

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

In the Matter of the Accusation Against:

MARINER'S PHARMACY
320 Superior, Suite 120
Newport Beach, CA 92663

YUNG CHENG KO, Pharmacist-in-Charge

Original Pharmacy Permit No. PHY 39924

and

YUNG CHENG KO
77 Ashford
Irvine, CA 92618

Pharmacist License No. RPH 43037

Respondents.

Case No. 2697

OAH No. L2004040136

PROPOSED DECISION

James Ahler, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter in Santa Ana, California on May 2 and 3, 2005.

Timothy L. Newlove, Deputy Attorney General, represented complainant Patricia F. Harris, the Executive Officer of the Board of Pharmacy.

Charles Benninghoff, Lay Representative, appeared on behalf of and assisted respondents Mariner's Pharmacy and Yung Cheng Ko. Yung Cheng Ko was present throughout the administrative proceeding.

On June 13, 2005, the matter was submitted.

FACTUAL FINDINGS

Jurisdictional Matters

1. On March 10, 2004, complainant Patricia F. Harris, the Executive Officer of the Board of Pharmacy (the Board), Department of Consumer Affairs, State of California, signed the Accusation.

The Accusation essentially alleged that between May 2001 and April 2002, Mariner's Pharmacy, through Ko, its pharmacist-in-charge, filled approximately 7,000 prescriptions for a variety of dangerous drugs (primarily pain-control medications) which were written by licensed California physicians for out-of-state patients. It alleged Medical Services Network, Inc., a company doing business through an Internet website, faxed or delivered the prescriptions to Mariner's Pharmacy, and neither Ko nor any other employee of Mariner's Pharmacy contacted the prescribing physicians to determine if the prescriptions were genuine or if there was a legitimate physician-patient relationship. The Accusation alleged such conduct violated California Code of Regulations, title 16, section 1761, established a failure to comply with existing pharmacy laws, and constituted unprofessional conduct.

The Accusation and other required jurisdictional documents were served on respondents Yung Cheng Ko (Ko) and Mariner's Pharmacy.

A Special Notice of Defense dated March 31, 2004, was filed on respondents' behalf by Attorney John W. Berger. In October 2004, respondents advised the Board of their appointment of Charles Benninghoff as their representative.

On May 2, 2005, the record in the administrative hearing was opened. Jurisdictional documents were presented. Sworn testimony and documentary evidence was received on May 2 and 3. On May 3, 2005, closing arguments were given.

A Proposed Decision was issued by the administrative law judge that was dated May 18, 2005. The Proposed Decision was forwarded to the Board.

In late May or early June 2005, Susan Capello, an Enforcement Analyst with the Board, left a message with the Office of Administrative Hearings advising that certain terms and conditions of probation set forth in the Board's current disciplinary guidelines (a copy of which had been provided by counsel for complainant) were not used in the Proposed Decision. She requested the administrative law judge modify the Proposed Decision to reflect the current language and to eliminate some terms of probation imposed against Ko personally which should have been imposed only against Mariner's Pharmacy.

After receiving that telephonic message, Administrative Law Judge Ahler contacted the attorneys for the parties to this action and advised them of the telephonic contact by the

Enforcement Analyst. The administrative law judge asked for and received written consent to reopen the record for the purpose of rewriting the Proposed Decision.

On June 7, 2005, the Office of Administrative Hearings received a letter from Susan Capello advising of the terms and conditions needing a review.

On June 13, 2005, the administrative law judge revised the Proposed Decision to include the requested changes, advised counsel of the foregoing, forwarded a copy of Susan Capello's letter to them, and closed the record.

On June 13, 2005, the matter was submitted.

License Histories

2. On October 11, 1989, the Board issued Pharmacy License No. RPH 43037 to Yung Cheng Ko, authorizing him to practice pharmacy in California. Ko's pharmacy license is renewed through September 30, 2005.

There is no history of any administrative discipline against Ko's pharmacy license.

3. On March 23, 1994, the Board issued Original Pharmacy Permit No. PHY 39924 to Ko to do business as Mariner's Pharmacy at 320 Superior, Suite 120, Newport Beach, CA 92663. Ko has been the Pharmacist-in-Charge since the original pharmacy permit was issued. The original pharmacy permit is in full force and effect.

There is no history of any administrative discipline against Mariner Pharmacy's original pharmacy permit.

Ko's Background and Experience

4. Ko was born in South Korea on September 13, 1957. His first languages are Korean and Mandarin.

Ko received a degree in pharmacy from Sung Kyun Kwan University in 1979. After receiving his degree, Ko was employed in the pharmaceutical industry in South Korea from 1980-1982. Ko later received a doctorate in Oriental medicine following five years of study.

5. Ko came to the United States in 1986. He took several classes in a successful effort to pass the Board's pharmacy examination. Ko became a licensed pharmacist in 1989.

After receiving his license, Ko worked as a pharmacist at Super Value Drugs in Anaheim for a year, as a pharmacist at Reliable Drugs in Tustin for a year, and as a pharmacist at Clark Drugs in Gardena for two and a half years.

6. In 1994, Ko purchased Mariner's Pharmacy, a 1,100 square foot pharmacy located in a medical complex in Newport Beach in close proximity to the Hoag Memorial Hospital. Ko became the Pharmacist-in-Charge. Mariner's Pharmacy is open six days a week, Monday through Friday from 9:00 a.m. to 6:00 p.m. and on Saturday from 9:00 a.m. to 1:00 p.m. Ko is the only registered pharmacist working at Mariner's Pharmacy. He employs six part-time clerks.

About 50% of the prescriptions filled by Mariner's Pharmacy are written by licensed physicians with offices in the same medical complex as Mariner's Pharmacy. The remaining prescriptions are written by physicians with offices in the area or are prescriptions filled for customers who live in the area.

7. Ko was not and is not computer savvy. He used existing pharmacy software on-site after he purchased Mariner's Pharmacy. His brother in law, Tien Tsou, upgraded Mariner Pharmacy's computer system in 2003. Ko does not use the Internet.

8. Ko has been married for 17 years to Lina Ko, whom Ko met in South Korea. They have three daughters, ages 15, 13 and 5. The family has a home in Irvine. Lina Ko does not work outside the family home, except on Saturdays when she assists her husband at Mariner's Pharmacy or if an emergency requires her presence at Mariner's Pharmacy.

9. Ko and his wife are exceedingly polite and deferential. They appeared to be very sincere, but are incredibly naive regarding some dangers inherent in operating a pharmacy, particularly with respect to possible scams involving the unlawful diversion of controlled substances into the community.

Mariner Pharmacy's Relationship with Medical Services Network

10. In June 2001, Ko was approached by Medical Services Network, Inc. (MSN). John Boss (Boss) and an associate, Esther Gallant (Gallant), asked Ko if Mariner's Pharmacy would provide "mail order pharmacy" services for MSN. Boss said MSN would forward prescriptions written by licensed physicians to Mariner's Pharmacy by fax or other means, together with relevant customer information, and provide the original prescriptions thereafter. Mariner's Pharmacy was expected to fill and package the prescriptions and to have filled prescriptions ready for customer delivery within 48 hours after delivery of the faxed prescription. MSN would provide a courier service by which the filled prescriptions would be delivered from Mariner's Pharmacy to customers. MSN agreed to pay Mariner's Pharmacy in accordance with a "Medication Pay Schedule," which Ko referred to as the "formulary."

Ko did not discuss the proposal with any associates or with an attorney. He did not conduct an investigation into MSN, nor did he visit MSN's offices, which were purportedly located in Newport Beach. Contract negotiations were carried on primarily with Gallant who, according to Ko's wife, was knowledgeable, businesslike and quite professional.

11. On December 26, 2001, Ko signed an 11-page "Administrative Services Agreement" in which "Pharmacy desires to have Company provide certain administrative services for certain customers of Pharmacy, and Company desire to furnish such services, on the terms and conditions set forth in this Agreement." The written contract set forth various reciprocal services and duties to be provided by Mariner's Pharmacy and MSN.

12. Unbeknownst to Ko, MSN was actively soliciting persons who wanted prescriptions for controlled substances filled over the Internet. MSN put these persons in touch with MSN's contracting physicians.

MSN's Internet website offered to arrange an appointment with "a doctor knowledgeable in the area of your concern," "to forward any prescription(s) that may be written for you to one of our network contracting Pharmacies," and to "arrange to have your prescription(s) shipped to you." The MSN website stated the cost of the appointment was \$100, represented a doctor would "conduct a medical examination during your phone appointment" and would "provide one (or more, if needed) prescription(s)" which would "allow for up to 2 refills, if needed."¹

13. At all times relevant to this matter, Dr. E. Williams was a licensed physician with offices in Pomona, California, whose specialty, if any, was unknown to Ko; Dr. Sean Aldridge was a licensed physician with offices in Palm Springs, California, whose specialty, if any, was unknown to Ko; and, Dr. Sanjay Sood was a licensed physician with offices in Los Angeles, California, whose specialty, if any, was unknown to Ko, but whose prescription form identified him as operating "Hollywood Family Practice."

These three licensed California physicians provided the bulk of the prescriptions delivered by MSN to Mariner's Pharmacy for filling and processing that form the basis of the Accusation. These physicians' offices were not located in the Newport Beach area and the physicians' prescribing practices were unknown to Ko, who likely never filled prescriptions for any of these physicians before entering into the agreement with MSN.

The Filling of Prescriptions for Out-of-State Customers

14. On June 14, 2001, Mariner's Pharmacy began filling prescriptions written by Dr. Williams for out-of-state customers, prescriptions that were faxed to Mariner's Pharmacy by MSN. About a half dozen prescriptions were filled on June 14, 2001. Each prescription was for a Schedule III or Schedule IV drug and most of the prescriptions were for Hydrocodone.

As an example, on June 14, 2001, Mariner's Pharmacy filled two prescriptions written by Dr. Williams, whose office was in Pomona, California, for customer Bobby C.,

¹ Notice is taken that at all times relevant to this matter, Business and Professions Code section 2242, subdivision (a), applied to physicians licensed in California and provided in part, "Prescribing . . . dangerous drugs . . . without a good faith prior examination and medical indication therefore, constitutes unprofessional conduct."

who lived in Huntsville, Alabama. One prescription was for 90 tablets of Hydrocodone (the generic name for Vicodin, a Schedule III narcotic analgesic), and the other prescription was for 30 tablets of Xanax (brand name for Alprazolam, a Schedule IV anti-anxiety agent). Each prescription called for two refills.

On June 14, 2001, the other half dozen prescriptions written by Dr. Williams for Hydrocodone or very similar medications were filled for customers living in Arizona, Arkansas, Michigan, New Jersey, Texas and Washington. Each prescription authorized two refills. Similar prescriptions written by Dr. Williams for out-of-state customers were regularly filled by Mariner's Pharmacy thereafter through mid-April 2002.

15. Ko telephoned Dr. Williams' office and confirmed that Dr. Williams was a licensed California physician. Ko did not ask why Dr. Williams was writing prescriptions for out-of-state customers or if he had a physician-patient relationship with these persons.

16. On July 13, 2001, Mariner's Pharmacy began filling prescriptions written by Dr. Sean Aldridge for out-of-state customers, prescriptions that were faxed to Mariner's Pharmacy by MSN. About a half dozen prescriptions were filled on June 14, 2001. Each prescription was for a Schedule III or Schedule IV drug, and most of the prescriptions were for Norco or Loratabs (brand names for Hydrocodone).

As an example, on July 13, 2001, Mariner's Pharmacy filled a prescription written by Dr. Aldridge, whose office was in Palm Springs, California, for customer Charles J., who lived in Akron, Ohio. The prescription was for 100 tablets of Hydrocodone (the generic name for Norco, a Schedule III narcotic analgesic). The prescription called for two refills.

On July 13, 2001, prescriptions written by Dr. Aldridge for Hydrocodone or very similar medications were filled for customers living in Alabama, Florida, Illinois, Rhode Island and Washington. Each prescription called for two refills. Similar prescriptions written by Dr. Aldridge for out-of-state customers were regularly filled by Mariner's Pharmacy thereafter through mid-April 2002.

17. Ko telephoned Dr. Aldridge's office and confirmed that Dr. Aldridge was a licensed California physician. Ko did not ask why Dr. Aldridge was writing prescriptions for out-of-state customers or if there was a physician-patient relationship with these patients.

18. On March 11, 2002, Mariner's Pharmacy began filling prescriptions written by Dr. Sanjay Sood for out-of-state customers, prescriptions that were faxed to Mariner's Pharmacy by MSN. About a half dozen such MSN prescriptions were filled on March 11, 2002. Each prescription was for a Schedule III or Schedule IV drug, and most of the prescriptions were for Hydrocodone.

As an example, on March 11, 2002, Mariner's Pharmacy filled two prescriptions written by Dr. Sood, whose office was in Los Angeles, California, for customer Matthew B., who lived in Allston, Massachusetts. One prescription was for 30 tablets of Diazepam (the

generic name for Valium, a Schedule IV anti-anxiety medication) and the other was for 50 tablets of Hydrocodone. There were two refills of the Diazepam prescription and no refills for the Hydrocodone prescription.

On March 11, 2001, prescriptions written by Dr. Sood for Hydrocodone or a very similar medication were filled for customers living in Georgia, South Carolina, Tennessee, Washington and Wisconsin. Most of the prescriptions called for two refills. Similar prescriptions written by Dr. Sood for out-of-state customers were regularly filled by Mariner's Pharmacy thereafter through mid-April 2002.

19. If there were an ambiguity or error on the face of the prescription, Ko called the prescriber's office to determine what medication, what quantity of medication or what dosage was being prescribed before filling the prescription. This occurred less than a dozen times. Ko never called to inquire into the validity of the physician-patient relationship or to determine the medical indication supporting the issuance of the prescription.

20. Ko and Mariner's Pharmacy filled about 6,900 prescriptions written by these three California physicians for out-of-state patients.

Ko testified his profit on the sale of the drugs Mariner's Pharmacy used to fill these prescriptions averaged about 23%, substantially less than his usual retail profit on the sale of prescription medications. Ko realized about \$50,000-\$55,000 in net profits arising out of his relationship with MSN, an estimate that was corroborated by tax returns.

*The California Medical Board's Investigation and
Mariner's Pharmacy's Termination of the Relationship with MSN*

21. The Medical Board of California began investigating MSN and the Internet prescribing practices of Dr. Williams, Dr. Aldridge and Dr. Sood. By letter dated April 5, 2002, Paul Nasca, a Medical Board Investigator, advised Ko he was investigating Dr. Aldridge and Dr. Sood he had "reason to believe that these two physicians may be prescribing without good faith examinations."

After receiving this letter, Ko wrote a letter to MSN (which was not produced, but the existence of which was well established) in which he terminated his relationship with MSN. Gallant contacted Ko after receiving his letter to assure him everything was legitimate.

In a fax dated April 10, 2002, Gallant confirmed an April 9, 2002 telephone conversation with Ko in which Ko withdrew his notice of termination. In that memo, Gallant represented that MSN had changed some of its procedures and that MSN believed the physicians were performing good faith examinations before issuing prescriptions, as well as its belief there was a bona fide doctor/patient relationship between the physicians and the patients. Gallant encouraged Ko to continue cooperating with the Medical Board.

On April 18, 2002, Alberto Perez (Investigator Perez), a Medical Board Investigator, met with Ko at Mariner's Pharmacy. Ko told Investigator Perez about Mariner's Pharmacy's agreement with MSN to fill prescriptions provided by MSN. Ko told Investigator Perez he thought MSN had a website, but he said he had never looked at it. Ko estimated Mariner's Pharmacy was filling 70-80 prescriptions per day, 20 or 30 of which were being presented by MSN. Ko was cooperative and said in retrospect that he realized there might be a legal problem in distributing controlled substances across state lines. Ko told Investigator Perez he would terminate his relationship with MSN.

By letter dated April 19, 2002, Ko advised MSN "as of date of today, we are not filling any prescriptions for Medical Service Network, Inc. until we hear any thing [sic] from Medical Board of California."

22. The California Medical Board ultimately filed disciplinary actions against Dr. Williams, Dr. Aldridge and Dr. Sood, most likely for prescribing controlled substances over the Internet without providing a good faith prior examination.

23. The California Medical Board forwarded the results of its investigation to the Pharmacy Board. In August or September 2002, several Board inspectors, including Sarah Lopez (Inspector Lopez), were assigned to look into the matter.

24. Inspector Lopez and several other Board inspectors contacted Ko on October 22, 2002. The relationship between MSN, Mariner's Pharmacy and Ko was discussed. Various records were reviewed. A written statement was prepared which Ko signed.

That statement said:

"Mariner's Pharmacy was approached by Medical Services Network to fill prescriptions for Medical Services Network. Medical Services Network and Mariner's Pharmacy signed a contract and Mariner's Pharmacy filled about 30 prescriptions/day from about May 2001-present (October 22, 2002). The prescriptions were faxed from Medical Services Network to Mariner's Pharmacy, and the original prescriptions were brought in by an employee of Medical Services Network. The patients resided in both California and out-of-state as well. In May 2001 until about April 2002, the patients were from out-of-state. Currently the patients reside in CA. The most common physicians were Dr. Williams, Dr. Sood, and Dr. Aldridge. The patients were residing outside of California and the physician was from California, but the physician was not called to verify a patient-doctor relationship. The reimbursement came from Medical Services Network every two weeks."

The inspectors made arrangements to gather additional documents. Ko was not told he was violating the law and was not given any advice.

25. Ko cooperated in the Board's investigation. He provided all documents upon request, including the Administrative Services Agreement with MSN, daily reports, original prescriptions, prescribing records for various physicians, controlled substance audit reports, and faxes from MSN.

The Diversion of Dangerous Drugs

26. As stated in the Board's Strategic Plan for 2000/01:

"There is a vast range of highly potent drugs available to prescribers to treat diseases in patients. To perform their intended function, these drugs must be properly prescribed, dispensed and used. Drugs that may save lives, alleviate pain and cure illness may also produce harmful effects or possibly kill if not dispensed and used correctly.

Also associated with prescription drugs are problems of abuse, misuse, health care fraud and illegal trafficking (diversion). The Drug Enforcement Administration estimates that the annual diversion of legal prescription drugs for illicit purposes is a \$25 billion industry nationwide. Consequently, the distribution and handling of dangerous drugs and devices must be carefully monitored, controlled and regulated. Without such controls greater amounts of legal drugs can be diverted through manufacturers, wholesalers and pharmacies to the illicit market, resulting in substantial public danger and harm."²

27. The Pharmacy Law (Bus. & Prof. Code § 4000 et seq.) deals with dangerous drugs and devices. A "dangerous drug" is defined generally as a drug that is unsafe for self-use. Dangerous drugs cannot ordinarily be furnished without a prescription. While there may be some dispute about what constitutes a "good faith prior examination" on a case-by-case basis, it is without dispute that physicians licensed in California are prohibited from prescribing dangerous drugs for a patient without a good faith prior examination and medical indication to support the issuance of the prescription.

A "controlled substance" is a specified narcotic or restricted dangerous drug listed in one of the five schedules set forth in the Health & Safety Code. A Schedule I drug is highly addictive and has no medical use. Heroin is an example of a Schedule I drug. A Schedule II drug is highly addictive but has medical use, often pain control. Codeine is an example of a Schedule II drug. A Schedule III drug carries a risk of addiction/abuse (though not as great as a Schedule II drug) and has medical use. Schedule III drugs include various kinds of amphetamines, depressants, and narcotic analgesics such as Vicodin. Schedule IV drugs have a minimal risk of addiction/abuse and have medical use. Schedule V drugs have the least risk of addition/abuse.

² Notice is taken of the Board's Strategic Plan for 2000/01, which was identified by respondents as an exhibit (Exhibit I) but was not received.

28. Since 2000, it has been unlawful to dispense or furnish dangerous drugs on the Internet for delivery in California without first having a prescription issued pursuant to a good faith prior examination. Any person or entity dispensing or furnishing the drugs over the Internet who knew or reasonably should have known that the prescription was not issued following a good faith examination, and persons and entities did not act in accordance with specified regulations, was subject to fines and civil penalties.³

29. At all times relevant to this matter, California Code of Regulations, title 16, section 1761 provided:

“(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

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

30. At all times relevant to this matter, Business and Professions Code section 4059.5, subdivision (e) provided in relevant part:

“(e) A dangerous drug . . . shall not be transferred, sold, or delivered to a person outside this state . . . unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States . . . Compliance with the laws of this state and the United States . . . to which the dangerous drugs . . . are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs . . . is authorized by law to receive the dangerous drugs . . . ”

Expert Testimony and the Standard of Care

31. A pharmacist must possess and exercise that degree of skill, prudence and diligence that other members of the profession commonly possess and exercise, which is known as the standard of care. The standard of care is the metric by which the professional conduct of a pharmacist is measured. It is a matter peculiarly within the knowledge of experts and must be established by expert evidence.⁴

³ Business and Professions Code section 4067.

⁴ See, *Elcome v. Chin* (2003) 110 Cal.App.4th 310, 317.

Complainant's Expert Witness

32. Judith K. Nurse, Pharm. D. (Ms. Nurse) received a doctorate in Pharmacy from the USC School of Pharmacy in 1974. Ms. Nurse is a licensed pharmacist in good standing who is currently employed as a Supervising Inspector with the Board of Pharmacy.

Ms. Nurse served as an Intern Pharmacist at Chapwood Pharmacy in Garden Grove from 1970-1974, as a Pharmacist with Beverly Enterprises in Southern California from 1974-1979, as a Pharmacist with Stier Drug in Oakland from 1979-1980, as a Staff Pharmacist with the State of California at Napa State Hospital and the California Veteran's Home in Yountville in 1980-1983, as the Pharmacist-in-Charge with Beverly Enterprises from 1983-1986, as the Pharmacist-in-Charge at the Edgemoor Geriatric Hospital in Santee from 1986-1994, , as a Staff Pharmacist at Sharp Cabrillo Hospital in San Diego from 1991-1994, as an Inspector with the Board of Pharmacy from 1994 through 2000 and as a Supervising Inspector with the Board of Pharmacy since then.

By reason of her education, training and experience, Ms. Nurse was familiar with standards of care in filling prescriptions for controlled substances and dangerous drugs, as well as with the Board's current interpretation of California Code of Regulations, title 16, section 1761.

Respondent's Expert Witness

33. Jack H. Raber, Pharm. D. (Dr. Raber) received a doctorate in Pharmacy from the USC School of Pharmacy in 1975. Dr. Raber is a licensed pharmacist in good standing who is currently self-employed as a clinical information specialist/medical writer and forensic expert. Dr. Raber currently serves as an Adjunct Assistant Professor of Pharmacy Practice at the USC School of Pharmacy.

Dr. Raber was a Clinical Pharmacist at St. Mary Medical Center in Long Beach from 1975-1987, as a Per Diem Pharmacist at St. Mary's and as a Relief Pharmacist at Kennedy Medical Center in Hawthorne from 1985-1989, as an executive with DTEC, Inc. from 1990-1992, as Director of Pharmacy Services at Charter Hospital of Long Beach from 1987-1992, and as the Pharmacist-in-Charge at Children's Homecare in Los Angeles from 1993-1994. Dr. Raber has been self-employed, doing business as Specialized Clinical Services, Inc., and Clinipharm Services since 1988.

By reason of his education, training and experience, Dr. Raber was familiar with standards of care in filling prescriptions for controlled substances and dangerous drugs. Dr. Raber had a different interpretation of California Code of Regulations, title 16, section 1761 than Ms. Nurse.

The Expert Opinions

34. In forming their opinions and conclusions in this matter, the two expert witnesses reviewed the documentation gathered by Inspector Lopez in the course of the investigation of Mariner's Pharmacy and each considered Ko's conduct in relationship to existing law and professional standards of care.

35. Both Ms. Nurse and Dr. Raber concluded under all the circumstances that Ko engaged in general unprofessional conduct (i.e. conduct falling below the standard of care) by filling the prescriptions written by the three California doctors for out-of-state patients. Each expressed somewhat different reasons in reaching this conclusion.

36. Ms. Nurse reached her conclusion because the ordinary, reasonable and prudent pharmacist would have known or should have known the MSN prescriptions were possibly not written by the prescribers in good faith for several reasons: the prescriptions being filled involved controlled substances having a potential for addiction or abuse; because of the way in which the prescriptions were received (six or seven prescriptions a day from the same physician for out-of-state patients for pain medications with virtually no prescriptions for other kinds of medications); and, because the out-of-state customers did not personally present to pick up the prescriptions.

37. Ms. Nurse believed the prescriptions were "irregular" and "uncertain" within the meaning of California Code of Regulations, title 16, section 1761 for the factual reasons set forth above and because an ordinary, reasonable and prudent pharmacist would not fill the prescriptions until he or she obtained sufficient information from a prescribing physician to validate the prescription. If that information was not given or if there was no objective basis on which the pharmacist could conclude there was a legitimate medical purpose for a prescription, then the ordinary, reasonable and prudent pharmacist would not dispense the controlled substances being prescribed.

38. Ms. Nurse testified that taken individually, the filling of a single prescription might be defensible, but Ko's conduct taken in its entirety was wholly inconsistent with the conduct of a reasonable and prudent pharmacist and fell below the standard of care.

39. Dr. Raber reached the conclusion that Ko acted unprofessionally because Ko did not engage in the kind of careful inquiry required of the ordinary, reasonable and prudent pharmacist, the nature and extent of which was discussed in the July 2001 publication of *The Script*. Dr. Raber testified *The Script* identified, but did not set professional standards of care, which were already in existence.

Dr. Raber testified there were certain accepted guidelines an ordinary, reasonable and prudent pharmacist followed in exercising the care required to fill prescriptions for controlled substances. Ko did not comply with these guidelines because he could not verify the true name and identity of the patients, he did not know the patients' diagnosis in most cases, and he was unable to evaluate customer demeanor since the prescriptions were being mailed. Ko

did not know anything about customer drug histories. The customers lived outside Mariner's Pharmacy normal trading area, which should have raised questions. The prescribing physicians, their medical specialties and their prescribing patterns were unknown to Ko. Each prescribing physician's percentage of prescriptions for controlled substances was high. There was no evident basis by which Ko could reasonably conclude there was a legitimate relationship between the customers and the prescribing physicians, such as a common insurance plan, a fraternal organization or the like; and, while a legitimate physician-patient relationship between the California prescribers and the MSN customers might be theoretically possible, it was highly unlikely.

40. Dr. Raber believed Ko clearly violated Business and Professions Code section Business and Professions Code section 4059.5, subdivision (e) by delivering dangerous drugs to persons outside the state.

41. Dr. Raber did *not* believe the prescriptions were "irregular" or "uncertain" within the meaning of California Code of Regulations, title 16, section 1761. He believed that regulation was designed to apply to significant errors, omissions, irregularities, uncertainties, ambiguities or alterations appearing on the face of the prescription itself.

42. Dr. Raber did *not* believe there was a duty on a pharmacist to make inquiry into the existence or validity of a physician-patient relationship every time a new prescription was presented, and he expressed the view that any duty in that regard should be determined on a case-by-case basis based upon the standard of care.

The Mail-Order Pharmacy Defense/Explanation

43. Throughout Ko's testimony (and to some extent, that of his wife) reference was made to Mariner's Pharmacy possibly being a "mail-order pharmacy" for MSN.

Inspector Lopez, Ms. Nurse and Dr. Raber recognized the existence of a "mail-order pharmacy." It was suggested Ko reasonably believed Mariner's Pharmacy served as a mail-order pharmacy for MSN customers.

Dr. Raber explained the concept of a mail-order pharmacy as being a standalone pharmacy which sells drugs in volume at discount to eligible customers, usually on behalf of a common insurance program or through a common medical plan; a good faith prior examination of a patient by a licensed physician and a medical indication must support the prescription before the prescription is written and filled; a mail-order pharmacy usually provides a wide range of medications to its customers (as opposed to providing a few kinds of medications, such as pain medications); and, virtually all prescriptions dispensed by a mail-order pharmacy are delivered by a third party to customers – a mail-order pharmacy does not have a walk-in clientele. Dr. Raber testified he was responsible for developing policies and procedures for an emerging Orange County mail-order pharmacy client to comply with the Pharmacy Law as it related to a mail-order pharmacy.

While Business and Professions Code section 4059.5, subdivision (e) specifically authorizes the delivery of dangerous drugs to persons outside this state, the transferor, seller or deliverer must comply with the law including making a determination that each recipient of the dangerous drug is authorized by law to receive it. A mail-order pharmacy is legal so long as there is full compliance with domestic and foreign laws.

Mariner's Pharmacy was *not* operating as a legitimate mail-order pharmacy for MSN even though Ko may have naively believed Mariner's Pharmacy was doing so. Ko did not engage in the due diligence required to assert that he reasonably believed he was complying with domestic and foreign laws.

Evidence in Explanation, Extenuation, Mitigation and Rehabilitation

44. Ko presented as a hardworking, respectful, unsophisticated, frightened, and contrite foreign-born pharmacist. Ko was absolutely candid throughout his testimony.

Wai-Shing Tsoi, the pastor of Ko's church, Lina Ko, Ko's wife, Ana Lin, Ko's sister in law and an employee of Mariner's Pharmacy, and Tien Tsou, Ko's brother in law, testified about Ko's good moral character and his regrets concerning the incident giving rise to the filing of the Accusation. Their testimony was credible and established Ko had no intent to violate the law.

Ko had no actual knowledge during his relationship with MSN that he was doing anything wrong by filling prescriptions written by licensed California physicians for out-of-state customers. The evidence supporting Ko's lack of fraudulent intent was demonstrated by his complete cooperation and candor with the Medical Board of California and the Board of Pharmacy in their investigations, even when it was to his detriment, his acknowledging that he had not contacted the California physicians to investigate the existence of a valid professional relationship with out-of-state patients, Ko's unwillingness to "spin" his unprofessional conduct by blaming others, the memos and correspondence he received from MSN assuring him that everything was legitimate and above board, and Ko's ultimate acceptance of responsibility for his professional misconduct once it was brought to his attention.

Ko did not initiate the relationship with MSN – Boss and Gallant came to Mariner's Pharmacy. MSN prepared the agreement. Ko failed to exercise due diligence in entering into the agreement, and once the relationship with MSN commenced, he failed to exercise the level of caution and oversight expected of reasonable and prudent licensed pharmacists. Once the problems relating to the prescribing of controlled substances to out-of-state customers by California physicians were brought to Ko's attention, he contacted MSN and terminated the agreement as it related to out-of-state customers.

Ko's tax returns established that he profited from his relationship with MSN, but the percentage of the profit on the MSN transactions was substantially less than profits Mariner's Pharmacy made compared to sales it made to its retail customers. The profit from the MSN

transactions was but a small percentage of Mariner's Pharmacy's total profits from its retail operations. The profit from Ko's relationship with MSN did not support a reasonable belief that Ko was engaged in a fraudulent scheme. No criminal action or action to impose a fine or civil penalty arose out of the misconduct.

Ko and Mariner's Pharmacy have no other disciplinary record (including warnings, citations and fines).

The Pharmacy Law violations established in this administrative hearing were not the result of Ko's poor moral character, but evidenced cultural naivety, a lack of initiative, and a lack of sophistication resulting in a dangerous level of professional incompetence.

Disciplinary Guidelines

45. The Board enacted comprehensive regulatory guidelines⁵ which are to be followed in all disciplinary actions. The Board recognizes that individual cases may necessitate a departure from these guidelines; in such cases, the mitigating circumstances should be detailed in any proposed decision, especially where a Category III violation is involved. A revocation should always be an option whenever grounds for discipline exist, and any suspension, where imposed, should be for at least 30 days for an individual and at least for 14 days for licensed premises.

The guidelines state a minimum three-year probationary period is appropriate in most cases when probation is imposed; however, a minimum five-year probationary period is appropriate where self-administration or diversion of controlled substances is involved. Terms and conditions of probation should provide consumer protection and should allow the probationer to demonstrate rehabilitation. A suspension may be required as part of the probationary order. The Board prefers that any stayed order be for revocation rather than for a period of suspension.

46. Under the guidelines, "Category I" discipline is recommended for violations which are relatively minor but are potentially harmful and for repeated violations of a relatively minor nature.

"Category II" discipline is recommended for violations with a serious potential for harm, violations involving a greater disregard for pharmacy law and public safety, violations which reflect on ethics, care exercised or competence, or for a criminal conviction not involving dangerous drugs or controlled substances. "General unprofessional conduct" is mentioned as being a kind of violation warranting the imposition of Category II discipline, as is a violation of California Code of Regulations, title 16, section 1761, subdivision (a).

"Category III" discipline is recommended for most criminal convictions involving dangerous drugs or controlled substances, knowing or willfully violating laws or regulations

⁵ California Code of Regulations, title 16, section 1760.

pertaining to dispensing or distributing dangerous drugs or controlled substances, fraudulent acts committed in connection with the licensee's practice, drug shortages a violation of a licensee's corresponding responsibility.

47. The factual circumstances in this matter best support the imposition of Category II discipline.

48. Under the Board's guidelines, the minimum discipline which should be imposed for a Category II violation is revocation stayed, three years probation (five years probation where self-administration or diversion of controlled substances is involved), with the imposition of standard terms and conditions of probation and such optional terms and conditions as may be appropriate. The maximum discipline which should be imposed for a Category II violation is outright revocation. The guidelines set forth various factors which should be evaluated in imposing a minimum, intermediate or maximum sanction.

49. In this matter, the imposition of minimum discipline is warranted after considering the disciplinary factors referred to by the Board in the guidelines.

In aggravation, the violations involved a pattern of unprofessional conduct which resulted in the potential of great harm to the general public and to specific consumers. The misconduct arose directly out of Ko's incompetence and unwarranted trust in others.

In mitigation, Ko's misconduct was the result of his genuine naivete and legal ignorance. Ko did not have actual knowledge at the time he filled the prescriptions written by California physicians for out-of-state customers that such conduct might be in violation of the law, although more sophisticated and knowledgeable pharmacists would immediately have been concerned that might be the case. The financial benefit to Ko and Mariner's Pharmacy was not insubstantial, but it was not so great to compel the conclusion that Ko was engaged in widespread fraud. Ko did not go out looking for the business opportunity; it came to him. Ko did not try to hide or minimize his activities, and his conduct was consistent with his uninformed belief that he had done nothing wrong. No criminal action arose out of the misconduct. Once Ko became aware of governmental concern about his out-of-state pharmacy practices, he ceased those practices. More than three years have passed since the most recent violation. Ko and Mariner's Pharmacy have no other disciplinary record (including warnings, citations and fines).

The Appropriate Measure of Discipline

50. Under all the circumstances, there is no reason not to revoke Ko's pharmacist license, to stay the order of revocation, and to impose three years probation with appropriate terms and conditions of probation including a 15-day actual suspension. Serving the suspension and reimbursing the Board its reasonable costs of investigation and prosecution will virtually eliminate any profit Ko may have realized from his relationship with MSN. The period of suspension will certainly gain Ko's attention, require him to be more proactive

and remind him of his obligation to ensure compliance with existing laws. A longer period of suspension would be punitive.

51. Under all the circumstances, there is no reason not to revoke Mariner's Pharmacy original pharmacy permit, to stay the order of revocation, to impose three years probation with appropriate terms and conditions of probation including a 15-day actual suspension. Serving the suspension and reimbursing the Board its reasonable costs of investigation and prosecution will virtually eliminate any profit Mariner's Pharmacy realized from its relationship with MSN.

Costs of Investigation and Enforcement

52. The declarations from three inspectors and the declaration of the deputy attorney general who prosecuted the matter were offered to support an order directing respondents to pay reasonable costs of investigation and enforcement.

Inspector Lopez also testified. Investigative services were billed at the rate of \$65 per hour, which is a reasonable rate. 100 hours were spent in that portion of the investigation that resulted in the findings that respondents violated the Pharmacy Law.

An award of \$6,500 (100 hours at \$65 per hour) represents a reasonable award of investigation costs under all the circumstances.

53. The deputy attorney general prosecuting the matter submitted a declaration stating that 193 attorney hours were billed at the rates of \$112-139 per hour in the prosecution of the matter. The deputy attorney general who prosecuted the matter was well prepared, highly skilled and effective.

An award of prosecution costs of \$13,000 is reasonable under all the circumstances.

54. Total reasonable costs of investigation and enforcement are \$19,500.

LEGAL CONCLUSIONS

The Standard of Proof

1. The practice of pharmacy, like the practice of medicine, is a profession. *Vermont & 110th Medical Arts Pharmacy v. Board of Pharmacy* (1981) 125 Cal.App.3d 19, 25. 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 853, 856.

2. The key element of "clear and convincing evidence" is that it must establish a high probability of the existence of the disputed fact, greater than proof by a preponderance

of the evidence. Evidence of a charge is clear and convincing so long as there is a “high probability” that the charge is true. *People v. Mabini* (2001) 92 Cal.App.4th 654, 662.

Pertinent Disciplinary Statutes and Regulations

3. Business and Professions Code section 4301 provides in part:

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

...

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

4. Business and Professions Code section 4113, subdivision (b) provides:

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

5. Business and Professions Code section 4059.5, subdivision (e) provides:

“A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.”

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

“(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has

objective reason to know that said prescription was not issued for a legitimate medical purpose.”

California Code of Regulations, title 16, section 1761

7. Does California Code of Regulations, title 16, section 1761 apply to the facts of this matter insofar as it requires a pharmacist to inquire into the validity of prescriptions for controlled substances written by California prescribers for out-of-state customers or is such an interpretation overly broad?

Statutes and regulations should be interpreted in a manner that carries out the legislative or regulatory intent. The intent of the drafters should be ascertained to effectuate the purpose of a regulation. The words used in the regulation are the primary source for identifying the drafter’s intent. Those words are given their usual and ordinary meaning whenever possible. Significance should be given to every word, avoiding an interpretation that renders any surplusage. The words contained in a regulation must be interpreted in context, harmonizing to the extent possible all provisions relating to the same subject matter. *Simi Corporation v. Garamendi* (2003) 109 Cal.App.4th 1496, 1505-1506.

There are two broad categories of factors relevant to assessing an administrative agency’s interpretation of a regulation. The categories include (1) factors indicating that the agency has a comparative advantage over the courts in interpreting the regulations at issue and (2) factors indicating that the interpretation in question is probably correct. In the first category are factors that assume the agency has expertise and technical knowledge, especially where the legal text to be interpreted is technical, obscure, complex, open-ended, or entwined with issues of fact, policy, and discretion. A court is more likely to defer to an agency’s interpretation of its own regulation than to its interpretation of a statute, since the agency is likely to be intimately familiar with regulations it authored and sensitive to the practical implications of one interpretation over another. With respect to the second category, a court may look to the form of the interpretation and whether it was prepared by senior agency officials or by staff members and may consider whether the agency has adhered consistently to the interpretation at issue and whether there was an opportunity for comment to be made on that interpretation. *Ibid.*, at 1504.

8. The Board interprets the regulation at issue to extend beyond consideration of significant errors, omissions, irregularities, uncertainties, ambiguities or alterations appearing on the face of the prescription and relating solely to the prescription itself, and it interprets the words “uncertainty” and “ambiguity” to require a pharmacist to make reasonable inquiry where an unknown California prescriber writes a prescription that is to be delivered to an out-of-state customer who will not be present at the pharmacy for evaluation.

The Board’s interpretation – as expressed by Ms. Nurse - carries out the legislative and regulatory intent of protecting the public by thwarting the unlawful diversion of dangerous drugs. The words “uncertainty” and “ambiguity” have meaning within this context. Nothing in the regulation limited the interpretation of those words to the extent Dr.

Raber believed. The Board's interpretation of subdivision (a) becomes harmonized with subdivision (b), so that even after conferring with the prescriber, a pharmacist should not compound or dispense a controlled substance prescription if the pharmacist knows or has objective reason to know the prescription was not issued for a legitimate medical purpose.

The Board's expertise and technical knowledge provide the Board, its agents and employees with a comparative advantage in interpreting the regulation over other persons, including administrative law judges. The regulation was duly enacted under the Government Code. Finally, the Board's interpretation was and is reasonable. No evidence was presented to establish that the application of the regulation in this matter was inconsistent with the application of the regulation to other disciplinary matters involving similar facts.

It is concluded the Board's interpretation of California Code of Regulations, title 16, section 1761, as applied in this matter, was reasonable. This conclusion is based on Factual Findings 1 (insofar as the Board's Executive Officer made such an interpretation), 19, 29, 32 and 36-38 and on Legal Conclusions 6, 7 and 9.

Relevant Appellate Authority

9. Society entrusts to persons practicing pharmacy and medicine with the responsibility for control over a force which, when properly used, has great benefit for mankind, but when abused is a force for evil and human destruction. Society cannot tolerate the presence of individuals within these professions who abdicate their professional responsibility and permit themselves to be used as a conduit by which these controlled substances reach the illicit market and become that force of evil. *Vermont & 110th Medical Arts Pharmacy v. Board of Pharmacy* (1981) 125 Cal.App.3d 19, 25.

10. The purpose of a license revocation proceeding is to protect the public. A license revocation proceeding is civil in nature, not criminal. By contrast, the purpose of a criminal proceeding is to punish someone for a specific act of wrongdoing, and the purpose of a civil proceeding is to provide financial compensation for a particular loss occasioned by negligence. Neither a criminal prosecution nor a malpractice action serves the purpose intended by license revocation proceedings. The purpose of such a proceeding is not to punish but to afford protection to the public upon the rationale that respect and confidence of the public is merited by eliminating from the ranks of practitioners those who are dishonest, immoral, disreputable or incompetent. *Fahmy v. Medical Board of California* (1995) 38 Cal.App.4th 810, 817.

11. The import of the phrase "including but not limited to" as set forth in Business and Professions Code section 4301 (previously Bus. & Prof. Code § 4305.5) was considered in *Smith v. State Board of Pharmacy* (1995) 37 Cal.App.4th 229, 246, where the appellate court reasoned:

“The gross negligence designation is simply one of several items that are specified as included for purposes of determining what is unprofessional conduct. The list of items expressly ‘is not limited to’ those specified.”

12. A statute providing “unprofessional conduct includes, but is not limited to” certain enumerated conduct does not mean an overly broad connotation is to be given the term “unprofessional conduct.” Unprofessional conduct is conduct which breaches the rules or ethical code of a profession, or conduct which is unbecoming a member in good standing of a profession. The term “unprofessional conduct” as utilized in a professional disciplinary statute may cover a number of specific acts connected with the practice; but when the statute does not provide that unprofessional conduct is limited to the acts so specified, the terms of the statute should not be constricted so as to defeat the legislative purpose. *Shea v. Board of Medical Examiners* (1978) 81 Cal.App.3d 564, 575.

13. The propriety of a penalty imposed by an administrative agency is a matter resting within the sound discretion of the agency and its decision will not be disturbed unless there has been an abuse of discretion. In reviewing the penalty imposed by an administrative body which is duly constituted to announce and enforce such penalties, neither a trial court nor an appellate court is free to substitute its own discretion in the matter; nor can the reviewing court interfere with the imposition of a penalty by an administrative tribunal because in the court’s own evaluation the penalty appears to be too harsh. However, if the penalty imposed, under all the facts and circumstances, clearly was excessive, this will be deemed an abuse of discretion and the reviewing court is not powerless to act. If reasonable minds might differ as to the propriety of the penalty imposed, this fact serves to fortify the conclusion the administrative body acted within the area of its discretion. *Pegues v. Civil Service Commission* (1998) 67 Cal.App.4th 95, 106-107.

14. The Board’s disciplinary guidelines were duly enacted and are set forth in California Code of Regulations, title 16, section 1760. The guidelines apply generally rather than to a specific case. They were adopted to implement the Pharmacy Law, which is enforced by the Board. The existence and use of the Board’s disciplinary guidelines do not constitute an “underground regulation.” See, *Modesto City Schools v. Education Audits Appeal Panel* (2004) 123 Cal.App.4th 1365, 1381.

15. Respondents’ argument that the factors discussed in July 2001 edition of *The Script* constituted an “underground regulation” was without merit. Complainant did not base its proof on violations of those factors, but instead provided expert testimony to establish that respondents violated the professional standard of care as well as various statutes and a regulation. Respondents’ own expert testified *The Script* did not set professional standards, but simply summarized existing standards. See, Factual Findings 34-40.

Cause Exists to Impose Administrative Discipline

16. Cause exists under Business and Professions Code sections 4301, subdivision (o), 4059.5, subdivision (e) and California Code of Regulations, title 16, section 1761 to

impose administrative discipline against Ko's pharmacy license and to impose administrative discipline against the original pharmacy permit issued to Mariner's pharmacy. The clear and convincing evidence established that between May, 2001 and April, 2002 Ko was the Pharmacist-in-Charge of Mariner's Pharmacy and he failed to make reasonable inquiry into the validity of the physician-patient relationship for more than 6,900 prescriptions Mariner's Pharmacy filled for controlled substances, prescriptions which were written by three licensed California physicians who were unknown to Ko and which were delivered to out-of-state customers.

This conclusion is based on Factual Findings 2, 3, 9-21, 24, 25, 27, 29, 30, 31-40 and 43, and on Legal Conclusions 1-8.

17. Cause exists under Business and Professions Code sections 4301, subdivision (o), 4113, subdivision (b), 4059.5, subdivision (e) and California Code of Regulations, title 16, section 1761 to impose administrative discipline against Ko's pharmacy license. The clear and convincing evidence established that between May, 2001 and April, 2002, Ko was the pharmacist-in-charge of Mariner's Pharmacy, he failed to make reasonable inquiry into the validity of the physician-patient relationship for more than 6,900 prescriptions Mariner's Pharmacy filled for controlled substances, prescriptions which were written by three licensed California physicians who were unknown to Ko and which were delivered to out-of-state customers, and he failed to ensure that the operation of Mariner's Pharmacy complied with state and federal laws.

This conclusion is based on Factual Findings 2, 3, 9-21, 24, 25, 27, 29, 30, 31-40 and 43, and on Legal Conclusions 1-8.

18. Cause exists under Business and Professions Code section 4301, subdivision to impose administrative discipline against Ko's pharmacy license and against the original pharmacy permit issued to Mariner's Pharmacy for general unprofessional conduct. The clear and convincing evidence established that between May, 2001 and April, 2002, Ko was the pharmacist-in-charge of Mariner's Pharmacy, Ko failed to make reasonable inquiry into the validity of the physician-patient relationship for more than 6,900 prescriptions Mariner's Pharmacy filled for controlled substances, the prescriptions which were written by three licensed California physicians who were unknown to Ko, and the prescriptions were delivered to out-of-state customers, conduct constituting general unprofessional conduct.

This conclusion is based on Factual Findings 2, 3, 9-21, 24, 25, 27, 29, 30, 31-40 and 43, and on Legal Conclusions 1-8.

The Appropriate Measure of Discipline

19. In accordance with the Board's disciplinary guidelines, the imposition of a revocation, stayed, with three years probation on appropriate terms and conditions of probation including an actual 30-day suspension of Ko's pharmacist license and an order

directing Ko to reimburse the Board its reasonable costs is appropriate under all the circumstances.

In accordance with the Board's disciplinary guidelines, the imposition of a revocation, stayed, with three years probation on appropriate terms and conditions of probation including an actual 14-day suspension of Mariner Pharmacy's original pharmacy permit and directing Mariner's Pharmacy to make payment of the Board's reasonable costs is appropriate under all the circumstances.

These conclusions are based on all Factual Findings (except Factual Findings 52-54) and on Legal Conclusions 1-18.

Recovery of Costs of Investigation and Prosecution

20. 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 . . . 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)”

21. Cause exists under Business and Professions Code section 125.3 to direct respondents Ko and Mariner's Pharmacy to pay to the Board its reasonable costs of investigation and enforcement in the amount of \$19,500.

This conclusion is based on Factual Findings 52-54 and on Legal Conclusions 16-19 and all Factual Findings referred to in those conclusions.

ORDERS

Pharmacist License No. RPH 43037

Pharmacist License No. RPH 43037 issued to respondent Yung Cheng Ko is revoked; however, the revocation is stayed and respondent is placed on probation for three (3) years upon the following terms and conditions.

1. As part of probation, respondent Yung Cheng Ko (Respondent Ko) shall be suspended from the practice of pharmacy for fifteen (15) days beginning on the effective date of this decision.

During suspension, Respondent Ko shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent Ko shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall Respondent Ko manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent Ko shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent Ko shall not direct or control any aspect of the practice of pharmacy. Respondent Ko shall not perform the duties of a pharmacy technician or an exemptee for any entity licensed by the board. Subject to the above restrictions, Respondent Ko may continue to own or hold an interest in any pharmacy in which he holds an interest at the time this decision becomes effective unless otherwise specified in this order.

2. Within sixty (60) days of the effective date of this decision, Respondent Ko shall enroll in the first available Physician Prescribing Course offered through the PACE program at UCSD, a two and one-half day small group program designed to improve the participant's prescribing behavior by providing education on the legal, biomedical and clinical aspects of prescribing drugs, especially controlled drugs. Respondent Ko shall complete this program during the first year of his probation at his own expense.

3. Respondent Ko shall maintain a separate file of all records pertaining to the acquisition or disposition of all controlled substances.

4. Respondent Ko shall report to the Board the total acquisition and disposition of controlled substances as the Board or its designee may direct. Respondent Ko shall specify the manner of disposition (e.g., by prescription, due to burglary) or acquisition (e.g., from a manufacturer, from another retailer). Respondent Ko shall report the acquisition and disposition of controlled substances on a quarterly basis, or as directed by the Board or its designee. The quarterly report shall be delivered or mailed to the Board no later than ten (10) days following the end of the reporting period.

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

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

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime, discipline, citation, or other administrative action filed by any state and federal agency which involves Respondent's pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

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

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

8. Respondent Ko shall cooperate with the Board's inspection programs and in the Board's monitoring and investigation of the Respondent Ko's and Mariner Pharmacy's compliance with the terms and conditions of his probation. Failure to cooperate shall constitute a violation of probation.

9. Respondent Ko shall provide evidence of his efforts to maintain that level of skill and knowledge required of a licensed pharmacist as directed by the Board.

10. Respondent Ko shall notify all present and prospective employers of the decision in case number 2697 and the terms, conditions and restrictions imposed on Respondent Ko by the decision. Within 30 days of the effective date of this decision, and within 15 days of Respondent Ko undertaking new employment, respondent shall cause his or her direct supervisor, pharmacist in-charge and/or owner to report to the board in writing acknowledging the employer has read the decision in case number 2697.

If Respondent Ko works for or is employed by or through a pharmacy employment service, Respondent Ko must notify the direct supervisor, pharmacist-in-charge, and/or owner at every pharmacy of the and terms and conditions of the decision in case number 2697 in advance of the respondent commencing work at each pharmacy.

“Employment” within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist, whether Respondent Ko is considered an employee or independent contractor.

11. Respondent Ko shall not supervise any intern pharmacist or perform any of the duties of a preceptor. Respondent Ko may be a pharmacist-in-charge; however, Respondent Ko shall retain an independent consultant and his own expense who shall be responsible for reviewing pharmacy operations on a quarterly basis for compliance with state and federal laws and regulations governing pharmacy and for Respondent Ko’s compliance with the obligations of a pharmacist-in-charge. The consultant shall be a California licensed pharmacist and shall not be on probation to the Board. The consultant’s name shall be submitted to the Board for its approval within thirty (30) days of the effective date of this decision. Respondent Ko shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he is not the sole owner.

12. Respondent Ko and Mariner’s Pharmacy shall be jointly and severally liable to pay to the Board its costs of investigation and prosecution in the amount of \$19,500.

Respondent Ko shall make said payments in a manner and at such times as is determined by the Board. If Respondent Ko fails to pay the costs as specified by the Board and on or before the date(s) determined by the Board, the Board shall, without affording Respondent Ko notice and the opportunity to be heard, revoke probation and carry out the disciplinary order that was stayed.

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

14. Respondent Ko shall at all times he is on probation maintain an active current license with the Board, including any period during which suspension or probation is tolled.

If Respondent Ko’s license expires by operation of law or otherwise, upon renewal or reapplication, Respondent Ko’s license shall be subject to all terms of this probation not previously satisfied.

15. Within ten (10) days of a change in employment - either leaving or commencing employment - Respondent Ko shall so notify the Board in writing of the address of his new employer. If Respondent Ko works for or is employed through a pharmacy employment service, Respondent Ko shall provide to the Board or its designee with a work schedule indicating dates and location of employment upon request.

16. If Respondent Ko leaves California to reside or practice outside this state, Respondent Ko must notify the Board in writing of the dates of departure and return within ten (10) days of departure or return. Periods of residency, except such periods where the

Respondent Ko is actively practicing pharmacy within California, or practice outside California shall not apply to reduction of the probationary period.

Should Respondent Ko, regardless of residency, for any reason cease practicing pharmacy in California, Respondent Ko must notify the Board in writing within ten (10) days of cessation of the practice of pharmacy or resuming the practice of pharmacy. "Cessation of practice" means any period of time exceeding thirty (30) days in which Respondent Ko is not engaged in the practice of pharmacy as defined in Business and Professions Code section 4052.

It is a violation of probation for Respondent Ko's probation to remain tolled pursuant to the provisions of this condition for a period exceeding a consecutive period of three (3) years.

Respondent Ko shall not practice pharmacy upon returning to California until notification by the Board the period of suspension has been completed.

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

If a Respondent Ko has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent Ko, and probation shall automatically be extended until all terms and conditions have been met or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty which was stayed.

18. Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the board for surrender. The board shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

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

19. If respondent leaves California to reside or practice outside this state, for any period exceeding 10 days (including vacation), respondent must notify the board in writing

of the dates of departure and return. Periods of residency or practice outside the state - or any absence exceeding a period of 10 days shall not apply to the reduction of the suspension period. Respondent shall not practice pharmacy upon returning to this state until notified by the board that the period of suspension has been completed.

20. Upon successful completion of probation, Respondent Ko's pharmacist license will be fully restored.

*Original Pharmacist Permit No. PHY 39924
Issued to Mariner's Pharmacy*

Permit No. PHY 39924 issued to Respondent Mariner's Pharmacy, is revoked; however, the revocation is stayed and Respondent Mariner's Pharmacy is placed on probation for three (3) years upon the following terms and conditions.

1. As part of probation, Respondent Mariner's Pharmacy is suspended from the operation of pharmacy for fifteen (15) days beginning the effective date of this decision. The period of suspension shall run concurrently with the period of suspension of Yung Cheng Ko.

During suspension, Respondent Mariner's Pharmacy may not order, maintain or dispose of any dangerous drugs or devices or controlled substances. The pharmacy may not make demand or bill for any drugs or services during the period of suspension and may not process any claims for pharmacy services during the period of suspension, except as to services rendered prior to the effective date of the suspension period. The pharmacy shall not receive or transmit any prescription, new or refill, during the period of suspension. The entire pharmacy must be closed during the period of suspension.

2. Respondent Mariner's Pharmacy shall prominently post a suspension notice provided by the Board in a place conspicuous and readable to the public. The suspension notice shall remain so posted during the entire period of actual suspension.

Respondent Mariner's Pharmacy shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person as to the nature of and reason for the closure of the licensed entity.

3. Respondent Mariner's Pharmacy shall maintain a separate file of all records pertaining to the acquisition or disposition of all controlled substances.

4. Respondent Mariner's Pharmacy shall report to the Board the total acquisition and disposition of such controlled substances as the Board or its designee may direct. Respondent Mariner's Pharmacy shall specify the manner of disposition (e.g., by prescription, due to burglary) or acquisition (e.g., from a manufacturer, from another retailer). Respondent Mariner's Pharmacy shall report on a quarterly basis, or as directed by

the Board or its designee. The report shall be delivered or mailed to the Board no later than ten (10) days following the end of the reporting period.

5. Respondent Mariner's Pharmacy shall obey all state and federal laws and regulations substantially related to or governing the practice of pharmacy.

Respondent Mariner's Pharmacy shall report any of the following occurrences to the board, in writing, within 72 hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime discipline, citation, or other administrative action filed by any state and federal agency which involves Respondent Mariner Pharmacy's original pharmacy permit or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

6. Respondent Mariner's Pharmacy shall report to the Board or its designee quarterly. The report shall be made either in person or in writing, as directed. If the final probation report is not made as directed, probation shall be extended automatically until such time as the final report is made.

7. Upon receipt of reasonable notice, Respondent Mariner's Pharmacy's pharmacist-in-charge shall appear in person for interviews with the Board or its designee upon request at various intervals at a location to be determined by the Board or its designee. Failure to appear for a scheduled interview without prior notification to Board staff shall be considered a violation of probation.

8. Respondent Mariner's Pharmacy and its pharmacist-in-charge shall cooperate with the Board's inspection programs and in the Board's monitoring and investigation of the Respondent Mariner's Pharmacy's compliance with the terms and conditions of probation. Failure to cooperate shall be considered a violation of probation.

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

decision are made aware of the terms and conditions by posting a notice, circulating a notice, or both.

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

10. Respondent Mariner’s Pharmacy and Yung Cheng Ko shall be jointly and severally liable to pay to the Board its costs of investigation and prosecution in the amount of \$19,500.

Respondent Mariner’s Pharmacy shall make said payments in a manner and at such times as is determined by the Board. If Respondent Mariner’s Pharmacy fails to pay the costs as specified by the Board and on or before the date(s) determined by the Board, the Board shall, without affording the Respondent Mariner’s Pharmacy notice and the opportunity to be heard, revoke probation and carry out the disciplinary order that was stayed.

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

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

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

If a Respondent Mariner’s Pharmacy has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent Mariner’s Pharmacy, and probation shall automatically be extended until all terms and conditions have been met or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty which was stayed.

14. Following the effective date of this decision, should Respondent Mariner's Pharmacy cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent Mariner's Pharmacy may tender its license to the board for surrender. The board shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent Mariner's Pharmacy will no longer be subject to the terms and conditions of probation.

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

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

16. Respondent Mariner's Pharmacy shall prominently post a suspension notice provided by the board in a place conspicuous and readable to the public. The suspension notice shall remain posted during the entire period of actual suspension. Respondent Mariner's Pharmacy shall not, directly or indirectly, engage in any conduct or make any statement, orally, electronically or in writing, which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person as to the nature of and reason for the closure of the licensed entity.

17. Upon successful completion of probation, Respondent Mariner's Pharmacy's original pharmacy permit will be fully restored.

DATED: 6/13/05



JAMES AHLER
Administrative Law Judge
Office of Administrative Hearings

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

In the Matter of the Accusation Against:

Mariner's Pharmacy
320 Superior, Suite 120
Newport Beach, CA 92663

Yung Cheng Ko, Pharmacist-in-Charge

Original Pharmacy Permit No. PHY 39924

And

Yung Cheng Ko
77 Ashford
Irvine, CA 92618

Pharmacist License No. RPH 43037

Respondent.

Case No. 2697

OAH No. L2004040136

DECISION AND ORDER

The attached Proposed Decision is hereby adopted by the Board of Pharmacy of the Department of Consumer Affairs, as its Decision in the above-entitled matter.

This decision shall become effective on August 12, 2005.

It is so ORDERED on July 13, 2005.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By



STANLEY W. GOLDENBERG
Board President

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8 Attorneys for Complainant

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

11 In the Matter of the Accusation Against:
12
13 MARINER'S PHARMACY
320 Superior, Suite 120
Newport Beach, CA 92663
14 YUNG CHENG KO, Pharmacist-in-Charge

Case No. 2697

A C C U S A T I O N

15 Pharmacy Permit No. PHY 39924

16 and

17 YUNG CHENG KO
77 Ashford
18 Irvine, CA 92618

19 Pharmacist License No. RPH 43037

20 Respondents.

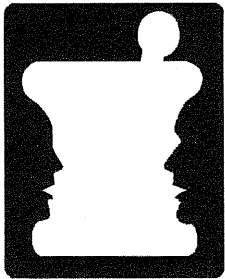
21
22 Complainant alleges:

23 PARTIES

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

27 ///

28 ///



California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
(916) 445-5014



The Pharmacy License of:
Mariner's Pharmacy
has been
SUSPENDED

From 8/12/05 to and including 8/26/05

As a result of proceedings conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code for violations of the California Pharmacy Law.