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

In the Matter of the Second Amended Accusation Against: **SIX TWELVE PHARMACY; JAMES A. WILSON, Owner** 107-A West Huntington Drive Arcadia, CA 91007 Pharmacy Permit No. PHY 36222 Respondent.	Case No. 4389

DECISION AND ORDER

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

This decision shall become effective on September 16, 2014.

It is so ORDERED on September 11, 2014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STAN C. WEISSER
Board President

KAMALA D. HARRIS
Attorney General of California
GREGORY J. SALUTE
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Attorneys for Complainant

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

In the Matter of the Second Amended Accusation Against: **SIX TWELVE PHARMACY; JAMES A. WILSON, Owner** **107-A West Huntington Drive** **Arcadia, CA 91007** **Pharmacy Permit No. PHY 36222** Respondent.	Case No. 4389 **STIPULATED SURRENDER OF LICENSE AND ORDER**

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

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy. She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Thomas L. Rinaldi, Deputy Attorney General.

2. Six Twelve Pharmacy; James A. Wilson, Owner (Respondent) is represented in this proceeding by attorney Herb Weinberg, whose address is1800 Century Park East, Los Angeles, CA 90067.

3. On or about April 6, 1990, the Board of Pharmacy issued Pharmacy Permit No. PHY 36222 to Respondent. The Pharmacy Permit was in full force and effect at all times relevant to

the charges brought in Second Amended Second Amended Accusation No. 4389 and expired on April 1, 2013.

JURISDICTION

4. Second Amended Second Amended Accusation No. 4389 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondent. The Second Amended Accusation and all other statutorily required documents were properly served on Respondent on February 25, 2014. Respondent timely filed his Notice of Defense contesting the Second Amended Accusation. A copy of Second Amended Accusation No. 4389 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Second Amended Accusation No. 4389. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Order.

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

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

CULPABILITY

8. Respondent understands that the charges and allegations in Second Amended Accusation No. 4389, if proven at a hearing, constitute cause for imposing discipline upon his Pharmacy Permit.

9. For the purpose of resolving the Second Amended Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Second Amended Accusation and that those charges constitute cause for discipline. Respondent hereby gives up his right to contest that cause for discipline exists based on those charges.

10. Respondent understands that by signing this stipulation he enables the Board to issue an order accepting the surrender of his Pharmacy Permit without further process.

RESERVATION

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

CONTINGENCY

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

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

14. This Stipulated Surrender of License and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions,

negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

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

ORDER

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 36222, issued to Respondent Six Twelve Pharmacy; James A. Wilson, is surrendered and accepted by the Board of Pharmacy. Respondent shall relinquish the premises wall license and renewal license to the Board within ten (10) days of the effective date of this decision.

1. The surrender of Respondent's Pharmacy Permit and the acceptance of the surrendered license by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board of Pharmacy.

2. Respondent owner shall, within ten (10) days of the effective date, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondent owner shall further provide written proof of such disposition and submit a completed Discontinuance of Business form according to board guidelines.

3. Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills

outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

4. Respondent understands and agrees that if he ever files an application for a licensed premises or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.

5. Respondent shall pay the agency its costs of investigation and enforcement in the amount of $26,000 prior to issuance of a new license.

6. Respondent owner may not reapply for any license from the board for three (3) years from the effective date of this decision. Respondent owner stipulates that should he or she apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board. Respondent is required to report this surrender as disciplinary action.

ACCEPTANCE

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

DATED: 6/13/2014

SIX TWELVE PHARMACY; JAMES A. WILSON, Owner
Respondent

I have read and fully discussed with Respondent Six Twelve Pharmacy; James A. Wilson the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: 6/13/14

HERB WEINBERG / NOAH B. JOSSIM
Attorney for Respondent

ENDORSEMENT

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

Dated: 8-15-2014

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General

THOMAS L. RINALDI
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Second Amended Accusation No. 4389

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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
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STATE OF CALIFORNIA

In the Matter of the Second Amended Accusation Against: **SIX TWELVE PHARMACY; JAMES A. WILSON, Owner** **107-A West Huntington 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 **SECOND AMENDED ACCUSATION**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Second Amended 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, 2015.

JURISDICTION

4. This Second Amended 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 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.

8. 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.

. . .

9. 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.

10. 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."

11. Section 4113, subdivision (c) of the Code states:

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

12. 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.

. . . .

13. California Code of Regulations, title 16, section 1735.2 states, 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.

. . . .

14. 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.

15. 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.

16. United States Code, Title 21, section 353 states, in pertinent part:

. . . .

(c) Sales restrictions.

(1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d), the term "drug sample" means a unit of a drug, subject to subsection (b), which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.

(2) No person may sell, purchase, or trade, offer to sell, purchase, or trade, or counterfeit any coupon. For purposes of this paragraph, the term "coupon" means a form which may be redeemed, at no cost or at a reduced cost, for a drug which is prescribed in accordance with subsection (b).

(3) (A) No person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug--

(i) which is subject to subsection (b), and

(ii) (I) which was purchased by a public or private hospital or other health care entity, or

(II) which was donated or supplied at a reduced price to a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 [26 USCS § 501(c)(3)].

(B) Subparagraph (A) does not apply to--

(i) the purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities which are members of such organization,

(ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an organization described in subparagraph (A)(ii)(II) to a nonprofit affiliate of the organization to the extent otherwise permitted by law,

(iii) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control,

(iv) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, or

(v) a sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b).

For purposes of this paragraph, the term "entity" does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law and the term "emergency medical reasons" includes transfers of a drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.

(d) Distribution of drug samples.

(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term "distribute" does not include the providing of a drug sample to a patient by a--

(A) practitioner licensed to prescribe such drug,

(B) health care professional acting at the direction and under the supervision of such a practitioner, or

(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).

. . . .

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, Respondents 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 written 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 written policy and procedure in place to address licensed employee theft and impairment.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Violation of Compounding Limitations)

22. 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 1735.2, subdivision (h). The circumstances are that during a routine inspection by the Board that began on August 9, 2011, pharmacy records revealed that on or around April 9, 2010, May 24, 2010, September 17, 2010, October 8, 2010, January 28, 2011, and April 26, 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 written compounding policy and procedure in place.

SEVENTH CAUSE FOR DISCIPLINE

(Unlicensed Reverse Distribution)

25. 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 or around August 15, 2012, it was determined that between August, 2011 and May, 2012, Respondents acted as reverse distributors for sixty-nine different prescription medications.

EIGHTH CAUSE FOR DISCIPLINE

(Receipt of Medications from Unlicensed Persons)

26. Respondents are subject to disciplinary action under section 4301 subdivisions (j) and (o), in that between December 8, 2010 and June 1, 2012, they failed to comply with section 4169, subdivision (a)(1), by receiving transferred medications from Valley Digestive Center, a surgical clinic that was not licensed by the board as a wholesaler or pharmacy.

NINTH CAUSE FOR DISCIPLINE

(Improper Furnishing of Dangerous Drugs or Devices)

27. Respondents are subject to disciplinary action under section 4301 subdivisions (j) and (o) in that they violated section 4059. The circumstances are that from December 8, 2010, through June 11, 2012, Respondents furnished Valley Digestive Center with dangerous drugs without providing proper sales records.

TENTH CAUSE FOR DISCIPLINE

(Violation of Federal Laws Pertaining to Drug Samples)

28. Respondents are subject to disciplinary action under section 4301 subdivisions (j) and (o), in that they violated provisions of federal law pertaining to drug samples. The circumstances are that during a routine inspection of Six Twelve pharmacy that began on August 9, 2011, large quantities of dangerous drug samples were found on the pharmacy premises that had no legitimate pharmacy purpose for being there. The discovery of the drug samples led to further investigation by pharmacy inspectors which revealed that from at least 2004 to 2011, Respondents were violating the following federal laws:

a. **Title 21, section 353(c)(1)**: Respondents transacted with prescribers including doctors and/or clinics to receive drug samples pursuant to "wish lists" that Respondent Wilson would prepare. In exchange for the drug samples, Respondents provided monetary credits to the prescribers that were applied to future purchases from Six Twelve Pharmacy.

b. **Title 21, section 353(d)**: Respondents engaged in the illegal distribution of drug samples. Recipients included orphanages in Mexico as well as the Flying Doctors of Mercy.

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; and

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

DATED: 2/25/14

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

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KAMALA D. HARRIS
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Attorneys for Complainant

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In the Matter of the First Amended Accusation Against: **SIX TWELVE PHARMACY; JAMES A. WILSON, Owner** **107-A West Huntington 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 **FIRST AMENDED ACCUSATION**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about 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 First Amended 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 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.

8. 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.

. . .

9. 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.

10. 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."

11. 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.

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12. 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.

13. 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.

14. 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.

15. 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.

16. Health and Safety Code section 111330 states:

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

17. 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).

18. 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.

19. 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)

20. 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)

21. 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 (e)(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)

22. 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)

23. 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)

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 1735.3,

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)

25. 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)

26. 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)

27. 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)

28. 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)

29. 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)

30. 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.

TWELFTH CAUSE FOR DISCIPLINE

(Improper Furnishing of Dangerous Drugs or Devices)

31. Respondents are subject to disciplinary action under section 4301 subdivisions (j) and (o) in that they violated section 4059. The circumstances are that from August, 2009 to August, 2012, Respondents furnished Valley Digestive Center, Arcadia Outpatient Surgery Center, and Foothill Surgery Center LP with dangerous drugs without providing proper sales records.

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;

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

DATED: 11/25/13

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

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Attorneys for Complainant

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

In the Matter of the Accusation Against: **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**

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"(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.

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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.

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"(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."

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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.

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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 (e)(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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