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

In the Matter of the Accusation Against: **WAYNE FUJITAKI** 2012 Vanderbilt Lane #1 Redondo Beach, CA 90278 Pharmacist License No. RPH 31483 **GENE KIM** 4541 Alcorn Drive LaCanada, CA 91011 Pharmacist License No. RPH 43406 Respondent.	Case No. 3161

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on May 26, 2010.

It is so ORDERED on April 26, 2010.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By Kenneth H. Schell

KENNETH H. SCHELL
Board President

EDMUND G. BROWN JR.
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GREGORY J. SALUTE
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Attorneys for Complainant

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

In the Matter of the First Amended Accusation Against: **WAYNE HAJIME FUJITAKI** 2012 Vanderbilt Lane #1. Redondo Beach, CA 90278 **Pharmacist License No. RPH 31483,** **and** **GENE KIM** 4541 Alcorn Drive LaCanada, CA 91011 **Pharmacist License No. RPH43406** Respondents.	Case No. 3161 OAH No. L2009080678 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

Parties hereby agree to the following Stipulated Settlement and Disciplinary Order which will be submitted to the Board for approval and adoption as the final disposition of the First Amended Accusation solely with respect to Respondents WAYNE HAJIME FUJITAKI and GENE KIM.[1]

[1] First Amended Accusation case no. 3161 was previously resolved as against Respondent Kyffin Pharmacy (Original Pharmacy Permit No. PHY 46023). Respondents Fujitaki and Kim are the only remaining Respondents.

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy. She brought this action solely in her official capacity and is represented in this matter by Edmund G. Brown Jr., Attorney General of the State of California, by Susan Melton Wilson, Deputy Attorney General.

2. Respondent Wayne Hajime Fujitaki (Respondent Fujitaki) is represented in this proceeding by Law Offices of McGuire Woods, by attorneys Herbert Weinberg and Noah Jussim, at 1800 Century Park East, 8th floor, Los Angeles, CA 90067. On or about August 29, 1977, the Board of Pharmacy issued Pharmacist License No. RPH 31483 to Wayne Hajime Fujitaki. The Pharmacist License was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 3161 and will expire on August 31, 2010, unless renewed.

3. Respondent Gene Kim (Respondent Kim) is also represented in this proceeding by Law Offices of McGuire Woods, by attorneys Herbert Weinberg and Noah Jussim, at 1800 Century Park East, 8th floor, Los Angeles, CA 90067. On or about July 23, 1990, the Board of Pharmacy issued Pharmacist License No. RPH 43406 to Gene Kim. The Pharmacist License was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 3161 and will expire on January 31, 2010, unless renewed.

JURISDICTION

4. First Amended Accusation No. 3161 was filed before the Board of Pharmacy (Board) Department of Consumer Affairs, and is currently pending against Respondents. The First Amended Accusation and all other statutorily required documents were properly served on Respondents on September 16, 2009. Respondents timely filed his Notice of Defense contesting the First Amended Accusation. A copy of First Amended Accusation No. 3161 is attached as **Exhibit A** and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in First Amended Accusation No. 3161. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order.

6. Respondent Fujitaki and Respondent Kim, and each of them, are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be represented by counsel at their own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

7. Respondents Fujitaki and Kim, and each of them, voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent Fujitaki understands the allegations and charges of First Amended Accusation No. 3161 and agrees that, at hearing, Complainant could establish a prima facie case for the causes for discipline against him. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up his right to contest the causes for discipline of the First Amended Accusation.

9. Respondent Fujitaki agrees that his Pharmacist License is subject to discipline and he agrees to be bound by the Board of Pharmacy's imposition of discipline as set forth in the Disciplinary Order below.

10. Respondent Kim understands the allegations and charges of First Amended Accusation No. 3161 and agrees that, at hearing, Complainant could establish a prima facie case for the causes for discipline against him. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up his right to contest the causes for discipline of the First Amended Accusation.

11. Respondent Kim agrees that his Pharmacist License is subject to discipline and he agrees to be bound by the Board of Pharmacy's imposition of discipline as set forth in the Disciplinary Order below.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondents, and each of them, understand and agree that they may not withdraw this agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

13. All parties understand and agree that facsimile copies of this Stipulated Settlement and Disciplinary Order, including facsimile signatures thereto, shall have the same force and effect as the originals.

14. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement.

It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 31483 issued to Respondent WAYNE HAJIME FUJITAKI is revoked; however, revocation is stayed and Respondent is placed on probation for four (4) years, subject to the terms and conditions listed below.

IT IS FURTHER ORDERED that Pharmacist License No. RPH 43406, issued to GENE KIM is revoked; however, revocation is stayed and Respondent is placed on probation for three (3) years, subject to the terms and conditions listed below.

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment

- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacy license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his

probation. Failure to cooperate shall be considered a violation of probation.

5. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 3161 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 3161, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 3161 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he has read the decision in case number 3161

and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board. Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

9. Status of License

Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

10. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

11. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent

shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

12. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of forty (40) hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of forty(40) hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and must further notify the board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least forty (40) hours, as defined by Business and Professions Code section 4000 et seq . "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least forty (40) hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

13. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

14. Ethics Course

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five days after completing

15. Tolling of Suspension

If respondent leaves California to reside or practice outside this state, or for any periods exceeding ten (10) days (including vacation), respondent must notify the board in writing of the dates of departure and return. Periods of residency or practice outside the state or any absence exceeding a period of ten days shall not apply to the reduction of the suspension period. In the event of such an absence, respondent shall not act as a pharmacist upon returning to this state until notified by the board that the period of suspension has been completed.

16. Remedial Education

Within ninety (90) days of the effective date of this decision, respondent shall submit to

the board or its designee, for prior approval, an appropriate program of remedial education related to record keeping, drug handling and storage, drug stocking and repackaging. The program of remedial education shall consist of at least Fifteen (15) hours, which shall be completed within first two years of probation at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at his or her own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

17. Violation of Probation

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

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a

violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

18. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

19. Suspension – Respondent Fujitaki

As part of probation, Respondent Wayne Hajime Fujitaki is suspended from the practice of pharmacy for One Hundred and Twenty (120) Days beginning the effective date of this decision. During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

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Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

20. Reimbursement of Board Costs – Respondent Fujitaki

As a condition precedent to successful completion of probation, Respondent Wayne Hajime Fujitaki shall pay to the board its costs of investigation and prosecution in the amount of Four Thousand, Eighty Dollars $ 4,080.00. Respondent shall make said payments on a quarterly basis, or in accord with a payment plan approved by the Board. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his responsibility to reimburse the board its costs of investigation and prosecution.

21. Community Services Program – Respondent Fujitaki

Within sixty (60) days of the effective date of this decision, Respondent Wayne Hajime Fujitaki shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least Two Hundred and Forty (240) hours to be completed during the first three and a half (3 ½) years of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. A record of this notification must be provided to the board upon request. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

22. Community Services Program – Respondent Kim

Within sixty (60) days of the effective date of this decision, Respondent Gene Kim shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least Seventy Five (75) hours to be completed during the first two years of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. A record of this notification must be provided to the board upon request. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

ACCEPTANCE BY RESPONDENT FUJITAKI

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Herbert Weinberg. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

WAYNE HAJIME FUJITAKI
Respondent

I have read and fully discussed with Respondent Wayne Hajime Fujitaki the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

Law Office of McGuire Woods
By: HERBERT WEINBERG
Attorney for Respondent

22. Community Services Program – Respondent Kim

Within sixty (60) days of the effective date of this decision, Respondent Gene Kim shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least Seventy Five (75) hours to be completed during the first two years of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. A record of this notification must be provided to the board upon request. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

ACCEPTANCE BY RESPONDENT FUJITAKI

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Herbert Weinberg. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12/17/09

WAYNE HAJIME FUJITAKI
Respondent

I have read and fully discussed with Respondent Wayne Hajime Fujitaki the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12/17/09

Law Office of McGuire Woods
By: HERBERT WEINBERG
Attorney for Respondent

I have read and fully discussed with Respondent Wayne Hajime Fujitaki the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

Law Office of McGuire Woods
By: NOAH E. JUSSIM
Attorney for Respondent

ACCEPTANCE BY RESPONDENT KIM

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Herbert Weinberg. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12/16/09

GENE KIM
Respondent

I have read and fully discussed with Respondent Gene Kim the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12/17/09

Law Office of McGuire Woods
By: HERBERT WEINBERG
Attorney for Respondent

I have read and fully discussed with Respondent Wayne Hajime Fujitaki the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12/16/09

Law Office of McGuire Woods
By: NOAH E. JUSSIM
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 12-22-09

Respectfully Submitted,

EDMUND G. BROWN JR.
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General

SUSAN MELTON WILSON
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 3161

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California State Board of Pharmacy

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

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