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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 **FIRST AMENDED 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
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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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
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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

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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.

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"(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."

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"(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."

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"(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

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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