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

IN THE MATTER OF THE FIRST AMENDED ACCUSATION AGAINST: **KYFFIN PHARMACY, INC.,** **MIRA ZIFFERN, PRESIDENT** **DOING BUSINESS AS** **KYFFIN'S PHARMACY** 6000 WOODMAN AVE. VAN NUYS, CA 91401 ORIGINAL PHARMACY PERMIT NO. PHY 46023; **AND** **WAYNE HAJIME FUJITAKI** 2012 VANDERBILT LANE #1 REDONDO BEACH, CA 90278 ORIGINAL PHARMACIST LICENSE NO. RPH 31483 **AND** **GENE KIM** 4541 ALCORN DRIVE LA CANADA, CA 91011 ORIGINAL PHARMACIST LICENSE NO. RPH 43406 RESPONDENTS.	Case No. 3161 **FIRST AMENDED ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about July 15, 2002, the Board of Pharmacy issued Original Pharmacy Permit No. 46023 to KYFFIN PHARMACY, INC., to do business as KYFFIN PHARMACY, located at 6000 Woodman Avenue, in the city of Van Nuys. (Respondent Pharmacy). Corporate officer of record since date of issuance is MIRA ZEFFREN, President of Kyffin Pharmacy Incorporated, and holder of a majority ownership of Kyffin Pharmacy Incorporated. The Original Pharmacy Permit was in full force and effect at all times relevant to the charges herein and will expire on July 1, 2009, unless renewed.

3. On or about August 29, 1977, the Board of Pharmacy issued Original Pharmacist License Number RPH 31483 to WAYNE HAJIME FUJITAKI (Respondent Fujitaki). The Original Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on August 31, 2010, unless renewed.

4. The **Pharmacist in charge** of Respondent Pharmacy between April 1, 2006 and at all times charged in the Accusation through December 31, 2008 was Respondent Fujitaki.

5. On or about July 23, 1990, the Board of Pharmacy issued Original Pharmacist License Number RPH 43406 GENE KIM (Respondent Kim). The Original Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on January 31, 2010, unless renewed.

6. The **Pharmacist in charge** of Respondent Pharmacy beginning on January 1, 2009 and at all times charged in the Accusation after that date, was Respondent Kim.

JURISDICTION

7. The original Accusation in this matter was filed by the Board of Pharmacy (Board) on or about July 17, 2008, and served to Respondents July 28, 2008, who thereafter filed their timely Notice of Defense.

8. This First Amended Accusation is brought before the Board under the authority of the following sections of the Business and Professions Code (Code).

9. Section 4300 of the Code permits the Board to take disciplinary action to suspend or revoke a license issued by the Board.

10. Section 118, subdivision (b), of the Code provides that the expiration of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

11. Section 4076 of the Code states:

"(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of certified nurse midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1., the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in

Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11)(A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

"(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose

medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

"(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052,

"(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000), the Nursing Practice Act (Chapter 6 (commencing with Section 2700), or the Vocational Nursing Act (Chapter 6.5 (commencing with Section 2840), who is acting within his or her scope of practice."

12. Section 4081 of the Code states:

"(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

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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.

"(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 exemptee, for maintaining the records and inventory described in this section.

"(c) The pharmacist in charge or exemptee shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist in charge or exemptee had no knowledge, or in which he or she did not knowingly participate."

13. Section 4113 of the Code states:

"(a) Every pharmacy shall designate a pharmacist-in-charge and within 30 days thereof, shall notify the Board in writing of the identity and license number of that pharmacist and the date he or she was designated.

"(b) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

14. 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 procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

"(c) Gross negligence.

. . . .

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

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 804) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

. . . .

(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."

15. Section 4333 of the Code states, in pertinent part, that 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.

16. Section 4342 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 (Part 5 (commencing with section 109875) of Division 104 of the Health and Safety Code).

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321.

17. 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."

18. California Code of Regulations, title 22, section 72371, subdivision (c), subsection (1) states:

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"(c) Patient's drugs supplied by prescription which have been discontinued and those which remain in the facility after discharge of the patient shall be destroyed by the facility in the following manner:

(1) Drugs listed in Schedules II, III or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 shall be destroyed by the facility in the presence of a pharmacist and a registered nurse employed by the facility. The name of the patient, the name and strength of the drug, the prescription number, the amount destroyed, the date of destruction and the signatures of the witnesses required above shall be recorded in the patient's health record or in a separate log. Such log shall be retained for at least three years.

19. Health and Safety Code section 111255 states:

"Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."

20. Health and Safety Code section 111340 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.

21. Section 125.3 of the Code provides, 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.

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DRUG CLASSIFICATIONS

22. Aricept is a brand name of the drug Donepezil and is a dangerous drug per Business and Professions Code section 4022. It is used in treatment of Alzheimer's disease.

23. Ambien is a brand name of the drug Zolpidem and is a Schedule IV controlled substance per Health and Safety code section 11057 (d) (32) and a dangerous drug per Business and Professions Code section 4022. It is used in treatment of insomnia.

24. Ativan is a brand name of the drug Lorazepam and is a Schedule IV controlled substance per Health and Safety code section 11057 (d)(16) and a dangerous drug per Business and Professions Code section 4022. It is used in treatment of anxiety and/or to cause sedation.

25. Klonopin is a brand name of the drug Clonazepam and is a Schedule IV controlled substance per Health and Safety code section 111057(d)(7) and a dangerous drug per Business and Professions Code section 4022. It is used as a sedative.

26. Clozaril is a brand name of the drug Clozapine and is a dangerous drug per Business and Professions Code section 4022. It is an antipsychotic medication, used in treatment of severe psychiatric disorders.

27. Darvocet N100 is a brand name of the drug Propoxyphene Napsylate with Acetaminophen and is a Schedule IV controlled substance per Health and Safety code section 11057(c)(2) and a dangerous drug per Business and Professions Code section 4022. It is used for narcotic pain relief.

28. Flomax is a brand name of the drug Tamsulosin and is a dangerous drug per Business and Professions Code section 4022. It is used in treatment of urinary obstruction and prostrate problems.

29. Procrit is a brand name of the drug Epoetin Alpha and is a dangerous drug per Business and Professions Code section 4022. It is used in treatment of anemia, and requires refrigeration.

30. Restoril is a brand name of the drug Temazepam and is a Schedule IV controlled substance per Health and Safety code Section 11057(d)(29) and a dangerous drug per Business and Professions Code section 4022. It is used in treatment of insomnia.

31. Zyprexa is a brand name of the drug Olanzapine and is a dangerous drug per Business and Professions Code section 4022. It is an antipsychotic medication, most often used in treatment of schizophrenia.

SUMMARY OF FACTS

32. The following facts are common to all charges of the First Amended Accusation:

a. Respondent Pharmacy is a large, closed door pharmacy operation, having about 70 - 75 employees and serving a large patient population (an estimated '5,000 beds') of mostly elderly residents of approximately 50 assisted living and skilled nursing facilities or similar institutions in Los Angeles, Ventura and Orange counties.

b. Some of the medications distributed by Respondent Pharmacy are dispensed in the form of 'bubble' or 'punch' cards[1], also sometimes called 'bubble packs', which Respondent Pharmacy creates at its facility.

FIRST BOARD INSPECTION - OCTOBER 2007

c. On or about **October 23, 2007**, in follow-up to an anonymous complaint, a Board investigator visited Respondent Pharmacy and initiated a 'selected' audit limited to the drug Procrit. The audit period was from January 1, 2007 through November 15, 2007. The audit revealed that during the audit period, Respondent Pharmacy had dispensed at least 4006 more units of the drug Procrit than the pharmacy could account for purchasing:

DRUG	STOCK ON HAND ESTIMATE	AMOUNT PURCHASED	AMOUNT DISPENSED	CREDITS/ RETURNS	DIFFERENCE
Procrit	**99**	**5197**	**9445**	**143**	[(5197 + 143) – 9445 = 4105] [4105–99=4006] **4006**[2]

[1] "Bubble" or "punch" cards, also called "bubble packs", are small plastic or paper cards on which multiple dosages of a medication are stored in indentations or 'bubbles' on the surface of the card. Each single dose is secured behind a film of paper (typically foil) which must be broken to retrieve the medication.

[2] The '4006' figure was calculated as follows: Records show that Respondent pharmacy had purchased 5197 units of the drug Procrit during the audit period, but had dispensed 9445

(continued...)

d. The Board inspector further determined that Respondents failed to maintain all records of sale, acquisition and disposition of the drug Procrit for three years, as required by statute.

SECOND BOARD INSPECTION - AUGUST 2008

e. On or about **August 14, 2008,** in follow-up to a second anonymous complaint, a Board inspector made an unannounced inspection of Respondent Pharmacy to investigate allegations that Respondents were improperly retrieving and repackaging unused portions of drugs previously dispensed to patients at skilled nursing facilities and similar institutions.

f. During the August 14, 2008 inspection, for which Respondent Fujitaki was present, a Board inspector observed work tables with hundreds of unlabeled capsules and tablets which had been sorted into 'Dixie' type paper cups and vials, rather than requisite USP containers, without requisite labeling, and without sufficient information to permit requisite labeling (drug name, strength, lot number, expiration date). The Inspector also observed a great deal of trash, including trash bags at the tables full of returned partial or empty 'bubble' or 'punch' cards.

g. During the August 14, 2008 inspection, when questioned by the Board Inspector, Respondent Fujitaki admitted that drugs on the work tables were being prepared by employees of Respondent Pharmacy for reuse and redispensing to other patients. At that time, the Inspector discussed improper practices related to processing returned drugs which she had observed with both Respondent Fujitaki and Respondent Pharmacy officer Mira Zeffren. The Board Inspector also issued a written notice dated August 14, 2008, which Respondent Fujitaki received and signed.

h. Analysis of samples of drugs taken from unlabeled paper cups on the work tables at the August 14, 2008 inspection showed controlled substances, including a large quantity (65 tablets) of the drug Clonazepam (brand name: Klonopin Clonazepam), and popular, costly prescriptions drugs, including Zyprexa, Flomax, Aricept and Lasix.

(...continued)
units, at least 4105 more units of the drug than the pharmacy could account for purchasing. Even reducing the 4006 total by 99 units ("stock on hand" per a count taken on October 23, 2007), Respondents show a discrepancy of at least 4006 units.

i. In a written statement submitted shortly after the August 14, 2008 inspection, Respondent Fujitaki admitted[3] that pharmacy technicians at Respondent Pharmacy routinely removed drugs from punch cards then sorted the drugs into irregular containers, without proper labeling, as observed by the Board's inspector on August 14, 2008, for the specific purpose of returning the drugs to inventory to be redispensed to other patients.

CA DHCS FINDS $7,986,497. 00 IN UNSUPPORTED BILLINGS - MARCH 2009

j. The California Department of Health Case Services ("DHCS"), pursuant to Welfare and Institutions code section 14124.2 and 14170 and 22 California Code of Regulations section 51021, monitors and has the authority to investigate companies receiving Medi-Cal payments for patient services.

k. On or about October 8, 2008, DHCS investigators initiated an audit of inventory, billing and other pertinent records of Respondent Pharmacy focusing on four medications frequently dispensed by Respondent Pharmacy, including Procrit. The time period selected for the audit was July 1, 2005 through June 31, 2008.

l. A DHCS inspector who made an unannounced visit to Respondent Pharmacy on October 24, 2008 noted that the pharmacy work area was untidy and appeared dirty, and that walkways were cluttered with totes, merchandise and miscellaneous business related materials.

m. On or about February 27, 2009, Respondent Kyffin, by and through corporate president Mara Zeffren, was issued formal notice of DHCS findings that its investigators had identified problems with Respondent Pharmacy's Medi-Cal billing procedures. Specifically, DHCS found that Respondent was unable to show documents or records supporting its Medi-Cal billings for the four drugs during the audit period (July 1, 2005 through June 31, 2008) and determined that Respondent Pharmacy had been overpaid $7, 986,497.00. Repayment was demanded within 60 days.

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[3] The referenced statement was dated August 19, 2008.

n. Of the nearly 8 million dollars in Medi-Cal billings during the audit period which DHCS found could not be supported by Respondent Pharmacy, $6,959,656.00 of that sum was billed for Procrit.

o. The statutory time period within which Respondent is permitted to appeal the DHCS findings closed on or about March 31, 2009. Title 22, California Code Regulations section 51022.

p. On or about April 24, 2009 Senior Counsel for DHCS issued a written notice to the effect that DHCS had entered into a monetary settlement with Kyffin Pharmacy, Inc. As a component of that agreement, Kyffin agreed to pay funds in compliance with the audit demand.

EXECUTION OF SEARCH WARRANT - APRIL 2009

q. On April 8, 2009, Board inspectors assisted California Department of Justice (Bureau of Medi-Cal Frauds) agents during execution of a search warrant at Kyffin Pharmacy.

r. On April 8, 2009, Board inspectors immediately checked work tables in the area of the pharmacy where (in August of 2008) a Board inspector previously observed hundreds of unlabeled capsules and tablets separated into 'Dixie' type paper cups and vials. Inspectors found evidence that substantially similar activity was continuing and in progress in that area of the Pharmacy, including several large brown trash bags filled with partial or empty 'bubble' or 'punch' cards. It appeared that workers at Respondent Pharmacy were in the process of removing drugs from punch cards, then sorting the drugs into irregular containers, without proper labeling. Inspectors found two cardboard boxes, one of which contained hundreds of unlabeled capsules and tablets in small 'ziplock' type plastic bags without requisite labeling, and without sufficient information to permit requisite labeling (drug name, strength, lot number, expiration date).

s. Board inspectors found another box stored beneath a desk in a different location of Respondent Pharmacy, filled with tablets and capsules sorted into 'ziplock' plastic bags without requisite labeling, and without sufficient information to permit requisite labeling (drug name, strength, lot number, expiration date). At least one of the plastic bags was attached with rubber bands to an overfilled manufacturer's container.

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t. In an area of Respondent Pharmacy identified as the pharmacist's dispensing area, Board inspectors found two medication bubble cards which had been dispensed with incorrect medications and returned to Respondent pharmacy from two different facilities:

1) Prescription 4040152 (filled by Respondent Pharmacy on 4-2-2009). The prescription was for Temazepam 30 mg; it had been erroneously filled with Temazepam 15 mg;

2) Prescription 6399550 (filled by Respondent Pharmacy on 3-31-2009). The prescription was for Clozapine 25 mg; it had been erroneously filled with Clozapine 100 mg.

FIRST CAUSE OF DISCIPLINE
(Sale of Contaminated or Nonconforming Pharmaceuticals)

33. RESPONDENT PHARMACY and RESPONDENT FUJITAKI are subject to discipline for unprofessional conduct as defined in section 4301(j) and (o) in conjunction with section 4342 and Health and Safety code section 111255, for sale of pharmaceuticals that lack quality, based on the following:

a. During a Board inspection on or about August 14, 2008, Respondent Pharmacy was found to be preparing hundreds of unlabeled capsules and tablets in 'Dixie' type paper cups and vials, rather than USP containers, and which were not properly labeled (with drug name, strength, expiration date) for reuse and redispensing to other patients.

b. Work spaces in Respondent Pharmacy were dirty, cluttered and untidy.

c. Analysis of samples of drugs taken from unlabeled paper cups on the work tables at the August 14, 2008 inspection showed a large quantity (65 tablets) of the drug Klonopin, an illegally returned controlled substance.

d. In a written statement submitted shortly after the August 14, 2008 inspection, Respondent Fujitaki admitted[4] that pharmacy technicians at Respondent Pharmacy routinely removed drugs from punch cards then sorted the drugs into irregular containers, without proper labeling, as observed by the Board's inspector on August 14, 2008, for the specific purpose of returning the drugs to inventory to be redispensed to other patients.

[4] The referenced statement was dated August 19, 2008.

SECOND CAUSE OF DISCIPLINE
(Sale of Contaminated or Nonconforming Pharmaceuticals)

34. RESPONDENT PHARMACY and RESPONDENT KIM are subject to discipline for unprofessional conduct as defined in section 4301(j) and (o) in conjunction with section 4342 and Health and Safety Code section 111255, for sale of pharmaceuticals that lack quality, based on the following:

a. Allegations of paragraph 33 above are realleged as though fully set forth.

b. Respondent Kim assumed responsibility for pharmacy operations as pharmacist-in-charge on or about January 1, 2009.

c. Despite warnings from the Board after the August 2008 inspection about improper conduct related to processing returned drugs (including but not limited to a written notice dated August 14, 2008), Respondent Pharmacy was found to be engaged in substantially similar reprocessing activity at the time of a subsequent inspection (coinciding with execution of a search warrant) on April 8, 2009, by reason of the following:

1) In the same work area where Board inspectors previously observed drugs sorted for reuse into 'Dixie' cups described above, Inspectors saw several large brown trash bags filled with partial or empty 'bubble' or 'punch' cards. Workers at Respondent Pharmacy were in the process of removing drugs from punch cards, then sorting the drugs into small 'ziplock' type plastic bags without requisite labeling, and without sufficient information to permit requisite labeling (drug name, strength, lot number, expiration date).

2) Board inspectors found a box in which an unlabeled 'ziplock' plastic bag filled with tablets was attached with rubber bands to the outside of an overfilled manufacturer's container. The box also contained additional unlabeled 'ziplock' plastic bags with sorted drugs.

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THIRD CAUSE OF DISCIPLINE
(Incorrectly Labeled Prescription Bottle)

35. RESPONDENT PHARMACY and RESPONDENT KIM are subject to discipline for unprofessional conduct as defined in section 4301(j) and (o) and section 4076(a)(7) requiring that a prescription container must be labeled with the correct strength of the medication dispensed, in that, per evidence obtained by Board inspectors, that on or about March 31, 2009 and April 2, 2009, Kyffin Pharmacy dispensed incorrectly labeled medications as follows:

a. **Prescription 4040152** (dispensed on 4-2-2009) - The prescription was for Temazepam 30 mg; it had been erroneously filled by Respondent Pharmacy with Temazepam 15 mg.

b. **Prescription 6399550** (dispensed on 3-31-2009) - The prescription was for Clozapine 25 mg; it had been erroneously filled by Respondent Pharmacy with Clozapine 100 mg.

FOURTH CAUSE FOR DISCIPLINE
(Unprofessional Conduct - Gross Negligence)

36. RESPONDENT PHARMACY, RESPONDENT FUJITAKI and RESPONDENT KIM are subject to discipline for unprofessional conduct as defined in section 4301(j) and (o) in conjunction with section 4342 and Health and Safety code section 111255 for gross negligence, in that in and about April of 2008 and again in April of 2009, Respondent Pharmacy adopted and/or engaged in routine practices for recovering and sorting previously dispensed medications for reuse and redispensing to other patients, which could potentially cause harm or injury to consumers, as described more fully in paragraphs 33, 34 and 35 above, as follows:

RESPONDENT PHARMACY and RESPONDENT FUJITAKI:

a. Respondents' practice in or about August of 2008 of sorting previously dispensed medications for reuse and redispensing to other patients into 'Dixie' type paper cups and vials which were not labeled (with drug name, strength, expiration date, lot number) was grossly negligent in that these Respondents:

1) Failed to insure that medications to be returned to stock for redispensing were correctly sorted by drug type, strength expiration date(s), and lot number;

2) Failed to assure proper storage of medications to reasonably insure that consumers of medication dispensed by the pharmacy would receive medications which conform to standards and tests as to quality and strength;

3) Prepared and/or stored medications in cluttered and unsanitary conditions inviting contamination.

RESPONDENT PHARMACY and RESPONDENT KIM:

b. Respondents' practice in or about April of 2009 of sorting previously dispensed medications for reuse and redispensing to other patients into plastic 'ziplock' type bags which were not labeled (with drug name, strength, expiration date, lot number) was grossly negligent in that these Respondents:

1) Failed to insure that medications to be returned to stock for redispensing were correctly sorted by drug type, strength, expiration date(s) and lot number;

2) Failed to assure proper storage of medications to reasonably insure that consumers of medication dispensed by the pharmacy would receive medications which conform to standards and tests as to quality and strength;

3) Prepared and/or stored medications in cluttered and unsanitary conditions inviting contamination;

4) Failed to change or correct pharmacy practices after substantially similar reprocessing activity was cited in a written notice from the Board in or about August of 2008.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Compromise of a Charge of Violation)

37. RESPONDENT PHARMACY, is subject to discipline for unprofessional conduct as defined in section 4301(m) for entering into a cash compromise of a charge in violation of provisions of the California Welfare and Institutions Code related to the Medi-Cal program, in two separate instances, in 2007-2008, and 2009, as follows:

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a. 2007-2008 re-payment

On or about December 13, 2007, Respondent Kyffin paid the Department of Health Care Services $350,000. in cash, based on Respondent's review of its records and determination, prompted by the Board's October 2007 inspection, that Kyffin had received an estimated $757,000. or a 40% excess reimbursement from its Medi-Cal billings. Kyffin volunteered to repay a total amount of $757,000. through DHCS to the Medi-Cal program, in a series of payments, to be completed by April 30, 2008.

b. 2009 settlement

(1) On or about October 8, 2008, DHCS investigators initiated an audit of inventory, billing and other pertinent records of Respondent Pharmacy focusing on four medications (including Procrit). The time period selected for the audit was July 1, 2005 through June 31, 2008.

(2) On or about February 27, 2009, Respondent Kyffin, was issued formal notice of DHCS findings that Respondent was unable to show documents or records supporting its Medi-Cal billings for the four drugs during the audit period and determined that Respondent Pharmacy had been overpaid $7,986,497.00. Repayment was demanded within 60 days.

(3) On or about April 24, 2009 Senior Counsel for DHCS issued a written notice to the effect that DHCS had entered into a monetary settlement with Kyffin Pharmacy, Inc. As a component of that agreement, Kyffin agreed to pay funds in compliance with the audit demand.

SIXTH CAUSE FOR DISCIPLINE
(Illegal Returns of Controlled Substances)

38. RESPONDENT PHARMACY and RESPONDENT FUJITAKI are subject to discipline for unprofessional conduct as defined in section 4301(j) and (o) in conjunction with 22 California Code of Regulations Section 72371(c)(1) and 72371(d)(1), prohibiting return of Schedule IV controlled substances to the issuing pharmacy, in that during a Board inspection on or about August 14, 2008, Respondent Pharmacy was found to be in possession of, and preparing for redispensing, 65 tablets of Clonazepam 0.5 mg that has been returned illegally from a skilled nursing facility.

SEVENTH CAUSE FOR DISCIPLINE
(Failure to Maintain Complete and Current Records of Drug Transactions)

39. RESPONDENT PHARMACY and RESPONDENT FUJITAKI are subject to discipline for unprofessional conduct as defined in section 4301(j) and (o) in conjunction with section 4081(a), section 4333 and 16 California Code of Regulations Section 1718 for failure to maintain complete and current inventory records related to drug inventories and distribution, in that Respondents dispensed at least 4006 more units of the drug Procrit than the pharmacy has records of acquiring, per an audit by Board inspectors of inventory records between January and November of 2007, as follows:

a. Commencing on January 1, 2007, a selected drug audit was performed by a Board inspector for the drug Procrit. The audit period was from January 1, 2007 through November 15, 2007, and revealed that Respondent pharmacy had purchased 5197 units of the drug Procrit during that period, but had dispensed 9445 units, at least 4105 more units of the drug than the pharmacy could account for purchasing. Even reducing the 4006 total by 99 units ("stock on hand" per a count taken on October 23, 2007), Respondents show a discrepancy of at least 4006 units, as follows:

DRUG	STOCK ON HAND ESTIMATE	AMOUNT PURCHASED	AMOUNT DISPENSED	CREDITS/ RETURNS	DIFFERENCE
Procrit	**99**	**5197**	**9445**	**143**	[(5197 + 143)– 9445 = 4105] [4105–99=4006] **4006**

b. Respondents failed to maintain all records of sale, acquisition and disposition of the drug Procrit for the required three year time period.

OTHER MATTERS

40. Business and Professions Code section 4307(a) provides, in pertinent part, that any person 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 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 placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a license.

PRAYER

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

1. Revoking or suspending Original Pharmacy Permit No. PHY 46023, issued to KYFFIN PHARMACY, INC., to do business as KYFFIN'S PHARMACY;

2. Revoking or suspending Original Pharmacist License No. RPH 31483issued to WAYNE HAJIME FUJITAKI;

3. Revoking or suspending Original Pharmacist License No. RPH 43406 issued to GENE KIM.

4. Ordering Respondents 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;

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

DATED: Sept 10, 2009

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

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