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

In the Matter of the Accusation Against: **SIX TWELVE PHARMACY; JAMES A. WILSON, Owner** **107-A West Hungtington Drive** **Arcadia, CA 91007** **Pharmacy Permit No. PHY 36222,** **and** **JAMES A. WILSON** **P.O. Box 2092** **Arcadia, CA 91077** **Pharmacist License No. RPH 23617** Respondent.	Case No. 4389 **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 April 6, 1990, the Board of Pharmacy issued Pharmacy Permit Number PHY 36222 to Six Twelve Pharmacy; James A. Wilson, Owner (Respondent Six Twelve Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2014, unless renewed.

3. On or about August 10, 1967, the Board of Pharmacy issued Pharmacist License Number RPH 23617 to James A. Wilson (Respondent Wilson). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and expired on December 31, 2013.

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 4040.5 of the Code states:

"Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, manufacturers, and other entities by receiving, inventorying, and managing the disposition of outdated or nonsalable dangerous drugs.

6. 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.

. . . .

7. Section 4104 of the Code states, in pertinent part:

(a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be

chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

. . .

8. Section 4169 of the Code states:

(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.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health.

9. Section 4081 of the Code states:

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

"(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

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

10. California Code of Regulations, title 16, section 1711 states, in pertinent part,

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

. . . .

11. Section 4342 of the Code states:

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

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

12. California Code of Regulations, title 16, section 1718 states:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

13. California Code of Regulations, title 16, section 1735.3 provides, in pertinent part:

(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. Exempt from the

requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

(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.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

14. California Code of Regulations, title 16, section 1735.5 provides, in pertinent part

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

(c) The policy and procedure manual shall include the following

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.

(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.

(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

15. Health and Safety Code section 111330 states:

Any drug or device is misbranded if its labeling is false or misleading in any particular.

16. Code of Federal Regulations, title 21, section 1304.21 provides, 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.

(b) Separate records shall be maintained by a registrant for each registered location except as provided in § 1304.04 (a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(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).

(d) In recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).

17. 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.

18. Section 118, subdivision (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.

FIRST CAUSE FOR DISCIPLINE

(Failure to Produce Records of Acquisition)

19. Respondents are subject to disciplinary action under section 4301 subdivisions (j) and (o), in that they failed to comply with section 4081, subdivision (a) when on or around August 9, 2011, Respondent failed to provide acquisition records for thirteen Demerol 50mg/ml ampules upon demand by the Board.

SECOND CAUSE FOR DISCIPLINE

(Lack of Policy and Procedure – Quality Assurance Programs)

20. Respondents are subject to disciplinary action under section 4301 subdivisions (j) and (o), in that they failed to comply with California Code of Regulations, title 16, section 1711, subdivision (c)(1). The circumstances are that on or around August 9, 2011, during a routine inspection by the Board, Respondents did not have a policy and procedure in place to address a quality assurance program.

THIRD CAUSE FOR DISCIPLINE

(Lack of Policy and Procedure – Theft and Impairment)

21. Respondents are subject to disciplinary action under section 4301 subdivisions (j) and (o) in that they failed to comply with section 4104, subdivision (b). The circumstances are that on or around August 9, 2011, during a routine inspection by the Board, Respondents did not have a policy and procedure in place to address licensed employee theft and impairment.

FOURTH CAUSE FOR DISCIPLINE

(Misbranded Drugs)

22. Respondents are subject to disciplinary action under section 4301 subdivisions (j) and (o), in that they failed to comply with Health and Safety Code section 111330. The circumstances are that on or around August 9, 2011, during a routine inspection by the Board, pharmacy records revealed that on or around April 9, 2010, May 24, 2010, September 17, 2010, January 28, 2011, April 26, 2011, and October 8, 2011, dangerous drugs were compounded using expired ingredients.

FIFTH CAUSE FOR DISCIPLINE

(Lack of Master Formula)

23. Respondents are subject to disciplinary action under section 4301 subdivisions (j) and (o), in that they failed to comply with California Code of Regulations, title 16, section 1735.3, subdivision (a). The circumstances are that on or around August 9, 2011, during a routine inspection by the Board, it was revealed that the pharmacy failed to maintain master formula records for all prescription drugs compounded and dispensed by the pharmacy.

SIXTH CAUSE FOR DISCIPLINE

(Lack of Policy and Procedure – Compounding)

24. Respondents are subject to disciplinary action under section 4301 subdivisions (j) and (o) in that they failed to comply with California Code of Regulations, title 16, section 1735.5, subdivision (a). The circumstances are that on or around August 9, 2011, during a routine inspection by the Board, it was determined that Respondents compounded and dispensed prescription drugs without having a compounding policy and procedure in place.

SEVENTH CAUSE FOR DISCIPLINE

(Compounding with Expired Ingredients)

25. Respondents are subject to disciplinary action under section 4301 subdivisions (j) and (o), in that between March 2010 and April, 2011, they failed to comply with section 4169 subdivision (a)(4) by dispensing dangerous drugs that were compounded using expired ingredients.

EIGHTH CAUSE FOR DISCIPLINE

(Unlicensed Reverse Distribution)

26. Respondents are subject to disciplinary action under section 4301 subdivisions (j) and (o) in conjunction with section 4160(a) in that during a follow-up inspection by the Board on August 15, 2012, it was determined that between August, 2011 and May, 2012, Respondents acted as reverse distributors for sixty-nine different prescription medications.

NINTH CAUSE FOR DISCIPLINE

(Lack of Acquisition Records)

27. Respondents are subject to disciplinary action under section 4301 subdivisions (j) and (o) in that they failed to comply with Code of Federal Regulations section 1304.21 when a follow-up inspection conducted by the Board on August 15, 2012 revealed that Respondents accepted six controlled substances from surgical clinics without maintaining proper documentation.

TENTH CAUSE FOR DISCIPLINE

(Failure to Records of Acquisition and/or Maintain Current Inventory)

28. Respondents are subject to disciplinary action under section 4301 subdivisions (j) and (o), in that they failed to comply with section 4081(a) in conjunction with California Code of Regulations, title 16, section 1718, when a follow-up inspection conducted by the Board on August 15, 2012 revealed that Respondents failed to keep a record of acquisition or a current inventory for sixty-nine prescription drugs as follows:

Drug
Actos 15mg tab
adenosine 6mg/2ml inj
amiodarone 150mg/3ml inj
amoxicillin 875mg tabs
ampicillin 2gm vial
atenolol 25mg tab
atropine 0.4ml ml x 1 ml
atropine 1mg/ml inj
atropine 1mg/ml x 1ml

Aviane 28 tabs
Beconase AQ 180 metered doses
calcium chloride100mg/ml x 10ml
carbamazepine 200mg tab
Celestone 6mg/ml x 5 ml inj
chloral hydrate 500mg/5ml syrup
Cleocin 300mg/2ml x 2ml inj
dantrium 20mg vial
diazepam 5mg tab unit dose
diazepam 5mg/ml x 2ml
diphenhydramine 50mg/ml x 1ml inj
dopamine 1600mcg/ml IV 250ml
Enalaprilat 1.25mg/ml x 1 ml
ephedrine 50mg/ml x 1 ml inj
epinephrine 0.1mg/ml inj
epinephrine 1mg/ml 30ml inj
epinephrine 1mg/ml x 1 aml amp
Ethiodol 10 ml ampule
flumazenil 0.5/5ml x 5ml inj
flumazenil 1mg/10ml x 10ml
furosemide 100mg/10ml x 10ml
furosemide 20mg/ml inj
heparin 1,000u ml x 1 ml
heparin 10u/ml x 3 ml
Humulin R 3ml
hydroxyzine 25ml/ml x 1 ml
Influenza Vaccine
kenolog 40mg 1ml inj
Kinevac 5mg vial
Lanoxin inj. 2ml
lidocaine 100mg/5ml inj
lidocaine 2gm/500ml inj
lidocaine 50mg/5ml inj
lisinopril 10mg tab
lorazepam 2mg/ml x1 ml vial
magnesium sulfate 1gm/2ml x 2ml
Marcaine 0.5% 50ml inj
methylprednisolone 80mg/ml x 1ml
Microgestin Fe 1/20 28 tabs
Necon 777 28 tabs

NitroQuick
Ondansetron 4mg tab
Ondansetron 4mg/2ml x 2 ml
Oxycodone/APAP 5-325 tablets
penylephrine 10mg/ml x 1 ml inj
Premarin 0.9mg tab
ProAir Inhaler
prochlopramine 10mg/2ml x 2ml inj
prochlorperazine 10mg supp
Propranolol 1mg/ml x 1 ml inj
Sodium Chloride 30ml vial
Solu Cortef 100mg/2ml
Solu Medrol 125mg/2ml
Solu Medrol 250mg/2ml
Tetracycline 500mg caps
Tigan 200mg/ml x 1 ml
Tussionex suspension
Valtrex 500mg tabs
Xylocaine 2% Jelly
Zantac 50mg/ml x 1 ml

ELEVENTH CAUSE FOR DISCIPLINE

(Receipt of Medications from Unlicensed Persons)

29. Respondents are subject to disciplinary action under section 4301 subdivisions (j) and (o), in that between March 2010 and April, 2011, they failed to comply with section 4169 subdivision (a)(1) by receiving transferred medications from surgical clinics and physician offices that were not licensed by the board as a wholesaler or pharmacy.

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 36222, issued to Six Twelve Pharmacy; James A. Wilson, Owner,

2. Revoking or suspending Pharmacist License Number RPH 23617, issued to James A. Wilson,

3. Ordering James A. Wilson 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;

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

DATED: 7/14/13

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

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