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

In the Matter of the Accusation Against: **SUNLIT PHARMACEUTICAL INC. DBA PICO PHARMACY, MEI-CHAO LIN, PIC** **2521 W. Pico Blvd.** **Los Angeles, CA 90006** **Pharmacy Permit License No. PHY 44830,** **and** **MEI-CHAO LIN** **6650 Eddinghill Drive** **Rancho Palos Verdes, CA 90275** **Pharmacist License No. RPH 42573** Respondents.	Case No. 5749 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about July 14, 2000, the Board of Pharmacy issued Pharmacy Permit License Number PHY 44830 to Sunlit Pharmaceutical Inc. dba Pico Pharmacy, Mei-Chao Lin, PIC (Respondent Pico). The Pharmacy Permit License was in full force and effect at all times relevant to the charges brought herein and will expire on July 1, 2017, unless renewed.

3. On or about May 24, 1989, the Board of Pharmacy issued Pharmacist License Number RPH 42573 to Mei-Chao Lin (Respondent Lin). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2018, unless renewed.

JURISDICTION

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

5. Section 4300 of the Code states:

"(a) Every license issued may be suspended or revoked.

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

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding one year.

"(4) Revoking his or her license.

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

"(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. The board may issue the license subject to any terms or conditions not contrary to public policy, including, but not limited to, the following:

"(1) Medical or psychiatric evaluation.

"(2) Continuing medical or psychiatric treatment.

"(3) Restriction of type or circumstances of practice.

"(4) Continuing participation in a board-approved rehabilitation program.

"(5) Abstention from the use of alcohol or drugs.

"(6) Random fluid testing for alcohol or drugs.

"(7) Compliance with laws and regulations governing the practice of pharmacy.

"(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions.

"(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

6. Section 4301 of the Code states:

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

"...

"(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, of any other state, or of the United States regulating controlled substances and dangerous drugs.

"...

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

"…"

7. Section 4300.1 of the Code states:

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

8. Section 680 of the Code states:

"(a) Except as otherwise provided in this section, a health care practitioner shall disclose, while working, his or her name and practitioner's license status, as granted by this state, on a name tag in at least 18-point type. A health care practitioner in a practice or an office, whose license is prominently displayed, may opt to not wear a name tag. If a health care practitioner or a licensed clinical social worker is working in a psychiatric setting or in a setting that is not licensed by the state, the employing entity or agency shall have the discretion to make an exception from the name tag requirement for individual safety or therapeutic concerns. In the interest of public safety and consumer awareness, it shall be unlawful for any person to use the title "nurse" in reference to himself or herself and in any capacity, except for an individual who is a registered nurse or a licensed vocational nurse, or as otherwise provided in Section 2800. Nothing in this section shall prohibit a certified nurse assistant from using his or her title.

"(b) Facilities licensed by the State Department of Social Services or the State Department of Public Health shall develop and implement policies to ensure that health care practitioners providing care in those facilities are in compliance with subdivision (a). The State Department of Social Services and the State Department of Public Health shall verify through periodic

inspections that the policies required pursuant to subdivision (a) have been developed and implemented by the respective licensed facilities.

"(c) For purposes of this article, "health care practitioner" means any person who engages in acts that are the subject of licensure or regulation under this division or under any initiative act referred to in this division."

9. Section 4104 subdivisions (a) and (b) of the Code state:

"(a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

"(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

"...."

10. Section 4115 subdivisions (a) and (e) of the Code state:

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

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

"...."

11. Section 4169 subdivision (a) of the Code states:

"(a) A person or entity may not do any of the following:

"(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

"(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

"(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

"(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

"(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

"...."

12. Section 4342 subdivision (a) of the Code states:

"(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law.

"...."

13. Section 11153 subdivision (a) of the Health and Safety Code states:

"(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.

"...."

14. Section 111335 of the Health and Safety Code states:

"Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 commencing with Section 110290)."

15. Section 111355 of the Health and Safety Code states:

"(a) Any drug is misbranded unless its label bears, to the exclusion of any other nonproprietary name except the applicable, systematic chemical name or the chemical formula, all of the following information:

"(1) The established name of the drug, if any.

"...."

16. Section 111340 of the Health and Safety Code states:

"Any drug or device is misbranded unless it bears a label containing all of the following information:

"(a) The name and place of business of the manufacturer, packer, or distributor.

"(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

"Reasonable variations from the requirements of subdivision (b) shall be permitted. Requirements for placement and prominence of the information and exemptions as to small packages shall be established in accordance with regulations adopted pursuant to Section 110380."

17. Section 4307 of the Code states:

"Individuals with Denied, Revoked, Suspended, etc. Licenses Prohibited From Pharmacy Ownership or Association with Board Licensed Entities"

"(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of

any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or 99 placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

"(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

"(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

"(b) "Manager, administrator, owner, member, officer, director, associate, or partner," as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that capacity in or for a licensee.

"(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law."

REGULATIONS

18. Section 1707.2 of title 16 of the California Code of Regulations states:

"(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

"1) upon request; or

"(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

"(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

"(A) whenever the prescription drug has not previously been dispensed to a patient; or

"B) 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.

"...."

19. Section 1707.5 of title 16 of the California Code of Regulations states:

"...

"(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter."

"...."

20. Section 1707.6 of title 16 of the California Code of Regulations states:

"...

"(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches."

21. Section 1714 subdivision (b) of title 16 of the California Code of Regulations states:

"...

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

"...."

22. Section 1718.1 subdivision (b) of title 16 of the California Code of Regulations states:

"All prescription drugs not bearing a manufacturer's expiration date pursuant to Title 21, Code of Federal Regulations, section 211.137 are deemed to have expired and may not be manufactured, distributed, held for sale, or dispensed by any manufacturer, distributor, pharmacist, pharmacy or other persons authorized to dispense such drugs in California."

23. Section 1761 subdivisions (a) and (b) of title 16 of the California Code of Regulations states:

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

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

24. Section 1304.04 subdivision (h) of Title 21 Code of Federal Regulations states:

"...

"(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

"(1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy.

"(2) Paper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescription file.

"(3) Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy.

"(4) Paper prescriptions for Schedules III, IV, and V controlled substances shall be maintained at the registered location either in a separate prescription file for Schedules III, IV, and V controlled substances only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for noncontrolled substances. However, if a pharmacy employs a computer

application for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

"(5) Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of part 1311 of this chapter. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the Administration or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

25. Section 1304.11 subdivision (a) of Title 21 Code of Federal Regulations states:

"(a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

"...."

26. Section 1305.04 subdivision (b) of Title 21 Code of Federal Regulations states:

"(a) Only persons who are registered with DEA under section 303 of the Act (21 U.S.C. 823) to handle Schedule I or II controlled substances, and persons who are registered with DEA under section 1008 of the Act (21 U.S.C. 958) to export these substances may obtain and use DEA Form 222 (order forms) or issue electronic orders for these substances. Persons not registered to handle Schedule I or II controlled substances and persons registered only to import controlled substances are not entitled to obtain Form 222 or issue electronic orders for these substances.

"(b) An order for Schedule I or II controlled substances may be executed only on behalf of the registrant named on the order and only if his or her registration for the substances being purchased has not expired or been revoked or suspended."

COST RECOVERY

27. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG CLASSIFICATIONS

28. Norco 10/325 mg is the brand name for hydrocodone/acetaminophen 10 mg/325 mg and is a dangerous drug pursuant to Business and Professions Code section 4022, and a Schedule III controlled substance pursuant to Health and Safety Code section 11056(e)(4). It is commonly used to treat pain.

29. Oxycontin 30 mg is the brand name for oxycodone 30 mg extended release and is a dangerous drug pursuant to Business and Professions Code section 4022, and a Schedule II controlled substance pursuant to Health and Safety Code section 11055(b)(1)(M). It is commonly used to treat pain.

30. Phenergan/Codeine Syrup 10 mg-6.25 mg/5 mL is the brand name for promethazine/codeine syrup 10 mg-6.25 mg/5 mL and is a dangerous drug pursuant to Business and Professions Code section 4022, and a Schedule V controlled substance pursuant to Health and Safety Code section 11058(c)(1). It is commonly used as a cough suppressant.

31. Soma 350 mg is the brand name for carisoprodol 350 mg and is a dangerous drug pursuant to Business and Professions Code section 4022, and a Schedule IV controlled substance pursuant to the Code of Federal Regulations section 1308.14(c)(6). It is commonly used to treat muscle spasms.

32. Xanax 2 mg is the brand name for alprazolam 2 mg and is a dangerous drug pursuant to Business and Professions Code section 4022, and a Schedule IV controlled substance pursuant to the Health and Safety Code section 11057(d)(1). It is commonly used to treat anxiety.

33. Tylenol #4 is the brand name for Acetaminophen/codeine 60/300 mg and is a dangerous drug pursuant to Business and Professions Code section 4022, and a Schedule III controlled substance pursuant to the Health and Safety Code section 11350(a). It is commonly used to treat pain.

FIRST CAUSE FOR DISCIPLINE

(Availability of Interpretive Services – Against Respondents Pico and Lin)

34. Respondents Pico and Lin are subject to disciplinary action under Business and Professions Code section 4301, subdivisions (j) and(o) in conjunction with title 16 of the California Code of Regulations sections 1707.5 and 1707.6 subdivision (c), which requires that a pharmacy have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label in the patient's language, and every pharmacy must place in a conspicuous and readable place a "Point to Your Language" sign, which offers interpreter services free of cost. The circumstances surrounding these violations are as follows:

35. During an inspection by the Board investigator which commenced on August 05, 2015, Respondents had no "Point to Your Language" sign posted in the pharmacy, and pharmacy staff stated there was no policy and procedure in place to address providing service to patients with limited English proficiency. Further, Respondents did not have a method in place to provide translation services for patients who spoke a language not spoken by pharmacy staff.

SECOND CAUSE FOR DISCIPLINE

(Requirement to Wear Name Badge – Against Respondents Pico and Lin)

36. Respondent Pico and Lin are subject to disciplinary action under Business and Professions Code section 4301, subdivisions (j) and(o) in conjunction with section 680, which requires a health care practitioner to disclose, while working, his or her name and practitioner's

license status, as granted by this state, on a name tag in at least 18-point type. The circumstances surrounding this violation are as follows:

37. During an inspection by the Board investigator which commenced on August 05, 2015, Respondent Lin was not wearing a name badge.

THIRD CAUSE FOR DISCIPLINE

(Drugs Lacking Quality and Strength – Against Respondents Pico and Lin)

38. Respondents Pico and Lin are subject to disciplinary action under Business and Professions Code section 4301, subdivisions (j) and(o) in conjunction with section 4342, which allow the Board to institute any action or actions as may be provided by law and that, in its discretion, that are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law. The circumstances surrounding this violation are as follows:

39. During an inspection by the Board investigator which commenced on August 05, 2015, several bottles of expired drugs were comingled with the pharmacy inventory.

FOURTH CAUSE FOR DISCIPLINE

(Records for Schedule II Controlled Substances to be Stored Separately – Against Respondents Pico and Lin)

40. Respondents Pico and Lin are subject to disciplinary action under Business and Professions Code section 4301, subdivisions (j) and(o) in conjunction with title 21 of the Code of Federal Regulations, section 1304.04 subdivision (h), which requires that inventories and records of all controlled substances listed in Schedule I and II be maintained separately from all other records of the pharmacy and that paper prescriptions for Schedule II controlled substances be maintained at the registered location in a separate prescription file. The circumstances surrounding this violation are as follows:

41. During an inspection by the Board investigator which commenced on August 05, 2015, prescription documents for Schedule II controlled substances were found to be comingled

with prescription documents for Schedule III-V controlled substances and non-controlled substances.

FIFTH CAUSE FOR DISCIPLINE

(Persons Entitled to Order Schedule II Controlled Substances-Against Respondents Pico and Lin)

42. Respondents Pico and Lin are subject to disciplinary action under Business and Professions Code section 4301, subdivisions (j) and(o) in conjunction with title 21 of the Code of Federal Regulations, sections 1305.04 and 1305.05, which require that only persons who are registered with Drug Enforcement Agency (DEA) under section 303 of the Act (21 U.S.C. 823) to handle Schedule I or II controlled substances… may obtain and use DEA Form 222 (order forms) or issue electronic orders for these substances, and that a registrant may authorize one or more individuals to issue orders for Schedule I and II controlled substances by executing a power of attorney for each such individual so long as the power of attorney is retained in the files, with executed Forms 222 for the same period as any order bearing the signature of the attorney. Said power of attorney must be available for inspection together with other order records. The circumstances surrounding this violation are as follows:

43. During an inspection by the Board investigator which commenced on August 05, 2015, four (4) DEA Forms 222 were found pre-signed by Respondent Lin without any other information on the form completed. Respondent Lin signed the forms to allow staff pharmacists to order Schedule II controlled substances in her absence, Respondent Lin was the only DEA registrant at Pico Pharmacy and no other persons had been granted power-of-attorney to order Schedule II controlled substances. No power-of-attorney documentation was found during the inspection.

SIXTH CAUSE FOR DISCIPLINE

(Policy Required to Address Theft, Impairment, Diversion by Licensed Staff – Against Respondents Pico and Lin)

44. Respondents Pico and Lin are subject to disciplinary action under Business and Professions Code section 4301, subdivisions (j) and(o) in conjunction with section 4104 subdivision (a) and (b), which require that the pharmacy have procedures in place for taking

action to protect the public when a licensed individual employed by the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. The pharmacy must further maintain written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy. The circumstances surrounding this violation are as follows:

45. During an inspection by the Board investigator which commenced on August 05, 2015, it was revealed that Respondents Pico and Lin did not have a written policy in place to address theft, impairment, or diversion by licensed staff.

SEVENTH CAUSE FOR DISCIPLINE

(Misbranded Drugs – Against Respondents Pico and Lin)

46. Respondents Pico and Lin are subject to disciplinary action under Business and Professions Code section 4301, subdivisions (j) and(o) in conjunction with California Health and Safety Code sections 111340 and 11355 subdivision (a), which states that all drugs or devices will be deemed misbranded unless it bears a label containing the name and place of business of the manufacturer, packer, or distributor; and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, as well as the established name of the drug, if any. Respondents Pico and Lin are further subject to disciplinary action under title 16 of the California Code of Regulations section 1718.1, which states that all prescription drugs not bearing a manufacturer's expiration date are deemed to have expired and may not be manufactured, distributed, held for sale, or dispensed in California. Finally, Respondents Pico and Lin are subject to disciplinary action under Business and Professions Code section 4169 subdivision (a), which precludes a person or entity from the purchase, trade, sale, or transfer of dangerous drugs that said person knew or reasonably should have known were misbranded. The circumstances surrounding this violation are as follows:

47. During an inspection by the Board investigator which commenced on August 05, 2015, multiple unlabeled and misbranded bottles of drugs were found in the Respondents'

inventory, and it was discovered by investigator that these drugs were pre-counted from larger stock bottles and were being used to fill prescriptions.

EIGHTH CAUSE FOR DISCIPLINE

(Requirement of Pharmacy Technicians to be Licensed by the Board of Pharmacy – Against Respondents Pico and Lin)

48. Respondents Pico and Lin are subject to disciplinary action under Business and Professions Code section 4301, subdivisions (j) and(o) in conjunction with section 4115 which requires that a pharmacy technician only perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting, and while under the direct supervision and control of a pharmacist, and that no person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician. The circumstances surrounding this violation are as follows:

49. During an inspection by the Board investigator which commenced on August 05, 2015, staff member H.G.[1], who was no longer licensed as a pharmacy technician in California, introduced himself to Board inspectors as a pharmacy technician and was observed performing duties of a pharmacy technician including filling prescriptions and selecting drug products from the pharmacy inventory for the purpose of filling prescriptions.

NINTH CAUSE FOR DISCIPLINE

(Pharmacist to Provide Consultation on New Prescriptions-Against Respondents Pico & Lin)

50. Respondents Pico and Lin are subject to disciplinary action under Business and Professions Code section 4301, subdivisions (j) and(o) in conjunction with title 16 of the California Code of Regulations Section 1707.2, which requires that a pharmacist provide oral consultation to his or her patient or agent upon request; or where the pharmacist deems it is warranted, as well as provide oral consultation whenever the prescription drug has not previously been dispensed to a patient; or whenever the dosage form, strength or directions are different. The circumstances surrounding this violation are as follows:

[1] Initials are used in lieu of real names in order to protect the individual's privacy rights.

51. During an inspection by the Board investigator which commenced on August 05, 2015, H.G., an unlicensed pharmacy staff member, provided consultation to two patients for new prescriptions under prescription numbers 1222769, 1222754, and 1222755. Additionally, H.G. provided consultation for prescription numbers 1222762 and 1222763, which had a change of dose and directions from the previous prescriptions. Respondent Lin was present when all five prescriptions were sold; however, Respondent Lin did not offer the patients an opportunity to receive consultation from Respondent Lin, nor did Respondent Lin attempt to initiate consultation.

TENTH CAUSE FOR DISCIPLINE

(Requirements of a DEA Biennial Inventory – Against Respondents Pico and Lin)

52. Respondents Pico and Lin are subject to disciplinary action under Business and Professions Code section 4301, subdivisions (j) and(o) in conjunction with Code of Federal Regulations section 1304.11 subdivision (a), which requires that each inventory contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and be maintained in written, typewritten, or printed form at the registered location, and that the inventory be taken either at the opening or close of business on the inventory date and said information must be indicated on the inventory. The circumstances surrounding this violations are as follows:

53. During an inspection by the Board investigator on August 05, 2015, it was discovered that the DEA Biennial Inventories dated 02/09/2013 and 02/10/2015 did not indicate if they were performed at the opening or closing of business.

ELEVENTH CAUSE FOR DISCIPLINE

(Operational Standards and Security – Against Respondents Pico and Lin)

54. Respondents Pico and Lin are subject to disciplinary action under Business and Professions Code section 4301, subdivisions (j) and(o) in conjunction with title 16 of the California Code of Regulations section 1714, which requires that each pharmacy licensed by the board maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly

prepared, maintained, secured and distributed. The circumstances surrounding this violations are as follows:

55. During an inspection by the Board investigator which commenced on August 05, 2015, its was discovered that between 02/09/2013 and 08/05/2015, Respondents could not account for the loss of the following controlled substances at minimum as identified during a self-audit:

Drug Name and Strength	Amount Short (-) or Amount Over (+): (S) – (T-D)
Acetaminophen with codeine 300/60 mg	**-3,814**
Alprazolam 2 mg	**-93,861**
Hydrocodone/acetaminophen 10/325 mg	**-75,246**
Promethazine with codeine syrup mL	**-314,662 ml or 665 pints**

TWELFTH CAUSE FOR DISCIPLINE

(Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist – Against Respondents Pico and Lin)

56. Respondents Pico and Lin are subject to disciplinary action under section Business and Professions Code section 4301, subdivision (d) in conjunction with 11153 subdivision (a) of the Health and Safety Code in conjunction with title 16 of California Code of Regulations section 1761, which requires that a prescription for a controlled substance be issued for a legitimate medical purposes, and that while the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, a corresponding responsibility rests with the pharmacist who fills the prescription. In addition, no pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration and upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription and 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. The circumstances surrounding this violations are as follows:

57. During an inspection by the Board investigator which commenced on August 05, 2015, it was discovered that from August 6, 2012 to August 6, 2015, Respondent's filled 6,596 prescriptions under the prescribing authority of Drs. Oparah, Wijegoonaratna, Ware, and Ridgill despite the following objective factors indicating prescriptions from these prescribers were not issued in the usual course of professional treatment for a legitimate medical need:

a) The majority of the prescriptions written by the listed prescribers were for commonly abused controlled substances including: Norco, Oxycontin, Phenergan/Codein e Syrup, Soma, Xanax and Tylenol #4.

b) The majority of the prescriptions written by the listed prescribers were purchased using cash.

c) The listed prescribers frequently prescribed the highest available doses of medication.

d) The listed prescribers had prescribing profiles which were seemingly incongruent with their self-reported areas of practice.

OTHER MATTERS

58. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 44830, issued to Sunlit Pharmaceutical Inc. dba Pico Pharmacy, while Mei-Chao Lin (Lin) was acting as the manager, administrator, owner, member, officer, director, associate, or partner of Sunlit Pharmaceutical Inc. dba Pico Pharmacy and had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 44830, issued to Sunlit Pharmaceutical Inc. dba Pico Pharmacy was revoked, suspended or placed on probation, Lin shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 44830 issued to Sunlit Pharmaceutical Inc. dba Pico Pharmacy is placed on probation or until Pharmacy Permit Number PHY 44830, issued to Sunlit Pharmaceutical Inc. dba Pico Pharmacy is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Pharmacy Permit License Number PHY 44830, issued to Sunlit Pharmaceutical Inc. dba Pico Pharmacy, Mei-Chao Lin, PIC

2. Revoking or suspending Pharmacist License Number RPH 42573, issued to Mei-Chao Lin

3. Prohibiting Mei-Chao Lin from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number 44830 issued to Sunlit Pharmaceutical Inc. dba Pico Pharmacy is placed on probation or until Pharmacy Permit Number 44830 issued to Sunlit Pharmaceutical Inc. dba Pico Pharmacy is reinstated if Pharmacy Permit Number 44830 issued to Sunlit Pharmaceutical Inc. dba Pico Pharmacy issued is revoked;

4. Ordering Pico Pharmacy and Mei-Chao Lin to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 2/9/17

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

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