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

In the Matter of the Accusation Against: **PHARM MED SERVICES** **2129 Hacienda Way, Suite J** **Sacramento, CA 95825** **JANIS ELAINE ONG, PIC/PARTNER** **LIGAYA S. SAULER, PARTNER** **Pharmacy Permit No. PHY 43141,** **JANIS ELAINE ONG** **520 Thornley Way** **Sacramento, CA 95864** **Pharmacist License No. RPH 35380,** **and** **LIGAYA SARAO** **8750 Sunset Avenue** **Fair Oaks, CA 95628** **Pharmacist License No. RPH 40744** Respondents.	Case No. 5168 **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 ("Board"), Department of Consumer Affairs.

2. On or about June 20, 1997, the Board issued Pharmacy Permit Number PHY 43141 to Pharm Med Services ("Respondent Pharm Med Services") with Janis Elaine Ong ("Respondent Ong") as pharmacist-in-charge and partner and Ligaya Sarao ("Respondent Sarao") as partner. The pharmacy permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2015, unless renewed.

3. On or about August 12, 1980, the Board issued Pharmacist License Number RPH 35380 to Respondent Ong. The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2015, unless renewed.

4. On or about May 2, 1987, the Board issued Pharmacist License Number RPH 40744 to Respondent Sarao. The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2015, unless renewed.

JURISDICTION

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

STATUTORY AND REGULATORY PROVISIONS

(Statutory Provisions)

6. Code section 4300 states, in pertinent part:

> (a) Every license issued may be suspended or revoked.
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> (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:
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> (1) Suspending judgment.
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> (2) Placing him or her upon probation.
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> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
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> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper . . .

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7. Code section 4300.1 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. Code section 4301 states, in pertinent part:

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

. . . .

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

. . . .

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

. . . .

(*l*) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. . . . .

. . . .

(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 . . . .

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9. Code section 4307 states, in pertinent part:

(a) Any person . . . whose license has been revoked or is 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 . . . revoked, suspended, or 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 . . .

10. Code section 4022 states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a --------," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

11. Code section 4081 states, in pertinent part:

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section . . .

12. Code section 4105 states, in pertinent part:

(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

. . . .

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

. . . .

(e)(1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises . . .

13. Code section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy".

14. Code section 4115 states, in pertinent part:

. . . .

(e) No person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

. . . .

(h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

15. Code section 4332 states:

Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

16. Code section 4333 states, in pertinent part:

(a) All prescriptions filled by a pharmacy and all other records required by Section 4081 shall be maintained on the premises and available for inspection by authorized officers of the law for a period of at least three years. In cases where the pharmacy discontinues business, these records shall be maintained in a board-licensed facility for at least three years.

. . . .

(c)(1) Notwithstanding subdivisions (a) and (b), the board may, upon written request, grant a waiver of the requirement that the records described in subdivisions (a) and (b) be maintained on the licensed premises or, in the event the pharmacy discontinues business, that the records be maintained in a board licensed facility. A person who maintains records in compliance with that waiver is not subject to the penalties set forth in subdivision (b) . . .

17. Code section 4342, subdivision (a), states:

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 (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

18. Health and Safety Code section 110290 states:

In determining whether the labeling or advertisement of a food, drug, device, or cosmetic is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account. The extent that the labeling or advertising fails to reveal facts concerning the food, drug, device, or cosmetic or consequences of customary use of the food, drug, device, or cosmetic shall also be considered.

19. Health and Safety Code section 111330 states that "[a]ny drug or device is misbranded if its labeling is false or misleading in any particular".

20. Health and Safety Code section 111355 states, in pertinent part:

(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 . . .

21. Health and Safety Code section 111440 states that "[i]t is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

22. Title 21, United States Code, section 802 states, in pertinent part:

As used in this title:

. . . .

(27) The term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household . . .

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23. Title 21, United States Code, section 822, states, in pertinent part:

. . . .

(g) Delivery of controlled substances by ultimate users for disposal.

(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this title may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if--

(A) the person receiving the controlled substance is authorized under this title to engage in such activity; and

(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances . . .

(Regulatory Provisions)

24. Title 21, Code of Federal Regulations, section 1300.01 states, in pertinent part:

(a) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802), except that certain terms used in part 1316 of this chapter are defined at the beginning of each subpart of that part.

(b) As used in parts 1301 through 1308 and part 1312 of this chapter, the following terms shall have the meanings specified:

. . . .

Administration means the Drug Enforcement Administration . . .

25. Title 21, Code of Federal Regulations, section 1304.11 states, in pertinent part:

(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.

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(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date . . .

26. Title 21, Code of Federal Regulations, section 1307.21 states, in pertinent part:

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant, he/she shall list the controlled substance or substances which he/she desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his/her area; or

(2) If the person is not a registrant, he/she shall submit to the Special Agent in Charge a letter stating:

(i) The name and address of the person;

(ii) The name and quantity of each controlled substance to be disposed of;

(iii) How the applicant obtained the substance, if known; and

(iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

(b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By delivery to an agent of the Administration or to the nearest office of the Administration;

(3) By destruction in the presence of an agent of the Administration or other authorized person; or

(4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons . . .

27. California Code of Regulations, title 16, section 1714, subdivision (d), states:

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

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28. California Code of Regulations, title 16, section 1718, states:

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

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

COST RECOVERY

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

CONTROLLED SUBSTANCES/DANGEROUS DRUGS

30. "Altace" is a brand of ramipril and a dangerous drug within the meaning of Code section 4022 in that it requires a prescription under federal law.

31. "Salsalate" is a dangerous drug within the meaning of Code section 4022 in that it requires a prescription under federal law.

32. "Cleocin" is a brand of clindamycin and a dangerous drug within the meaning of Code section 4022 in that it requires a prescription under federal law.

33. "Zyprexa" is a brand of olanzapine and a dangerous drug within the meaning of Code section 4022 in that it requires a prescription under federal law.

34. "Invega" is a brand of paliperidone and a dangerous drug within the meaning of Code section 4022 in that it requires a prescription under federal law.

35. "Abilify" is a brand of aripiprazole and a dangerous drug within the meaning of Code section 4022 in that it requires a prescription under federal law.

36. "Clozaril" is a brand of clozapine and a dangerous drug within the meaning of Code section 4022 in that it requires a prescription under federal law.

37. "Lyrica", a brand of pregabalin, is a Schedule V controlled substance as designated by Health and Safety Code section 11058.

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38. "Ambien", a brand of zolpidem tartrate, is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(32).

39. "Klonopin", a brand of clonazepam, is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(7).

BACKGROUND

I. Board Inspection of November 8, 2012:

40. On or about November 8, 2012, Board Inspectors P. and I. went to Pharm Med Services to conduct a routine inspection. There was no sign on the outside of the pharmacy and the door was locked. The inspectors knocked on the door and were let inside. Respondent Sarao ("Sarao") came out of one of the rooms and introduced herself. Sarao told the inspectors that Respondent Ong ("Ong"), their pharmacist-in-charge, was in China until approximately November 23, 2012. The inspectors asked Sarao if the pharmacy provided prescriptions to long term care facilities. Sarao stated that they provided services almost exclusively to board and care homes, that they were a "closed pharmacy" in that the public did not come to the pharmacy to pick up prescriptions, and that their technicians and drivers delivered the prescriptions to the board and care homes. The pharmacy consisted of three small rooms and a bathroom. There was a narrow corridor leading to the back room ("RM1") and it was lined with grocery bags stacked on top of one another. The bags contained filled bubble pack prescriptions.[1]

Unlicensed Practice:

41. Inspector P. observed 3 technicians working in the next room ("RM2"), including pharmacy technician M. G. M. G. was filling bubble packs with drugs. Inspector P. asked the technicians if their licenses were posted. They said yes and pointed to a bulletin board on the wall. Inspector P. noticed that M. G.'s pharmacy technician license had expired (the Board's website showed that M. G.'s license had expired on September 30, 2012). Inspector P. asked Sarao if she had a staff work schedule. Sarao provided Inspector P. with a document entitled "Employee

[1] Bubble packs are multi-dose calendar packs used to dispense medications. Drugs are placed manually into the bubble packs by pharmacy staff and are visible to the user (the drugs are encased in clear "bubbles" backed by a film that is easily punched out).

Hours", which indicated that M. G. was employed as a pharmacy technician and worked from 9:30 a.m. to 6:00 p.m. Inspector P. asked Sarao if M. G. had been working as a technician during her scheduled work shifts and Sarao said yes.

42. Inspectors I. and P. found additional areas of non-compliance during their inspection, including, but not limited to, the following:

Unauthorized Off-Site Storage of Pharmacy Records:

43. Sarao informed Inspectors I. and P. that the pharmacy had a public storage site where they stored most of their records. Inspector P. asked Sarao if she had at least 3 years of records on site at the pharmacy. Sarao said no, then stated that the records were in storage. The inspectors asked Sarao if she had obtained an off-site storage waiver from the Board. Sarao indicated that she did not know about the waiver. The inspectors told Sarao that all of the records that were in storage were to be returned to the pharmacy immediately and that she could submit a request to the Board for the waiver, but had to return all of the records until it was issued.

Failure to Complete DEA Biennial Inventory:

44. The inspectors requested the pharmacy's DEA Biennial Controlled Substance Inventory. Sarao provided the inspectors with her last "inventory paper". The document showed the pharmacy's inventory of Schedule III to V controlled substances only; there were no Schedule II controlled substances listed. The document also did not contain the signature of the pharmacist responsible for the inventory or the date and time the inventory was completed.

Expired, Unlabeled and Partially Labeled Drugs Found in Active Inventory:

45. While inspecting RM2, Inspector P. observed various blue tote bins containing drugs. Inspector P. found multiple expired drugs mixed in with the active drug stock in the bins, and removed the expired drugs and placed them in a white tote. Inspector P. also found a large number of unlabeled, clear, amber vials mixed in with the active drug inventory (the vials contained loose pills). When Inspector P. opened the vials, she noticed, in many instances, that they were filled with the same pills found in the stock bottle contained in the same blue tote. For example, Inspector P. found an unlabeled vial of clindamycin 300 mg capsules and a stock bottle of clindamycin 300 mg capsules in the same tote (Inspector P. compared the markings on the

capsules to verify that they were the same drug). In other blue totes, Inspector P. found unlabeled vials containing tablets she could not identify as well as vials of drugs that were only partially labeled. The inspectors found a vial marked "salsalate 500 mg"; the label did not list the manufacturer, lot number or expiration date of the drug. The inspectors also found a bottle of Altace 2.5 mg which had expired in April 2010. Inspector P. removed some of the drugs from the blue totes and placed them in a brown tote. Inspector P. asked Sarao if this was the area where pharmacy staff pulled drugs to fill prescriptions for patients. Sarao said yes. Inspector P. pulled the rest of the unlabeled or partially labeled drug vials and placed them in a red tote. The inspectors told Sarao that all of the expired drugs and the drugs stored in unlabeled or partially labeled amber vials were to be documented on a log and sent for destruction or return immediately.

II. Follow-Up Inspection of November 13, 2012/Board's Drug Audit:

46. On or about November 13, 2012, Board inspectors P., H., and H. went to Pharm Med Services to conduct a follow up inspection. Sarao and pharmacist K. S. were present at the pharmacy along with several technicians and drivers. The inspectors went into the break room ("RM3") and observed a male subject, later identified as R. S., one of the drivers, pushing bottles into a drawer. R. S. closed the door quickly and left the building. The inspectors opened the drawer and found a large bottle of olanzapine 15 mg as well as multiple unlabeled and partially labeled vials of drugs. On one side of RM3, there were multiple red totes stacked on the floor (some of the totes appeared to contain the pharmacy's current order from Cardinal Health). Other red totes contained bubble packs and open stock bottles of drugs used to fill the bubble packs. In another area of the room, there were multiple bags containing bubble packs of returned drugs (the outside of the bags were marked "return" in black marker), some of which were labeled with the name of a board and care facility. There were more bags in other areas of the room that contained a mixture of returned medication vials and unlabeled and partially labeled vials of drugs.

47. The inspectors noticed several medication lists tacked on the wall. The lists contained the names of various drugs, their National Drug Code, and a description of the drug (color of the tablet and any markings on the tablet). Many of the drugs the inspectors found in the unlabeled

and partially labeled amber vials were included on the lists. The inspectors asked Sarao why pills were being punched out of the returned bubble packs, sorted by individual drug, and placed in the amber vials. Sarao claimed that they were sorting the pills by individual drug and returning the drugs in amber vials as required by their reverse distributor, PharmaLink, Inc. (Inspector P. was informed on February 13, 2013, by a representative of PharmaLink, Inc. that they had never received any drugs from Pharm Med Services in amber vials with just the name on them). The inspectors told Sarao that usually the pills were left in the bubble packs and placed in a Sharps container or other similar container to be sealed and sent for destruction.

48. The inspectors decided to conduct a drug audit to determine whether Pharm Med Services staff were re-using the returned drugs to dispense prescriptions to different patients (patients other than the original user). The inspectors selected 9 drugs that were found on the medication lists and in the unlabeled and partially labeled vials in RM3 (which indicated that they had been punched out of returned bubble packs): Invega 3 mg; Invega 6 mg; Invega 9 mg; Zyprexa 15 mg; olanzapine 15 mg; Zyprexa 20 mg; Abilify 30 mg; Abilify 10 mg; and clozapine 200 mg. The inspectors had M. G. count the number of tablets on hand of each drug; only drugs in the pharmacy's active inventory were counted (none of the drugs found in the bottles or vials in RM3 were included). The inventory of the 9 drugs revealed that all but two of the stock bottles contained more tablets than were designated by the manufacturer (pharmacies that are engaged in re-dispensing previously dispensed medications will often have over-filled manufacturer bottles in their active inventory). The inspectors requested copies of the pharmacy's acquisition records from their 3 wholesalers, Cardinal Health ("Cardinal"), McKesson Pharmaceuticals ("McKesson"), and ParMed Pharmaceuticals ("ParMed"), for the period from January 1, 2012 to November 13, 2012, for each of the 9 drugs. Sarao produced records from Cardinal and McKesson (Sarao stated that she would send the records from ParMed later), but the records were for the wrong time period. [2] The inspectors also requested and obtained copies of the pharmacy's DUR (drug

[2] The inspectors had to clarify which records they needed several times before they received the final acquisition records for McKesson and Cardinal from Pharm Med Services. The inspectors ultimately used the records provided directly by Cardinal, McKesson, and ParMed in their drug audit due to the incomplete acquisition records provided by the pharmacy.

utilization report) records from January 1, 2012 to November 13, 2012 for the 9 audited drugs (DUR reports show the total number of tablets dispensed for a specific drug over a selected time period).

49. Later, Inspector P. asked Sarao where the expired and improperly labeled vials of drugs were that had been removed by the inspectors and placed into totes during the inspection of November 8, 2012. Sarao admitted that the drugs had been taken to their storage unit. Sarao also had not returned the pharmacy records that were stored off site. The inspectors told Sarao to return the drugs to the pharmacy immediately. Sarao told the inspectors that the drugs would be returned within the next hour. Sarao then stated that pharmacy technician P. S. had placed the drugs in the storage unit so Sarao could better "count them to return". The inspectors told Sarao that a technician was not permitted to have unsupervised access to the drugs in the storage unit. Later, the inspectors went through the piles of drugs that had been returned to the pharmacy and examined the returned bubble packs. The inspectors found various controlled substances mixed in with the other drugs, including the controlled substances clonazepam 0.5 mg, zolpidem 10 mg, and Lyrica 50 mg. The inspectors also found expired and unexpired stock bottles of drugs mixed in with the bags of returned bubble packs, including clozapine 200 mg (the expiration date on the bottle was July 2014). A couple of hours later, P. S. arrived at the pharmacy with boxes of drugs that she had retrieved from the storage unit. The inspectors noticed that some of the drugs in the boxes marked for disposal contained drugs that were not expired.

50. On and between December 31, 2012 and May 7, 2013, Inspector P. requested and obtained from ParMed, Cardinal, and McKesson purchase and return records for Pharm Med Services for the period from January 1, 2012 to November 13, 2012, for the 9 drugs audited.

51. On or about February 22, 2013, Inspector P. received a letter from Ong, indicating that the records located in the storage unit were not being moved back to the pharmacy until approximately November 26, 2012.

III. Follow-Up Inspection of March 26, 2013:

52. On or about March 26, 2013, Inspector P. returned to Pharm Med Services to conduct a follow-up inspection. Inspector P. asked Sarao to explain certain inventory discrepancies that

had been identified in the drug audit as of that time. Sarao told Inspector P. that Pharm Med Services had two computer systems and that the inspectors had not received all of the DUR's that were stored on their "old" computer. Inspector P. requested that Sarao print out both the "old" and "new" DUR's for the same date range of January 1, 2012 to November 13, 2012. Sarao produced the records as requested.

IV. Results of the Drug Audit:

53. The audit data and evidence collected during the Board's inspections and investigation revealed that Pharm Med Services dispensed and/or billed for more drugs than they purchased from Cardinal, McKesson, and ParMed, specifically, Zyprexa 15 mg, Zyprexa 20 mg, Invega 9 mg, Invega 6 mg, Abilify 10 mg and Abilify 30 mg, for the time period from January 1, 2012 to November 13, 2012, as summarized in the table set forth below. The audit data also showed that the Pharm Med Services purchased, but could not account for, approximately 2,072 olanzapine 15 mg tablets.

Drug Name	Beginning Inventory[3]	WLS 1 ParMed	WLS 2 McKesson	WLS 3 Cardinal	Purchase or Acquisition Totals	Disposition or DUR totals	Returns	Ending Inventory	Disp. Total	Variance
Zyprexa 15 mg	0	0	60	90	150	2911	0	153	3064	-2914
Zyprexa 20 mg	0	0	150	120	270	2884	0	47	2931	-2661
Olanzapine 15 mg	0	10190	0	120	10310	8194	0	44	8238	2072
Invega 3 mg	0	0	150	480	630	665	0	63	728	-98
Invega 9 mg	0	0	1530	1620	3150	3473	0	33	3506	-356
Invega 6 mg	0	0	660	960	1620	1947	0	66	2013	-393
Abilify 10 mg	0	0	1560	1680	3240	3870	0	83	3953	-713
Abilify 30 mg	0	0	2490	2850	5340	6110	0	33	6143	-803
Clozapine 200 mg	0	16200	1400	2900	20500	24242	0	54	24296	-3796

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[3] The inspectors conducted a zero-based audit since they did not have a beginning inventory of the pharmacy's active inventory. While zero-based audits are generally not effective in determining small losses or small inventory discrepancies, they are effective or useful in determining significant inventory discrepancies.

FIRST CAUSE FOR DISCIPLINE

(Substantially Related Criminal Conviction)

54. Respondents Ong, and Sarao are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (*l*), in that Respondents both were convicted of a criminal charge substantially related to the practice of pharmacy as follows:

a. On or about December 11, 2014, in the Sacramento County Superior Court case entitled *People v. Ligaya Sarao and Janis Elain Ong*, case number 14F03930, Respondents Sarao and Ong were convicted upon each of their pleas of no contest to one count each of violating Health and Safety Code section 111440. The circumstances are that between approximately January 1, 2012, and November 13, 2012, Respondents unlawfully sold, delivered, held, or offered for sale drugs that were misbranded.

SECOND CAUSE FOR DISCIPLINE

(Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

55. Respondents Pharm Med Services, Ong, and Sarao are subject to disciplinary action pursuant to Code section 4301, subdivision (f), for unprofessional conduct, in that Respondents committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption, as follows:

a. On and between January 1, 2012 and November 13, 2012, Respondents re-used various dangerous drugs, including, but not limited to, Zyprexa 15 mg, Zyprexa 20 mg, Invega 9 mg, Invega 6 mg, Abilify 10 mg and Abilify 30 mg, that were returned to the pharmacy by board and care facilities, in order to re-dispense the drugs to different patients.

b. On and between January 1, 2012 and November 13, 2012, Respondents failed to account for approximately 2,072 tablets of olanzapine 15 mg tablets, as set forth above.

c. On or about November 8, 2012 and November 13, 2012, Respondents had in their active drug inventory vials of medications or pills whose labels were false or misleading in that the vial labels did not contain the name of the drug, manufacturer, strength, lot number and/or expiration date. Consequently, the drugs were misbranded.

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THIRD CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and Federal and State Laws and Regulations Governing Pharmacy)

56. Respondents Pharm Med Services, Ong, and Sarao are subject to disciplinary action pursuant to Code section 4301, subdivision (o), for unprofessional conduct, in that Respondents violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.) and federal and state laws and regulations governing pharmacy, as follows:

a. On or about November 8, 2012 and November 13, 2012, Respondents had in their active drug inventory various expired drugs, a large number of unlabeled vials of drugs, and partially labeled vials of drugs whose labels were false or misleading in that the labels did not contain the name of the drug, manufacturer, strength, lot number and/or expiration date, in violation of Code section 4342. Further, Respondents had in their active drug inventory overfilled stock bottles of drugs and as a result thereof, the actual lot number and expiration date of the drugs were unclear.

b. On and between January 1, 2012, and November 13, 2012, Respondents unlawfully sold, delivered, held, or offered for sale drugs that were misbranded as identified in paragraph 55, subparagraph (a), above, and by doing so violated Health and Safety Code section 111440.

c. On or about November 8, 2012, Respondents failed to have a current, complete and/or accurate DEA Biennial Inventory of all stocks of controlled substances on hand at the pharmacy in that the inventory provided to Board Inspector C. did not list or show the pharmacy's stock of Schedule II controlled substances and did not contain the signature of the pharmacist responsible for the inventory or the date and time the inventory was completed, in violation of Title 21, Code of Federal Regulations, section 1304.11, subdivision (a).

d. On or about November 8, 2012, Respondents failed to maintain on their premises and have available for inspection by the Board's inspectors all records or other documentation of sale, acquisition, and/or disposition of dangerous drugs and devices in a readily retrievable form, in violation of Code sections 4081, 4105, and 4333. Further, Respondents stored their pharmacy

records in an off-site storage unit without obtaining a waiver from the Board, and failed to return the records to the pharmacy until approximately November 26, 2012, despite the inspectors' request to return the records immediately.

e. On or about November 8, 2012, Respondents authorized or permitted M. G. to act in the capacity as a pharmacy technician, including filling bubble packs with drugs, while her pharmacy technician license was expired or invalid, in violation of Code section 4115.

f. On or about November 13, 2012, Respondents failed to maintain or ensure the security of the prescription department and/or include provisions for effective control against theft or diversion of dangerous drugs and devices in that Respondents allowed dangerous drugs to be stored at the public storage unit, and authorized or permitted pharmacy technician P. S. to have unsupervised access to the drugs, in violation of California Code of Regulations, title 16, section 1714, subdivision (d).

g. On or about November 13, 2012, Respondents received delivery of previously dispensed controlled substances from facilities or ultimate users that were intended for disposal, including, but not limited to, clonazepam 0.5 mg, zolpidem 10 mg, and Lyrica 50 mg when, in fact, Respondents were not authorized to dispose of the controlled substances, in violation of Title 21, United States Code section 822 and Title 21, Code of Federal Regulations, section 1307.21.

h. On and between January 1, 2012 and November 13, 2012, Respondents failed to maintain accurate or complete records of sale, acquisition, or disposition of their stock of dangerous drugs, failed to maintain a current or accurate drug inventory, and failed to demonstrate complete accountability of their inventory, in violation of Code sections 4081, subdivision (a), and 4332 and California Code of Regulations, title 16, section 1718.

FOURTH CAUSE FOR DISCIPLINE

(Violations of U.S. Statutes Regulating Controlled Substances)

57. Respondents are subject to disciplinary action pursuant to Code section 4301, subdivision (j), for unprofessional conduct, in that on or about November 13, 2012, Respondents violated United States Code section 822, as set forth in subparagraph 56 (g) above.

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OTHER MATTERS

Respondent Janis Elaine Ong

58. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 35380, issued to Respondent Janis Elaine Ong, Janis Elaine Ong shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner for any licensee during the time the discipline is imposed.

59. Respondent Janis Elaine Ong had knowledge of and/or knowingly participated in the acts or omissions alleged above constituting grounds for discipline against Respondent Pharm Med Services.

60. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 43141, issued to Pharm Med Services, Respondent Janis Elaine Ong shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner for any licensee during the time the discipline is imposed.

Respondent Ligaya Sarao

61. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 40744, issued to Respondent Ligaya Sarao, Ligaya Sarao shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner for any licensee during the time the discipline is imposed.

62. Respondent Ligaya Sarao had knowledge of and/or knowingly participated in the acts or omissions alleged above constituting grounds for discipline against Respondent Pharm Med Services.

63. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 43141, issued to Pharm Med Services, Respondent Ligaya Sarao shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner for any licensee during the time the discipline is imposed.

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PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 43141, issued to Pharm Med Services;

2. Revoking or suspending Pharmacist License Number RPH 35380, issued to Janis Elaine Ong;

3. Prohibiting Janis Elaine Ong from serving as a manager, administrator, owner, member, officer, director, associate, or partner for any licensee during the time the discipline is imposed on Pharmacist License Number RPH 35380, issued to Janis Elaine Ong, and/or Pharmacy Permit Number PHY 43141, issued to Pharm Med Services;

4. Revoking or suspending Pharmacist License Number RPH 40744, issued to Ligaya Sarao;

5. Prohibiting Ligaya Sarao from serving as a manager, administrator, owner, member, officer, director, associate, or partner for any licensee during the time the discipline is imposed on Pharmacist License Number RPH 40744, issued to Ligaya Sarao and/or Pharmacy Permit Number PHY 43141, issued to Pharm Med Services;

6. Ordering Pharm Med Services, Janis Elaine Ong, and Ligaya Sarao 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;

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

DATED: 4/5/15

Virginia Herold

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

SA2014115497