 patients who appeared at the pharmacy in an impaired condition. Respondent Miller repeatedly
9 dispensed prescriptions to the following customers who appeared impaired when they were in
10 the pharmacy to pick up the drugs: Patients K.B., E.N., L.S., and D.S.

11 **XV.**

12 **PHARMACY PRACTICE PERFORMED IN A GROSSLY NEGLIGENT MANNER**

13 Respondent Miller's pharmacy practice in dispensing controlled substances was
14 performed in a grossly negligent manner as follows:

15 **A.**

16 Failure to understand and learn about the effective use of controlled substances
17 in the practice of pain management: When a pharmacist begins to take on a speciality within the
18 practice of pharmacy, it is the standard practice for that pharmacist to become educated within
19 that specialty field. The majority of prescriptions filled at Shasta Pharmacy were from Dr.
20 Fisher for the treatment of chronic pain (77%), it is Respondent Miller's duty as a pharmacist to
21 become educated within this field of pain management. Respondent Miller was grossly
22 negligent as to his dispensing practices regarding pain medication. He lacked the additional
23 education in the pain management field.

24 **B.**

25 Failure to verify legitimacy of narcotic prescriptions: It is the standard pharmacy
26 practice for the pharmacist to honor valid prescriptions and refuse highly suspected
27 prescriptions. Respondent Miller failed to verify Dr. Fisher's prescriptions. This conduct
28 constituted gross negligence, an extreme departure from the pharmacy standards of practice.

1 C.

2 Failure to communicate directly with prescribing physician: It is the standard
3 pharmacy practice for the pharmacist to be the liaison between the patient and the healthcare
4 provider to ensure open communication and understanding about prescribed drugs. Respondent
5 Miller minimally communicated with Dr. Fisher. Most communications from Shasta Pharmacy
6 were by Ms. Miller. This unlawful delegation of duty is gross negligence, an extreme departure
7 from the pharmacy standards of practice.

8 D.

9 Failure to comply with CCR, Title 16, section 1715.5 by not reporting
10 appropriate information as required under the Controlled Substance Utilization Review and
11 Evaluation System: Measures have been imposed to assist in the proper use of Schedule II
12 narcotics. One such measure is the reporting of all filled Schedule II narcotics via the CURES.
13 Respondent Miller's decision to fail to comply with this regulation constituted gross
14 negligence, an extreme departure from the pharmacy standards of practice.

15 E.

16 Failure to recognize early refills of controlled substances: It is the pharmacy
17 standard of practice to deny refills for controlled substances based upon the previous
18 prescription and daily usage indicated by the physician. Respondent Miller filled many
19 prescriptions prior to the expected refill dates. This constituted gross negligence, an extreme
20 departure from the pharmacy standards of practice and evidences a complete disregard for
21 patient safety and well being.

22 F.

23 Failure to obtain, retain, and update appropriate information documenting the
24 course of, and need for, ongoing opiate therapy: It is the pharmacy standard of practice for the
25 pharmacist to dispense medications when, to do so, is in the patient's best interests. Generally
26 such an event involves communication with either the patient or prescribing physician, or both.
27 Respondent Miller had no documentation whatsoever to explain the ongoing opiate therapy of
28 his patients. Such behavior is indicative of the fact that Respondent Miller simply filled and

1 dispensed controlled substances at Shasta Pharmacy, without evaluation. This conduct
2 constituted gross negligence, an extreme departure from the pharmacy standards of practice.

3 **G.**

4 Failure to observe and recognize patients impaired mental condition: It is the
5 normal pharmacy standard of practice for a pharmacist to observe his patients prior to filling
6 any controlled substance, specifically narcotic controlled substances. Respondent Miller on
7 different occasions, dispensed a controlled substance to patients who appeared intoxicated or
8 under the influence of drugs. This constituted gross negligence, an extreme departure from the
9 pharmacy standards of practice.

10 **H.**

11 Failure to retain scheduled narcotics in their original stock bottle form: The
12 standard pharmacy practice prohibits the pharmacist from repackaging manufacturer's bottles.
13 Respondent Miller repackaged drugs such as Dilaudid 4 mg to contain 200, 300, 400 or 500
14 tablets per bottle. Some original containers for many Schedule II drugs were missing, while
15 other pre-counted generic Vicodin ES bottles containing 60, 90, and 120 tablets were not
16 labeled with any information. This pharmacy practice constituted gross negligence, an extreme
17 departure from the pharmacy standards of practice.

18 **I.**

19 Failure to properly label a prescription bottle containing a controlled substance:
20 The standard pharmacy practice requires the pharmacist to properly label containers which
21 contain controlled substances. The containers found in the bathroom area
22 were not properly labeled. This constituted gross negligence, an extreme departure from the
23 pharmacy standards of practice.

24 **J.**

25 The delegation of non-delegated duties: The standard pharmacy practice
26 prohibits a pharmacist from delegating specific duties to ancillary personnel. Respondent
27 Miller's decision to delegate the prescription verification and medical physician
28 communications to an unlicensed person, his wife, constituted gross negligence, an extreme

1 departure from the pharmacy standards of practice.

2 K.

3 Failure to properly conduct drug utilization review (DUR) for prescriptions
4 filled at Shasta Pharmacy: The standard pharmacy practice requires a pharmacist upon filling
5 any prescription to conduct a drug utilization review. The purpose of this review is to obtain
6 information regarding either compliance, abuse, drug/drug or drug/disease state interactions and
7 appropriateness of drug therapy. Respondent Miller's failure to perform this important duty
8 constituted gross negligence, an extreme departure from the pharmacy standards of practice.

9 L.

10 Failure to consult on any new prescription and/or when a consultation would be
11 justified: The standard pharmacy practice requires a pharmacist-patient consultation on any new
12 prescription, or whenever the pharmacist deems it warranted. Respondent Miller rarely
13 consulted with his patients. Based on prescription volume, Respondent Miller did not have
14 time for patient consultations. He was too busy dispensing medications. Respondent Miller's
15 failure to consult on new prescriptions constituted gross negligence, an extreme departure from
16 the pharmacy standards of practice.

17 M.

18 Failure by continuing to dispense large quantities of controlled substances such
19 that potentially toxic amounts of acetaminophen were being ingested: The standard pharmacy
20 practice requires the pharmacist to refuse to fill a controlled substance if in doing so would put
21 the patient at risk, or in the alternative, provide appropriate documentation reflecting his
22 decision. Respondent Miller's failure to deny filling acetaminophen combination narcotics or
23 provide appropriate documentation constituted gross negligence, an extreme departure from the
24 pharmacy standards of practice.

25 XVI.

26 **PHARMACY PRACTICE PERFORMED IN AN INCOMPETENT MANNER**

27 Respondent Miller's failure to perform the duties of a pharmacist as outlined in
28 the gross negligence section A, B, C, F, H, J, K and M, constituted incompetence. These

1 failures resulted in directly endangering patients' health and safety. Respondent Miller's
2 decision to exclude himself from his patient health care team evidences his incompetence. This
3 directly endangered patients' health and safety.

4 **XVII.**

5 Pursuant to Business and Professions Code section 4300 and 4301, Shasta
6 Pharmacy (PHY 39684) is subject to disciplinary action for all of the vilations of law
7 committed by Respondent Miller, as alleged herein.

8 WHEREFORE, complainant prays that a hearing be held and that the Board
9 make its order:

- 10 1. Revoking or suspending Pharmacist Certificate Number RPH 28932,
11 issued to Stephen Miller.
- 12 2. Ordering Respondents to pay to the Board its costs in investigating,
13 presenting and prosecuting the case according to proof at the hearing pursuant to Business and
14 Professions Code section 125.3.
- 15 3. Revoking or suspending Pharmacy Permit Number PHY 39684 issued to
16 Shasta Pharmacy; and,
- 17 4. Taking such other and further action as may be deemed proper and
18 appropriate.

19
20 Dated: 3/29/00

P. F. Harris

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

Complainant