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

In the Matter of the Accusation Against: **RSF PHARMACEUTICALS** 1790 LA COSTA MEADOWS DR., STE. 103 SAN MARCOS, CA 92078 Pharmacy License No. PHY 49086 **JASON KIM** 1502 SANDBAR DRIVE SAN MARCOS, CA 90078 Pharmacist License No. RPH 55902 Respondents.	Case No. 4088 **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.

2. On or about June 13, 2008, the Board of Pharmacy issued Pharmacy License Number PHY 49086 to RSF Pharmaceuticals (Respondent RSF). The Pharmacy License was in full force and effect at all times relevant to the charges brought herein, but expired on June 1, 2011, and has not been renewed.

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3. On or about August 24, 2004, the Board of Pharmacy issued Pharmacist License Number RPH 55902 to Jason Kim (Respondent Kim). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2011, unless renewed. Respondent Kim has been the Pharmacist in Charge (PIC) for Respondent RSF since June 13, 2008.

JURISDICTION

4. 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.

5. Section 4300 of the Code states:

> (a) Every license issued may be suspended or revoked.
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> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
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> (1) Suspending judgment.
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> (2) Placing him or her upon probation.
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> (3) Suspending his or her right to practice for a period not exceeding one year.
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> (4) Revoking his or her license.
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> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
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> . . . .
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> (e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

6. Section 4032 defines "license" to include any license, permit, registration, certificate, or exemption issued by the board.

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

STATUTORY PROVISIONS

8. Section 4033 (a) (1) of the Code states:

"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.

9. Section 4059 of the Code states, in pertinent part:

(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7., or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied.

10. Section 4081 of the Code states, in pertinent part:

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

11. Section 4126.5 of the Code states, in pertinent part:

(a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

. . . .

12. Section 4160 of the Code states, in pertinent part:

(a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

13. Section 4301 of the Code states, in pertinent part:

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

. . .

(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.

. . . .

14. Section 4342(a) of the Code states:

The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

15. Health and Safety Code section 11165 states, in pertinent part:

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) Full name, address, and the telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

16. Health and Safety Code section 11170 provides that no person shall prescribe, administer, or furnish a controlled substance for himself.

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FEDERAL REGULATIONS

17. Title 21, Code of Federal Regulations (CFR), section 1304.21, states in pertinent part:

(a) Every registrant required to keep records pursuant to §1304.03 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.

. . .

(c) Separate records shall be maintained by a registrant for each independent activity for which he/she is registered, except as provided in §1304.22(d).

18. CFR section 1304.22 states, in pertinent part:

Each person registered or authorized (by §1301.13(e) or §§1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export or conduct research with controlled substances shall maintain records with the information listed below.

. . .

(c) Records for dispensers and researchers. Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. In addition to the requirements of this paragraph, practitioners dispensing gamma-hydroxybutyric acid under a prescription must also comply with §1304.26.

19. CFR section 1306.04 states, in pertinent part:

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

COST RECOVERY

20. 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.

FACTS

21. At all times mentioned herein, Respondent RSF was registered with the Board to do business as a retail pharmacy at 1790 La Costa Meadows Dr., Ste. 103, San Marcos, California. At all times mentioned herein, the following two entities that are not licensed by the Board also did business at the same location: RSF Pharmaceuticals, Inc., (RSF Manufacturing), which re-packaged and/or re-labeled dangerous drugs and controlled substances; and SportPharm Pharmaceuticals, Inc. (SportPharm), which owned software, marketing materials, logos, and a client list of team physicians for professional and college sports teams, who regularly purchase prescription medications, including controlled substances and dangerous drugs for treating the team staff and athletes.

22. Prior to October of 2008, SportPharm was owned by a licensed California pharmacy. In October of 2008, SportPharm was purchased by a Hong Kong corporation. The foreign corporation that purchased SportPharm did not obtain Food and Drug Administration ("FDA"), Drug Enforcement Administration ("DEA"), or California licenses at any time mentioned herein. SportPharm was an unlicensed entity, yet operated as a broker or wholesaler of dangerous drugs, controlled substances and compounded medications in California.

23. At all times mentioned herein, the mode of business between Respondent RSF, RSF Manufacturing and SportPharm was as follows. RSF Pharmacy would purchase controlled substances and dangerous drugs from a drug manufacturer or distributor/wholesaler. RSF Pharmacy would then transfer these purchased drugs to RSF Manufacturing for labeling with the SportPharm label. SportPharm would then ship the drugs to the purchasers.

24. SportPharm advertised the sale of prescription medications over the internet and received orders for dangerous drugs and controlled substances from its clients. SportPharm accepted and processed these orders via email or by telephone. Clients of SportPharm, who were generally athletic trainers for national sports teams, called the toll free number for SportPharm or sent an email to SportPharm, and thereby placed orders for dangerous drugs and controlled substances. Orders were then transmitted from SportPharm to Respondent RSF. A staff pharmacist from Respondent RSF would then call the SportPharm client, verify the prescription, change it into an oral prescription, fill the order, send the filled prescription to SportPharm who would prepare the invoice and ship the drugs to the clients. SportPharm is paid directly by the client who ordered the prescription drugs.

25. SportPharm also ships repackaged bulk medications to non-licensed facilities, such as sport team locations. These activities involving brokering and wholesaling prescription drugs require a license issued by the Board, yet SportPharm is not licensed.

Investigation

26. On or about April 13, 2010, the Board received a complaint that SportPharm was operating without the proper DEA, FDA and California licenses, and in violation of several California laws. An investigation by the DEA and Board investigators ensued.

27. On or about May 24, 2010, the San Diego Field Division of the DEA received a report that a team member of the San Diego Chargers had been arrested for controlled substance violations. This arrest and media coverage of another NFL team suspected of controlled substance violations prompted the DEA San Diego Field Division to conduct a review of the DEA's Automated Records and Ordering System ("ARCOS")[1] and California's Controlled

[1] The distribution of drugs by drug manufacturers and distributors to pharmacies, physicians, and other registrants is monitored nationally through ARCOS. The Controlled Substances Act of 1970 (Title 21 USC § 801 *et seq.*) requires manufacturers and distributors to report transactions for controlled substances to the Attorney General of the United States, which has been delegated to the Drug Enforcement Administration (DEA).

ARCOS is an automated, comprehensive drug reporting system that monitors the flow of controlled substances from their point of manufacture, through commercial distribution channels, to point of sale or distribution at the dispensing/retail level in hospitals, retail pharmacies, teaching institutions, and through practitioners. The transactions are summarized into reports that give investigators in federal and state government agencies information to identify the diversion

(continued...)

Substance Utilization Review and Evaluation System ("CURES")[2]. A review of CURES for the period of June 10, 2008 to June 10, 2010 for the DEA number issued to the San Diego Chargers' team physician revealed that at least fifty (50) controlled substance prescriptions were written by this physician *naming the physician himself*, as the patient. Respondent RSF filled these prescriptions without reporting them to CURES.

28. A comparison of the CURES reports for Respondent RSF with those of several physicians revealed that Respondents filled prescriptions for at least eight-one (81) different physicians in 27 different states where the physician listed himself or herself as the patient in the prescription. These prescriptions were written by team physicians for professional and college sports teams throughout the United States and were apparently intended for office use and distribution by the physicians to either team staff or team players, despite the fact that each prescription indicates that the patient was the physician who wrote the prescription. Pharmacists are required to verify prescriptions to make sure the drugs being dispensed are for a legitimate medical purpose. Physicians are not permitted to write prescriptions for controlled substances for themselves.

29. A review of CURES for the DEA number issued to Respondent RSF for the period September 1, 2009 through June 10, 2010 revealed no prescriptions having been filled under that DEA registration number, however, CURES identified that Respondent RSF reported filling over 1200 prescriptions under an expired DEA number previously issued to Respondent RSF. Respondents failed to accurately report these transactions under the current DEA registration number.

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of controlled substances into illicit channels of distribution.

[2] In California, drug purchasing is monitored through CURES, which is a California Department of Justice (DOJ) computer database that records the dispensing of controlled substances in California. Pursuant to California Health and Safety Code section 11165(d), all California licensed pharmacies must provide weekly reports to the DOJ for every prescription dispensed for Schedule II - IV controlled substances. The Prescription Drug Monitoring Program (PDMP) aspect of CURES, allows pre-registered licensed healthcare prescribers, pharmacists, law enforcement, and regulatory boards to access real-time patient controlled substance history information in order to make better prescribing decisions and reduce prescription drug abuse.

Board Inspection of RSF

30. On June 29, 2010, Inspectors for the Board inspected the premises of RSF. They found packages of dangerous drugs and controlled substances that were labeled to indicate that they had been returned to SportPharm at the La Costa Meadows address in San Marcos. As an unlicensed entity, SportPharm, is not authorized to accept returned medications.

31. During their inspection, Board Inspectors reviewed compounding log formula worksheets that showed expired drugs were used in the compounding of dangerous drugs and controlled substances, thereby diluting or changing their strength and quality.

32. Controlled substances, and dangerous drugs furnished by Respondent RSF to SportPharm to provide to its clients were repackaged and then sold by SportPharm in multiple units, labeled with the SportPharm label, without any indication that Respondent RSF actually furnished the drugs.

33. The records to track the flow of dangerous drugs and controlled substances through the pharmacy of Respondent RSF revealed no written records to show that drugs had been transferred from Respondent RSF to RSF Manufacturing and then to SportPharm. Between June of 2009 and June of 2010, Respondent RSF directly transferred dangerous drugs and controlled substances originally acquired from a wholesaler to Respondent RSF without any record of the disposition. There were at least 113 controlled substance transactions from the wholesaler detailing the direct transfer.

34. The labeling of dangerous drugs and controlled substances dispensed by Respondent RSF contained no dosage or frequency instructions for the intended patients, but instead were labeled to be taken, "as directed."

35. Respondent Kim admitted to Board Inspectors that Respondent RSF was doing business as SportPharm and that SportPharm is not licensed as a pharmacy, wholesaler, broker or repacker of drugs.

36. RSF Pharmacy acquired manufacturer's original stock drugs, and transferred them to RSF Manufacturing for manipulation of the original stock product. However, RSF

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Manufacturing manipulated some but not all of the original stock drugs. The drugs that were not manipulated were merely labeled with the SportPharm label and then shipped to the prescriber at wholesale.

37. On or about June 30, 2011, Respondent RSF surrendered its DEA registration license to dispense controlled substances.

FIRST CAUSE FOR DISCIPLINE

(Unauthorized Furnishing of Dangerous Drugs)

38. Respondent RSF and Respondent Kim are subject to disciplinary action for unprofessional conduct under Code section 4301 (j) for violation of Code section 4126.5(a) subdivisions (1) and (2), in that between June 2009 and June of 2010, Respondents furnished dangerous drugs to RSF Manufacturing, a different manufacturer from whom the dangerous drugs were originally purchased, as set forth above in paragraphs 21-37, which are incorporated by reference.

SECOND CAUSE FOR DISCIPLINE

(Incomplete Record Keeping of the Purchase and Distribution of Dangerous Drugs)

39. Respondent RSF and Respondent Kim are subject to disciplinary action for unprofessional conduct under Code section 4301 (j) for violation of Code section 4059(b), in that between June 2009 and June of 2010, Respondents furnished controlled substances and dangerous drugs without sales and purchase records that correctly gave the date, the names and addresses of the supplier and the buyer, the drug or device, and/or its quantity, as set forth above in paragraphs 21-37, which are incorporated by reference.

THIRD CAUSE FOR DISCIPLINE

(Inadequate Recordkeeping)

40. Respondent RSF and Respondent Kim are subject to disciplinary action for unprofessional conduct under Code section 4301 (j) for violation of Title 21, CFR, section 1304.21(a) and (c), in that between June 2009 and June of 2010, Respondents failed to maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of, and that Respondents failed to

maintain separate records for each independent activity for which they were registered or licensed, as set forth above in paragraphs 21-37, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Furnished Drugs Lacking in Quality or Strength)

41. Respondent RSF and Respondent Kim are subject to disciplinary action for unprofessional conduct under Code section 4301 (j) for violation of Code section 4342(a), in that between June 2009 and June of 2010, Respondents compounded dangerous drugs with expired ingredients, as set forth above in paragraph 21-37, which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Dispensing with Inaccurate Patient Information)

42. Respondent RSF and Respondent Kim are subject to disciplinary action for unprofessional conduct under Code section 4301 (j) for violation of Health and Safety Code Section 11165(d)(1) and Title 21, CFR, section 1306.04(b), in that between June 2009 and June of 2010, Respondents filled prescriptions for dangerous drugs and controlled substances written by physicians for themselves as the named patients, for purposes of supplying the individual physicians with drugs for general dispensing to their patients, as set forth above in paragraphs 21-37, which are incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Failed to Maintain Records For Three Years)

43. Respondent RSF and Respondent Kim are subject to disciplinary action for unprofessional conduct under Code section 4301 (j), for violation of Code section 4081(a), in that between June 2009 and June of 2010, Respondents made at least 113 controlled substance transactions without maintaining records of their disposition for at least three years, as set forth above in paragraphs 21-37, which are incorporated herein by reference.

SEVENTH CAUSE FOR DISCIPLINE

(Aiding and Abetting Unlicensed Activity)

44. Respondent RSF and Respondent Kim are subject to disciplinary action for unprofessional conduct under Code section 4301(o) for aiding and abetting SportPharm in

furnishing dangerous drugs and controlled substances without being licensed as a wholesaler or otherwise to be authorized to do so, as set forth above in paragraphs 21-37, which are incorporated herein by reference.

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 Pharmacist License Number RPH 55902, issued to Jason S. Kim;

2. Ordering Jason S. Kim 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;

3. Revoking or suspending Pharmacy License Number PHY 49086, issued to RSF Pharmaceuticals;

4. Ordering RSF Pharmaceuticals to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

DATED: 11/9/11

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

SD2011800639