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

In the Matter of the Accusation Against: **FVS HOLDINGS, INC. DBA UNIVERSITY SPECIALTY PHARMACY; SCOT SILBER; NANCY SILBER; SCOTT SCHUMAKER; GLEN TRUITT** **3328 Garfield Avenue** **Commerce, CA 90040** **Pharmacy Permit No. PHY 50160** and **RONALD YUAN** **2620 Fairfield Place** **San Marino, CA 91108** **Pharmacist License No. RPH 36525** **LAUREN FALLIERAS** **12920 Dickens St.** **Studio City, CA 91604** **Pharmacist License No. RPH 65381** Respondents.	Case No. 4688 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RONALD YUAN ONLY**

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 at 5:00 p.m. on October 14, 2016.

It is so ORDERED on September 14, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

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 Kamala

D. Harris, Attorney General of the State of California, by Shawn P. Cook, Deputy Attorney General.

2. Respondent Ronald Yuan ("Respondent") is represented in this proceeding by attorney Noah E. Jussim Esq., whose address is: Noah E. Jussim Esq., Hinshaw & Culbertson LLP; 11601 Wilshire Blvd., Suite 800; Los Angeles, CA 90025.

3. On or about August 18, 1981, the Board of Pharmacy issued Pharmacist License Number RPH 36525 to Respondent. Respondent was Pharmacist-in-Charge (PIC) at Respondent University Specialty Pharmacy from June 13, 2011 to March 5, 2012. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2016, unless renewed.

JURISDICTION

4. Accusation No. 4688 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondent. The First Amended Accusation ("Accusation") and all other statutorily required documents were properly served on Respondent on April 14, 2016. Respondent timely filed his Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 4688 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 4688. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at his own expense; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his 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.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 4688, if proven at a hearing, constitute cause for imposing discipline upon his Pharmacist License.

10. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up his right to contest those charges.

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

RESERVATION

12. The admissions made by Respondent herein are only for the purposes of this proceeding, or any other proceedings in which the Board of Pharmacy or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees 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, Respondent understands and agrees that he may not withdraw his 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.

14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

15. 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.

16. 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 36525 issued to Respondent Ronald Yuan is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

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 contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime

- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacist 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.

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6. **Notice to Employers**

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 4688 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 4688, 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 4688 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 4688 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. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $5329. Respondent shall make said payments on 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.

9. **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.

10. **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.

11. **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.

12. **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.

13. **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.

14. **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.

15. **Completion of Probation**

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

16. **Restricted Practice**

Respondent's practice of pharmacy shall be restricted to not compounding drugs until he has completed the required remedial education. Respondent shall submit proof satisfactory to the board of compliance with this term of probation.

17. **Remedial Education**

Within ninety 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 pharmacy compounding. The program of remedial education shall consist of at least fifteen hours, which shall be completed within one year 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 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.

18. **Supervised Practice**

The provisions of this Section 18 shall not apply regarding Respondent's work as a staff

pharmacist at either of Kedren Psychiatric Hospital Pharmacy, HSP 46765, or Prime Pharmacy Services, PHY 48954, where Respondent represents and warrants that no compounding is done. Should that situation change at either pharmacy, where compounding is done at some future time, then the below Section 18 shall apply as to continued employment by Respondent at such pharmacy where compounding is done. Should Respondent accept work at any other pharmacy, then this Section 18 shall apply as to his employment at such pharmacy, as follows:

During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, respondent shall not practice pharmacy and his license shall be automatically suspended until a supervisor is approved by the board or its designee. The supervision shall be, as required by the board or its designee, either:

Continuous – At least 75% of a work week

Substantial - At least 50% of a work week

Partial - At least 25% of a work week

Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Within thirty (30) days of the effective date of this decision, respondent shall have his supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number 4688 and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure that his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

If respondent changes employment, it shall be the respondent's responsibility to ensure that his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Respondent shall have his new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number 4688 and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and his license

shall be automatically suspended until the board or its designee approves a new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

Within ten (10) days of leaving employment, respondent shall notify the board in writing.

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 controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, 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.

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.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Noah E. Jussim Esq. 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: 4/19/2016

RONALD YUAN
Respondent

I have read and fully discussed with Respondent FVS Holdings, Inc. dba University Specialty Pharmacy; Scot Silber; Nancy Silber; Glen Truitt; Ronald the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 4/19/16

Noah E. Jussim, Esq.
Attorney for Respondent

ENDORSEMENT

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

Dated: 4/19/16

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
MARC D. GREENBAUM
Supervising Deputy Attorney General

SHAWN P. COOK
Deputy Attorney General
Attorneys for Complainant

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Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs. On or about August 16, 2010, the Board of Pharmacy (Board) issued Pharmacy Permit Number PHY

50160 to FVS Holdings, Inc. (FVS) dba University Specialty Pharmacy; Scot Silber. President and CEO; Nancy Silber, Treasurer/CFO; Scott Schumaker, COO; and Glen Truitt, Secretary (Respondent USP). The Pharmacy Permit will expire on August 1, 2014, unless renewed.

2. On or about August 18, 1981, the Board of Pharmacy issued Pharmacist License Number RPH 36525 to Ronald Yuan (Respondent Yuan). Yuan was Pharmacist-in-Charge (PIC) at Respondent USP from June 13, 2011 to March 5, 2012. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2014, unless renewed.

3. On or about April 12, 2011, the Board of Pharmacy issued Pharmacist License Number RPH 653815 to Lauren L. Fallieras (Respondent Fallieras). Fallieras was Pharmacist-in-Charge (PIC) at Respondent USP from March 5, 2012 to the present. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2014, unless renewed.

4. FVS Holdings, Inc. is the parent company for GreenValleyMed (GVM) located in Henderson, NV and also is the parent company for Physicians Sales and Service (PSS) located in Fullerton, CA.

5. Neither GVM nor PSS are licensed by the Board or the Nevada Board of Pharmacy. FVS is not licensed by the Nevada Board of Pharmacy.

JURISDICTION

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

7. Section 118 subd. (b), of the Code provides that the suspension/ expiration/ surrender/ cancellation of a license shall not deprive the Board/Registrar/Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

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8. Section 475 of the Code states:

"(a) Notwithstanding any other provisions of this code, the provisions of this division shall govern the denial of licenses on the grounds of:

"(4) Commission of any act which, if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.

"(b) Notwithstanding any other provisions of this code, the provisions of this division shall govern the suspension and revocation of licenses on grounds specified in paragraphs (1) and (2) of subdivision (a) ."

9. Section 480 states, in pertinent part:

"(a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:

"(3) Done any act which if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.

"The board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions or duties of the business or profession for which application is made."

10. Section 4022 of the Code states

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

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

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

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

11. Section 4300 of the Code states:

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

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

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

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

"(4) Revoking his or her license.

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

12. 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:

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

. . . .

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

. . . .

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

"(p) Actions or conduct that would have warranted denial of a license.

. . . .

13. Section 4033 of the Code states in pertinent part:

(a) (1) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer."

14. Section 4115 subd. (f)(1) of the Code provides in pertinent part:

"(f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs."

15. Section 4161 subd. (a) of the Code provides in pertinent part:

"(a) A person located outside this state that (1) ships, sells, mails, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler."

16. Section 4169 subd. (a) of the Code provides in pertinent part:

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

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

17. California Code of Regulations, title 16, section 1735.2 subd. (h) provides in pertinent part:

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs

or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

18. California Code of Regulations, title 16, section 1735.3 states:

"(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.

(7) The equipment used in compounding the drug product.

(8) A pharmacy assigned reference or lot number for the compounded drug product.

(9) The expiration date of the final compounded drug product.

(10) The quantity or amount of drug product compounded."

19. California Code of Regulations, title 16, section 1751.1 subd. (b)(6) states:

"(b) In addition to the records required by section 1735.3 and subdivision (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be made and kept by the pharmacy:

(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results."

20. California Code of Regulations, title 16, section 1751.3 subd. (b) provides that for any pharmacy engaged in compounding sterile injectable drug products:

"(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist."

21. California Code of Regulations, title 16, section 1751.7 subd. (a)(4) provides:

"(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

(4) Written justification of the chosen expiration dates for compounded sterile injectable products. that for any pharmacy engaged in compounding sterile injectable drug products. "

22. California Code of Regulations, title 16, section 1751.7 subd. (c) provides that for any pharmacy engaged in compounding sterile injectable drug products:

"(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens."

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

24. DRUG CLASSIFICATIONS:

BRAND NAME	GENERIC NAME	B&P 4022 DANGER DRUG	H&S Code CONTROLLED SUBSTANCE	INDICATIONS FOR USE
Ascorbic Acid	Ascorbic Acid	Yes	No	Vitamin C supplement
Hylenex	Hyaluronidase	Yes	No	Enzyme for Inflammation
Depo Testosterone	Testosterone Cypionate	Yes	H&S Code sec. 11056(f)(30)	Hormone Replacement Therapy
Depo Provera	Medroxyprogsterone	Yes	No	Birth Control injection
Depo Medrol	Methylprednisolone	Yes	No	Injectable steroid for inflammation

Decadron	Dexamethasone	Yes	No	Injectable steroid for inflammation
Methionine	Methionine	No	No	To stabilize aqueous suspensions with pH controlling effect
Advate	antihemophilic factor (recombinant) plasma/albumin-free	Yes	No	Hemophilia
Humate-P	antihemophilic factor viii/von willebrand factor (human)	Yes	No	Hemophilia
Kogenate FS	antihemophilic factor viii (recombinant)	Yes	No	Hemophilia
Prograf	tacrolimus	Yes	No	Immunosuppressant
Lupron Depot	leuprolide acetate	Yes	No	Endometriosis

FIRST CAUSE FOR DISCIPLINE

(Pharmacist to Pharmacy Technician Ratio-Against Respondents USP and Yuan)

25. Respondents USP and Yuan are each subject to disciplinary action under section 4115 subd. (f)(1), which states that a pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The circumstances are that on January 24, 2012 at USP's premises on Garfield Ave., Commerce, CA, Respondent Yuan was the only pharmacist present supervising the two pharmacy technicians inside the clean room in which pharmacy technician William Brown was weighing chemicals for compounding and pharmacy technician Tran H. Dinh was compounding inside the laminar flow hood. This is a violation of pharmacy law.

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SECOND CAUSE FOR DISCIPLINE

(Sterile Injectable Quality Assurance- Against Respondents USP and Yuan)

26. Respondents USP and Yuan are subject to disciplinary action under 16 California Code of Regulations (CCR) section 1751.7 subd. (4), which states that any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following: (4) Written justification of the chosen expiration dates for compounded sterile injectable products. The circumstances of the violation are that on January 24, 2012 at USP's premises on Garfield Ave. Commerce, CA, pharmacist-in-charge Yuan had no written justification to extend the Beyond Use Date (BUD) listed on the USP label to a date greater than what USP's Medisca Master Formulas stated for the following drugs:

DRUG	USP's Medisca Master Formula	USP BUD Labeling	RPH Sign off
Ascorbic Acid 500 mg/ml	14 days	180 days on 11/28/11 to 5/27/12	Fallieras
Ascorbic Acid 500 mg/ml	14 days	180 days on 11/30/11 to 5/29/12	Yuan
Hyaluronidase	35 days	90 days on 1/18/12 to 4/17/12	Fallieras
Testosterone Cyp 200 mg/ml	30 days	180 days on 12/1/11 to 5/30/12	Yuan
Medroxyprogsterone 150 mg/ml	14 days	180 days on 11/15/11 to 5/14/12	Yuan
Methylprednisolone	14 days	180 days on 12/27/11 to 6/26/12	Yuan
Dexamethasone 4 mg/ml	14 days	180 days on 1/19/12 to 7/8/12	Yuan

THIRD CAUSE FOR DISCIPLINE

(Sterile Injectable Recordkeeping Requirements- Against Respondents Yuan and Fallieras)

27. Respondents Yuan and Fallieras are subject to disciplinary action under 16 California Code of Regulations (CCR) section 1751.3 subd. (b), which states that the ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist. The circumstances are that on January 24, 2012, at USP's premises located at Garfield Avenue in Commerce, pharmacist Ronald Yuan and pharmacist Lauren Fallieras signed off on the following compounded drugs without reviewing and comparing the USP's Medisca Master Formulas provided by PIC Yuan to the Formula Worksheets-Compound Assist that were completed by the technicians and as a result, the pharmacist did not review the preparation records with mislabeled beyond use dates:

DRUG	USP's Medisca Master Formula	USP BUD Labeling	RPH Sign off
Ascorbic Acid 500 mg/ml	14 days	180 days on 11/28/11 to 5/27/12	Fallieras
Ascorbic Acid 500 mg/ml	14 days	180 days on 11/30/11 to 5/29/12	Yuan
Hyaluronidase	35 days	90 days on 1/18/12 to 4/17/12	Fallieras
Testosterone Cyp 200 mg/ml	30 days	180 days on 12/1/11 to 5/30/12	Yuan
Medroxyprogsterone 150 mg/ml	14 days	180 days on 11/15/11 to 5/14/12	Yuan
Methylprednisolone	14 days	180 days on 12/27/11 to 6/26/12	Yuan
Dexamethasone 4 mg/ml	14 days	180 days on 1/19/12 to 7/8/12	Yuan

FOURTH CAUSE FOR DISCIPLINE

(Sterile Injectable Compounding Quality Assurance- Against Respondents USP and Yuan)

28. Respondents USP and Yuan are subject to disciplinary action under 16 California Code of Regulations (CCR) section 1751.7 subd. (c), which states that batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to

documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. The circumstances are that , on January 24, 2012 at University Specialty Pharmacy located at 3328 Garfield Avenue in Commerce, pharmacist-in-charge Ronald Yuan did not have end product testing for sterility and pyrogen testing on the batch compounded drugs from non-sterile ingredients which were not quarantined but released for the following batched drugs: ascorbic acid compounded on November 28 and 30, 2011; hyaluronidase compounded on January 8, 2012; testosterone cypionate compounded on December 11, 2011; medroxyprogesterone compounded on November 15, 2011; methylprednisolone compounded on December 27, 2011 and dexamethasone compounded on January 9, 2012. This is a violation of pharmacy law.

FIFTH CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements- Against Respondents USP and Yuan)

29. Respondents USP and Yuan are subject to disciplinary action under 16 California Code of Regulations (CCR) section 1735.2 subd. (h), which states that every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This beyond use date (BUD) of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist. The circumstances are that on January 24, 2012, at USP's premises on Garfield Avenue in Commerce, CA, pharmacist-in-charge Ronald Yuan signed off on a testosterone cypionate 200 mg/ml batch compounded on December 11, 2011, in which the ingredient benzyl benzoate USP/NF was recorded to expire in March 2012, but the finished product was given 180 days expiration and labeled to expire on May 30, 2012. Additionally, Respondent Yuan signed off on a medroxyprogesterone 150 mg/ml batch compounded on November 28, 2011 in which the ingredient polyethylene glycol 3350 was recorded to expire in January 2012 but the finished

product was given 180 days expiration and labeled to expire on May 14, 2012. This is a violation of pharmacy law.

SIXTH CAUSE FOR DISCIPLINE

(Sterile Injectable Recordkeeping Requirements- Against Respondents USP and Yuan)

30. Respondents USP and Yuan are subject to disciplinary action under 16 California Code of Regulations (CCR) section 1751.3 subd. (b) which states the ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist and as it relates to the California Code of Regulations Section 1751.1(b)(6) which states in addition to the records required by section 1735.3 and subdivision (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be made and kept by the pharmacy: (6) preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results. Specifically, on January 24, 2012 at USP's premises in Commerce, CA, Respondent Yuan, the PIC, maintained and provided the USP Formula Worksheet-Compound Assist and Medisca Master Formula records but failed to review the compounding instructions for the medroxyprogesterone 150 mg batch on January 22, 2011 that listed the chemical ingredient methionine on both records but omitted the methionine ingredient in the compounding instructions. This is a violation of pharmacy law.

SEVENTH CAUSE FOR DISCIPLINE

(Manufacture- Against Respondent USP)

31. Respondent USP is subject to disciplinary action under Business and Professions Code sec. 4033 subd. (a)(1) that defines "Manufacturer" to include every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer. The circumstances are that on January 24, 2012 at USP's premises located on Garfield Avenue in Commerce, CA, USP received orders for compounded drugs from an unlicensed out of state broker, GreenValleyMed (GVM) located in Henderson, NV and its partner, Physician Sales & Services (PSS). PSS sales representatives would send physician orders for compounded

dangerous drugs to GVM as the "supplier". GVM brokered the sales of compounded dangerous drugs manufactured by USP, for which the compounding orders are not patient specific and were invoiced, billed and payments collected separately directly from the supplier, GVM, that split the profits 50/50 with PSS. This is a violation of pharmacy law.

EIGHTH CAUSE FOR DISCIPLINE

(Prohibited Acts- Against Respondent USP)

32. Respondent USP is subject to disciplinary action under Business and Professions Code sec. 4169 subd. (a)(1) that states a person or entity may not do any of the following: (1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy. The circumstances are that on January 24, 2012, at its premises on Garfield Avenue in Commerce, CA, UPS manufactured compounded medication orders for sterile injectable drugs for GVM located in Henderson, NV. GVM was not licensed as a wholesaler or pharmacy in either Nevada or California. This is a violation of pharmacy law.

NINTH CAUSE FOR DISCIPLINE

(Prohibited Acts- Against Respondent USP)

33. Respondent USP is subject to disciplinary action under Business and Professions Code sec. 4169 subd. (a)(1) that states a person or entity may not do any of the following: (1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the Board as a wholesaler or pharmacy. The circumstances are that from in or about February 2010 to January 2011, at its premises on Garfield Avenue in Commerce, California, USP received dangerous drugs, including Advate, Humate-P, Kogenate FS, Prograf and Lupron Depot from an unlicensed out -of--state entity, Green Valley Med Pharmacy, as follows:

Invoice #	**Invoice Date**	**Invoice #**	**Invoice Date**	**Invoice #**	**Invoice Date**
		5080752	2/23/2010	5083815	3/15/2010
5083913	3/16/2010	5085149	3/23/2010	5086663	4/1/2010
5087571	4/7/2010	5087932	4/9/2010	5088156	4/12/2010
5088171	4/12/2010	5089801	4/22/2010	5137351	1/20/2011
5137317	1/20/2011	5133187	1/20/2011	5133197	1/20/2011

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 50160, issued to FVS Holdings, Inc. dba University Specialty Pharmacy; Scot Silber. President and CEO; Nancy Silber, Treasurer/CFO; Scott Schumaker, COO; and Glen Truitt, Secretary;

2. Revoking or suspending Pharmacist License Number RPH 36525, issued to Ronald Yuan;

3. Revoking or suspending Pharmacist License Number RPH 65381, issued to Lauren Fallieras;

4. Ordering University Specialty Pharmacy; Ronald Yuan and Lauren Fallieras to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: 14 April 2016

Shawn P. Cook for

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

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Attorneys for Complainant

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

In the Matter of the Accusation Against: **FVS HOLDINGS, INC. DBA UNIVERSITY SPECIALTY PHARMACY; SCOT SILBER; NANCY SILBER; SCOTT SCHUMAKER; GLEN TRUITT** **3328 Garfield Avenue** **Commerce, CA 90040** **Pharmacy Permit No. PHY 50160** **and** **RONALD YUAN** **2620 Fairfield Place** **San Marino, CA 91108** **Pharmacist License No. RPH 36525** **LAUREN FALLIERAS** **12920 Dickens St.** **Studio City, CA 91604** **Pharmacist License No. RPH 65381** Respondents.	Case No. 4688 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs. On or about August 16, 2010, the Board of Pharmacy (Board) issued Pharmacy Permit Number PHY

50160 to FVS Holdings, Inc. (FVS) dba University Specialty Pharmacy; Scot Silber. President and CEO; Nancy Silber, Treasurer/CFO; Scott Schumaker, COO; and Glen Truitt, Secretary (Respondent USP). The Pharmacy Permit will expire on August 1, 2014, unless renewed.

2. On or about August 18, 1981, the Board of Pharmacy issued Pharmacist License Number RPH 36525 to Ronald Yuan (Respondent Yuan). Yuan was Pharmacist-in-Charge (PIC) at Respondent USP from June 13, 2011 to March 5, 2012. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2014, unless renewed.

3. On or about April 12, 2011, the Board of Pharmacy issued Pharmacist License Number RPH 653815 to Lauren L. Fallieras (Respondent Fallieras). Fallieras was Pharmacist-in-Charge (PIC) at Respondent USP from March 5, 2012 to the present. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2014, unless renewed.

4. FVS Holdings, Inc. is the parent company for GreenValleyMed (GVM) located in Henderson, NV and also is the parent company for Physicians Sales and Service (PSS) located in Fullerton, CA.

5. Neither GVM nor PSS are licensed by the Board or the Nevada Board of Pharmacy. FVS is not licensed by the Nevada Board of Pharmacy.

JURISDICTION

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

7. Section 118 subd. (b), of the Code provides that the suspension/ expiration/ surrender/ cancellation of a license shall not deprive the Board/Registrar/Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

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8. Section 475 of the Code states:

"(a) Notwithstanding any other provisions of this code, the provisions of this division shall govern the denial of licenses on the grounds of:

"(4) Commission of any act which, if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.

"(b) Notwithstanding any other provisions of this code, the provisions of this division shall govern the suspension and revocation of licenses on grounds specified in paragraphs (1) and (2) of subdivision (a) ."

9. Section 480 states, in pertinent part:

"(a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:

"(3) Done any act which if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.

"The board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions or duties of the business or profession for which application is made."

10. Section 4022 of the Code states

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

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

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

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

11. Section 4300 of the Code states:

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

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

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

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

"(4) Revoking his or her license.

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

12. 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:

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

. . . .

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

. . . .

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

"(p) Actions or conduct that would have warranted denial of a license.

. . . .

13. Section 4033 of the Code states in pertinent part:

(a) (1) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer."

14. Section 4115 subd. (f)(1) of the Code provides in pertinent part:

"(f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs."

15. Section 4161 subd. (a) of the Code provides in pertinent part:

"(a) A person located outside this state that (1) ships, sells, mails, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler."

16. Section 4169 subd. (a) of the Code provides in pertinent part:

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

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

17. California Code of Regulations, title 16, section 1735.2 subd. (h) provides in pertinent part:

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs

or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

18. California Code of Regulations, title 16, section 1735.3 states:

"(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.

(7) The equipment used in compounding the drug product.

(8) A pharmacy assigned reference or lot number for the compounded drug product.

(9) The expiration date of the final compounded drug product.

(10) The quantity or amount of drug product compounded."

19. California Code of Regulations, title 16, section 1751.1 subd. (b)(6) states:

"(b) In addition to the records required by section 1735.3 and subdivision (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be made and kept by the pharmacy:

(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results."

20. California Code of Regulations, title 16, section 1751.3 subd. (b) provides that for any pharmacy engaged in compounding sterile injectable drug products:

"(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist."

21. California Code of Regulations, title 16, section 1751.7 subd. (a)(4) provides:

"(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

(4) Written justification of the chosen expiration dates for compounded sterile injectable products. that for any pharmacy engaged in compounding sterile injectable drug products. "

22. California Code of Regulations, title 16, section 1751.7 subd. (c) provides that for any pharmacy engaged in compounding sterile injectable drug products:

"(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens."

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

24. DRUG CLASSIFICATIONS:

BRAND NAME	GENERIC NAME	B&P 4022 DANGER DRUG	H&S Code CONTROLLED SUBSTANCE	INDICATIONS FOR USE
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Hylenex	Hyaluronidase	Yes	No	Enzyme for Inflammation
Depo Testosterone	Testosterone Cypionate	Yes	H&S Code sec. 11056(f)(30)	Hormone Replacement Therapy
Depo Provera	Medroxyprogsterone	Yes	No	Birth Control injection
Depo Medrol	Methylprednisolone	Yes	No	Injectable steroid for inflammation

Decadron	Dexamethasone	Yes	No	Injectable steroid for inflammation
Methionine	Methionine	No	No	To stabilize aqueous suspensions with pH controlling effect

FIRST CAUSE FOR DISCIPLINE

(Pharmacist to Pharmacy Technician Ratio-Against Respondents USP and Yuan)

25. Respondents USP and Yuan are each subject to disciplinary action under section 4115 subd. (f)(1), which states that a pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The circumstances are that on January 24, 2012 at USP's premises on Garfield Ave., Commerce, CA, Respondent Yuan was the only pharmacist present supervising the two pharmacy technicians inside the clean room in which pharmacy technician William Brown was weighing chemicals for compounding and pharmacy technician Tran H. Dinh was compounding inside the laminar flow hood. This is a violation of pharmacy law.

SECOND CAUSE FOR DISCIPLINE

(Sterile Injectable Quality Assurance- Against Respondents USP and Yuan)

26. Respondents USP and Yuan are subject to disciplinary action under 16 California Code of Regulations (CCR) section 1751.7 subd. (4), which states that any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following: (4) Written justification of the chosen expiration dates for compounded sterile injectable products. The circumstances of the violation are that on January 24, 2012 at USP's premises on Garfield Ave. Commerce, CA, pharmacist-in-charge Yuan had no written justification to extend the Beyond Use Date (BUD)

listed on the USP label to a date greater than what USP's Medisca Master Formulas stated for the following drugs:

DRUG	USP's Medisca Master Formula	USP BUD Labeling	RPH Sign off
Ascorbic Acid 500 mg/ml	14 days	180 days on 11/28/11 to 5/27/12	Fallieras
Ascorbic Acid 500 mg/ml	14 days	180 days on 11/30/11 to 5/29/12	Yuan
Hyaluronidase	35 days	90 days on 1/18/12 to 4/17/12	Fallieras
Testosterone Cyp 200 mg/ml	30 days	180 days on 12/1/11 to 5/30/12	Yuan
Medroxyprogsterone 150 mg/ml	14 days	180 days on 11/15/11 to 5/14/12	Yuan
Methylprednisolone	14 days	180 days on 12/27/11 to 6/26/12	Yuan
Dexamethasone 4 mg/ml	14 days	180 days on 1/19/12 to 7/8/12	Yuan

THIRD CAUSE FOR DISCIPLINE

(Sterile Injectable Recordkeeping Requirements- Against Respondents Yuan and Fallieras)

27. Respondents Yuan and Fallieras are subject to disciplinary action under 16 California Code of Regulations (CCR) section 1751.3 subd. (b), which states that the ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist. The circumstances are that on January 24, 2012, at USP's premises located at Garfield Avenue in Commerce, pharmacist Ronald Yuan and pharmacist Lauren Fallieras signed off on the following compounded drugs without reviewing and comparing the USP's Medisca Master Formulas provided by PIC Yuan to the Formula Worksheets-Compound Assist that were completed by the technicians and as a result, the pharmacist did not review the preparation records with mislabeled beyond use dates:

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DRUG	USP's Medisca Master Formula	USP BUD Labeling	RPH Sign off
Ascorbic Acid 500 mg/ml	14 days	180 days on 11/28/11 to 5/27/12	Fallieras
Ascorbic Acid 500 mg/ml	14 days	180 days on 11/30/11 to 5/29/12	Yuan
Hyaluronidase	35 days	90 days on 1/18/12 to 4/17/12	Fallieras
Testosterone Cyp 200 mg/ml	30 days	180 days on 12/1/11 to 5/30/12	Yuan
Medroxyprogsterone 150 mg/ml	14 days	180 days on 11/15/11 to 5/14/12	Yuan
Methylprednisolone	14 days	180 days on 12/27/11 to 6/26/12	Yuan
Dexamethasone 4 mg/ml	14 days	180 days on 1/19/12 to 7/8/12	Yuan

FOURTH CAUSE FOR DISCIPLINE

(Sterile Injectable Compounding Quality Assurance- Against Respondents USP and Yuan)

28. Respondents USP and Yuan are subject to disciplinary action under 16 California Code of Regulations (CCR) section 1751.7 subd. (c), which states that batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. The circumstances are that , on January 24, 2012 at University Specialty Pharmacy located at 3328 Garfield Avenue in Commerce, pharmacist-in-charge Ronald Yuan did not have end product testing for sterility and pyrogen testing on the batch compounded drugs from non-sterile ingredients which were not quarantined but released for the following batched drugs: ascorbic acid compounded on November 28 and 30, 2011; hyaluronidase compounded on January 8, 2012; testosterone cypionate compounded on December 11, 2011; medroxyprogesterone compounded on November 15, 2011; methylprednisolone compounded on December 27, 2011 and dexamethasone compounded on January 9, 2012. This is a violation of pharmacy law.

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FIFTH CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements- Against Respondents USP and Yuan)

29. Respondents USP and Yuan are subject to disciplinary action under 16 California Code of Regulations (CCR) section 1735.2 subd. (h), which states that every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This beyond use date (BUD) of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist. The circumstances are that on January 24, 2012, at USP's premises on Garfield Avenue in Commerce, CA, pharmacist-in-charge Ronald Yuan signed off on a testosterone cypionate 200 mg/ml batch compounded on December 11, 2011, in which the ingredient benzyl benzoate USP/NF was recorded to expire in March 2012, but the finished product was given 180 days expiration and labeled to expire on May 30, 2012. Additionally, Respondent Yuan signed off on a medroxyprogesterone 150 mg/ml batch compounded on November 28, 2011 in which the ingredient polyethylene glycol 3350 was recorded to expire in January 2012 but the finished product was given 180 days expiration and labeled to expire on May 14, 2012. This is a violation of pharmacy law.

SIXTH CAUSE FOR DISCIPLINE

(Sterile Injectable Recordkeeping Requirements- Against Respondents USP and Yuan)

30. Respondents USP and Yuan are subject to disciplinary action under 16 California Code of Regulations (CCR) section 1751.3 subd. (b) which states the ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist and as it relates to the California Code of Regulations Section 1751.1(b)(6) which states in addition to the records required by section 1735.3 and subdivision (a), for sterile products compounded from one or more non-sterile

ingredients, the following records must be made and kept by the pharmacy: (6) preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results. Specifically, on January 24, 2012 at USP's premises in Commerce, CA, Respondent Yuan, the PIC, maintained and provided the USP Formula Worksheet-Compound Assist and Medisca Master Formula records but failed to review the compounding instructions for the medroxyprogesterone 150 mg batch on January 22, 2011 that listed the chemical ingredient methionine on both records but omitted the methionine ingredient in the compounding instructions. This is a violation of pharmacy law.

SEVENTH CAUSE FOR DISCIPLINE

(Manufacture- Against Respondent USP)

31. Respondent USP is subject to disciplinary action under Business and Professions Code sec. 4033 subd. (a)(1) that defines "Manufacturer" to include every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer. The circumstances are that on January 24, 2012 at USP's premises located on Garfield Avenue in Commerce, CA, USP received orders for compounded drugs from an unlicensed out of state broker, GreenValleyMed (GVM) located in Henderson, NV and its partner, Physician Sales & Services (PSS). PSS sales representatives would send physician orders for compounded dangerous drugs to GVM as the "supplier". GVM brokered the sales of compounded dangerous drugs manufactured by USP, for which the compounding orders are not patient specific and were invoiced, billed and payments collected separately directly from the supplier, GVM, that split the profits 50/50 with PSS. This is a violation of pharmacy law.

EIGHTH CAUSE FOR DISCIPLINE

(Prohibited Acts- Against Respondent USP)

32. Respondent USP is subject to disciplinary action under Business and Professions Code sec. 4169 subd. (a)(1) that states a person or entity may not do any of the following: (1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy. The circumstances are

that on January 24, 2012, at its premises on Garfield Avenue in Commerce, CA, UPS manufactured compounded medication orders for sterile injectable drugs for GVM located in Henderson, NV. GVM was not licensed as a wholesaler or pharmacy in either Nevada or California. This is a violation of pharmacy law.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 50160, issued to FVS Holdings, Inc. dba University Specialty Pharmacy; Scot Silber. President and CEO; Nancy Silber, Treasurer/CFO; Scott Schumaker, COO; and Glen Truitt, Secretary;

2. Revoking or suspending Pharmacist License Number RPH 36525, issued to Ronald Yuan;

3. Revoking or suspending Pharmacist License Number RPH 65381, issued to Lauren Fallieras;

4. Ordering University Specialty Pharmacy; Ronald Yuan and Lauren Fallieras to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: 2/4/14

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

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