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

In the Matter of the Accusation Against: **A&O SPECIALTY PHARMACY** **536 Abbott Street** **Salinas, CA 93901** **Pharmacy License No. PHY 47448** **Sterile Compounding License No. LSC 99382** **DAVID MARK SMITH** **536 Abbott Street** **Salinas, CA 93901** **Pharmacist License No. RPH 36789** **AKIRA AOYAMA** **608 San Miguel Avenue** **Salinas, CA 93901** **Pharmacist License No. RPH 24477** Respondents.	Case No. 5077 **ACCUSATION**

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 March 10, 2006, the Board of Pharmacy issued Pharmacy License Number PHY 47448 to A&O Specialty Pharmacy (Respondent A&O). The Pharmacy License

was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2015, unless renewed.

3. On or about August 2, 2006, the Board of Pharmacy issued Sterile Compounding License Number LSC 99382 to Smith Riker Pharmacy Inc. to do business as A&O Speciality Pharmacy. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2015, unless renewed.

4. On or about November 3, 1981, the Board of Pharmacy issued Pharmacist License Number RPH 36789 to David Mark Smith (Respondent Smith). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2015, unless renewed.

5. On or about August 12, 1966, the Board of Pharmacy issued Pharmacist License Number RPH 24477 to Akira Aoyama (Respondent Aoyama). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2014, unless renewed.

JURISDICTION

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

7. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

8. Code section 4300 provides that every license issued by the Board may be suspended or revoked.

9. Code section 4300.1 provides that the expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any

investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY AND REGULATORY PROVISIONS

10. Section 4300 of the Code states:

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

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

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

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

"(4) Revoking his or her license.

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

. . ."

11. Section 4301 of the Code states:

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

. . .

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

. . .

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

. . .

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

. . . "

12. Section 4059.5(a) of the Code states:

"(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative shall sign for and receive the delivery."

13. Section 4113(c) of the Code states:

"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."

14. Section 4115(f)(a) of the Code states:

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

15. Section 4169(a) of the Code states, in pertinent part:

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

. . .

"(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."

16. California Code of Regulations, title 16, section 1735 states, in pertinent part:

"(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.

"(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace."

17. California Code of Regulations, title 16, section 1735.2(h) states:

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

18. California Code of Regulations, title 16, section 1735.3 lists records that are required to be created and maintained in a readily retrievable form by the pharmacy for three (3) years, for each compounded drug product prepared by a pharmacy; subdivisions (a)(5) and (a)(6) thereof require that for each compounded drug product pharmacy records include the quantity of each component used in compounding the drug product ((a)(5)) and the manufacturer and lot number of each component, unless the manufacturer name is demonstrably unavailable in which case the

name of the supplier may be substituted ((a)(6)).

19. California Code of Regulations, title 16, section 1751.4(d) provides:

"(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination."

20. California Code of Regulations, title 16, section 1751.7 provides, in pertinent part:

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

"(1) Cleaning and sanitization of the parenteral medication preparation area.

"(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

"(3) Actions to be taken in the event of a drug recall.

"(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

. . .

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

. . ."

21. California Code of Regulations, title 16, section 1770, states:

"For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a

crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare."

22. California Code of Regulations, title 16, section 1793.2 provides:

""Nondiscretionary tasks" as used in Business and Professions Code section 4115, include:

"(a) removing the drug or drugs from stock;

"(b) counting, pouring, or mixing pharmaceuticals;

"(c) placing the product into a container;

"(d) affixing the label or labels to the container;

"(e) packaging and repackaging."

23. Health and Safety Code section 11209(a) provides:

"(a) No person shall deliver Schedule II, III, or IV controlled substances to a pharmacy or pharmacy receiving area, nor shall any person receive controlled substances on behalf of a pharmacy unless, at the time of delivery, a pharmacist or authorized receiving personnel signs a receipt showing the type and quantity of the controlled substances received. Any discrepancy between the receipt and the type or quantity of controlled substances actually received shall be reported to the delivering wholesaler or manufacturer by the next business day after delivery to the pharmacy."

COST RECOVERY

24. 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.

CONTROLLED SUBSTANCES/DANGEROUS DRUGS

25. Section 4022 of the Code states

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

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

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

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

26. Prostaglandin/papaverine/phentolamine is a dangerous drug per Code section 4022, and is used for erectile dysfunction.

27. Benzalkonium chloride is a dangerous drug per Code section 4022, and is used as an antiseptic for irrigation of body cavities or eye irrigation.

28. Acetic Acid is a dangerous drug per Code section 4022, and is used for irrigation or for pH adjustment of compounded products.

29. Hydroxocobalamin is a dangerous drug per Code section 4022, and is used for vitamin B12 deficiency.

30. Ascorbic acid 1/25%/glutathione 1/25%/DMSO 6/25% ophthalmic solution is a dangerous drug per Code section 4022, and is used for reversing cataracts.

31. EDTA dental solution is a dangerous drug per Code section 4022, and is used for root canal cleaning.

32. Itraconazole/mupirocin/tac/xylitol nasal spray is a dangerous drug per Code section 4022, and is used for allergic fungal sinusitis.

33. Lidocaine/prilocaine/tetracaine is a dangerous drug per Code section 4022, and is used as an anesthetic.

34. Liothyronine is a dangerous drug per Code section 4022, and is used for thyroid disorder.

35. (Diltiazem) nifedipine/lidocaine/bupivacaine/(babapentin)(nitroglycerin) is a dangerous drug per Code section 4022, and is used for treating anal fissures.

36. Prednisone is a dangerous drug per Code section 4022, and is a corticosteroid.

37. Progesterone is a dangerous drug per Code section 4022, and is used for hormone replacement.

38. Testosterone is a dangerous drug per Code section 4022, and is used for hormone replacement.

Respondent A&O, Pharmacy License No. PHY 47488

FIRST CAUSE FOR DISCIPLINE

(EXCEEDED ALLOWABLE PHARMACIST TO TECHNICIAN RATIO)

39. Respondent A&O is subject to disciplinary action under Code sections 4115(f)(1), 4301(j) and/or (o), and/or California Code of Regulations, title 16, section 1793.2, in that it exceeded the allowable pharmacist to technician ratio. During a routine inspection on December 3, 2012, three pharmacy technicians at A&O Specialty Pharmacy were observed performing technician duties such as counting, pouring and mixing pharmaceuticals, while only one pharmacist, David Mark Smith, was on duty.

SECOND CAUSE FOR DISCIPLINE

(DELIVERIES OF DANGEROUS DRUGS SIGNED FOR AND RECEIVED BY NON-PHARMACIST)

40. Respondent A&O is subject to disciplinary action under Code sections 4059.5(a) and 4301(j) and/or (o), and/or Health and Safety Code section 11209(a), in that from January 11, 2011 to December 2012, deliveries of dangerous drugs and/or Schedule II-IV controlled substances, from Amerisource Bergen Drug Co. to A&O Speciality Pharmacy were signed for and received by non-pharmacists.

Respondent A&O, Sterile Compounding License No. LSC 99382

THIRD CAUSE FOR DISCIPLINE

(FAILURE TO QUARANTINE BATCH-PRODUCED STERILE INJECTABLE DRUGS FOR END PRODUCT TESTING)

41. Respondent A&O is subject to disciplinary action under Code sections 4301(j) and/or (o), and/or California Code of Regulations, title 16, section 1751.7(c), in that sterile injectable products compounded from one or more non-sterile ingredients were dispensed to multiple

patients from A&O Specialty Pharmacy without being quarantined to conduct sterility and/or pyrogen[1] testing.

a. From August 29, 2011 to January 12, 2012, Tri-Mix 20 mg/0.67 mg/6.6 mcg injectable solution (lot 08192011@14) was compounded with stock solutions of prostaglandin 500 mcg/ml (lot 07272011) and papaverine/phentolamine 30mg/1mg/ml (lot 08192011) which were never tested for sterility and pyrogens prior to being dispensed.

b. Phentolamine 10mg/ml (lot 05242012@15), a solution made from non-sterile active pharmaceutical ingredients never tested for sterility and pyrogens, was used to compound Tri-Mix 30mg/6mg/60mcg/ml (lot 06242012@10) and was dispensed to a patient on June 4, 2012 and August 8, 2012, and to compound Tri-Mix 15 mg/5mg/2mcg (lot 06042012@11) which was dispensed to a patient on June 4, 2012.

c. From July 27, 2012 to November 8, 2012, prostaglandin 500 mcg/ml (lot 07132012@8, lot 07122012@8) and phentolamine 10mg/ml (lot 06182012@2), stock solutions made from non-sterile active pharmaceutical ingredients that were not tested for sterility and pyrogens, were used to compound Tri-Mix 30mg/6mg/60mcg (lot 10292012@8), Tri-Mix 22.5 mg/0.83mg/8.33mcg (lot 07302012@5, lot 11082012@18), Tri-Mix 30mg/2mc/10mcg (lot 10102012@1), and were dispensed to different patients.

d. From February 14, 2012 to December 17, 2012, multiple batches of hydroxocobalamine injectable, including 5mg/ml (lot 04022012@4, lot 07092012@15 and lot 12172012@12), 10mg/ml (lot 02142012@3 and lot 04202012@14, and 25mg/ml (lot 08312012@15 and lot 11292012@12), compounded from non-sterile ingredients were not quarantined for end-product testing for sterility and endotoxins prior to being dispensed.

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[1] A thermostable bacterial toxin.

FOURTH CAUSE FOR DISCIPLINE

(USE OF INGREDIENTS PAST THEIR BEYOND USE DATES)

42. Respondent A&O is subject to disciplinary action under Code sections 4169(a)(4), and/or 4301(j) and/or (o), and/or California Code of Regulations, title 16, sections 1735.2 and 1735.2(h) in that it used compounded stock solutions past their beyond use dates to compound injectable products.

a. From May 18, 2012 to August 8, 2012, prostaglandin 500mcg/ml (lot 07272011@15), a stock solution made from non-sterile ingredients, with a beyond use date of January 23, 2012, was used to compound different strengths of Tri-Mix products that were then dispensed to different patients.

b. From July 16, 2012 to December 28, 2012, several products were compounded with a stock solution, benzalkonium chloride 1% (lot 01302012@18), which bore a beyond use date of April 9, 2012.

c. From February 14, 2012 to April 2, 2012, two batches of compounded hydroxocobalamine were assigned beyond use dates of May 14, 2012 and July 1, 2012, which exceeded the beyond use date of April 14, 2012 of one of its ingredients, a stock solution, acetic acid 10% (lot 02142012).

d. From April 20, 2012 to December 17, 2012, multiple batches of hydroxocobalamine injectable products were compounded with a stock solution, acetict acid 10% (lot 02142012), which bore a beyond use date of April 14, 2012.

e. From August 31, 2012 to November 30, 2012, three lots of ophthalmic solution were compounded with a stock solution, benzalkonium chloride 10%, which bore a beyond use date of August 19, 2012.

FIFTH CAUSE FOR DISCIPLINE

(COMPOUNDED DRUG PRODUCTS WITH BEYOND USE DATES EXCEEDING 180 DAYS)

43. Respondent A&O is subject to disciplinary action under Code sections 4301(j) and/or (o), and/or California Code of Regulations, title 16, section 1735.2, in that during an inspection

that took place on January 13, 2013, the following compounded products were discovered with assigned and labeled beyond use dates exceeding 180 days in the active inventory:

Compounded Products Name/Strength	Lot Number	Date Made	Labeled BUD
Diltiazem/lidocaine/ntg/hydrocortisone 2/2/0.3/2% ointment	04122012@4	4/12/2012	4/7/2013
Progesterone vaginal 100 mg capsules	04182012@7	4/7/2012	4/13/2013
Nifedipine/gabapentin/bupivacaine 0.3/3/0.75 ointment	05252012@16	5/25/2012	5/20/2013
Nifedipine/lidocaine 0.3/2%ointment	07052012@4	07/05/2012	6/5/2013
Lidocaine/priilocaine/tetracaine 5/5/2% dental gel	08072012@4	08/07/2012	4/30/2013
Diltiazem/lidocaine/hydrocortisone 2/2/2% ointment	08152012@5 12102012@15	8/15/2012	8/10/2013 12/5/2013
Progesterone cream 10% versabase	09052012@5	9/5/2012	8/31/2013
Liothyribube (T3) 37.5mcg capsules S.R.	10102012@3	10/10/2012	10/5/2013
Lidocaine HCL 5% ointment	11302012@7	11/3/2012	11/20/2014
Diltiazem/lidocaine/hydrocortisone 2/2/2% ointment	1210/2012@5	12/10/2012	12/5/2013
Diltiazem 2% ointment	12142012@4	12/14/2012	12/9/2013
Testosterone versabase 0.5% cream	12172012@15	12/17/2012	10/24/2013 or 12/12/2013
Diltiazem/lidocaine 2/2% ointment	12202012@6	12/20/2012	12/15/2013
Progesterone SR 150 mg capsules	01022013@18	1/2/2013	12/28/2013
Progesterone Cream 15% versabase	12192012@9	12/19/2012	10/24/2012 or 12/14/2013

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SIXTH CAUSE FOR DISCIPLINE

(FAILURE TO MAINTAIN ACCURATE LOT NUMBERS FOR RECORDS OF COMPOUNDED DRUG PRODUCTS)

44. Respondent A&O is subject to disciplinary action under Code sections 4301(j) and/or (o), and/or California Code of Regulations, title 16, sections 1735.3 and 1735.3(a)(6), in that it failed to maintain accurate lot numbers of records of compounded drug products as follows:

a. From July 16, 2012 to January 11, 2013, a stock solution of benzalkonium chloride 1% (lot 01302012@18) was used as one of the ingredients to compound several drug products, including EDTA Dental 17% solution (lot 07162012@11), and intraconazole/mupirocin/tac/xylitol 0.2/0.2/0.03/0.2% nasal spray (lot 12202012@11 and lot 01112013@3). The lot number of the stock solution was not accurately recorded on the compounding worksheets of the final products.

b. From April 2, 2012 to December 17, 2012, a stock solution of acetic acid 10% (lot 02142012) was used as one of the ingredients to compound different batches of hydroxocobalamine, including 1/mg/ml (lot 04272012@4, lot 08302012@4), 5mg/ml (lot 04222012@4, lot 07092012@15, 12172012@12, lot 12172012@17), 10mg/ml (lot 04202012@14) and 24mg/ml (lot 08312012@15). The lot number of the stock solution was not accurately recorded on the compounding worksheets of the final products.

SEVENTH CAUSE FOR DISCIPLINE

(FAILURE TO DISINFECT)

45. Respondent A&O is subject to disciplinary action under Code sections 4301(j) and/or (o), and/or California Code of Regulations, title 16, sections 1751.4 and 1751.4(d) in that it failed to disinfect weekly. On February 14, 2013, a review of the cleaning log during an inspection at A&O Specialty Pharmacy indicated the walls, ceiling and storage units in the cleanroom where sterile injectable drug products were compounded, were not disinfected weekly.

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EIGHTH CAUSE FOR DISCIPLINE

(DISPENSING OF MISBRANDED PRODUCTS)

46. Respondent A&O is subject to disciplinary action under Code sections 4169(a)(3) and/or 4301(j) and/or (o), in that it dispensed misbranded products. On unknown dates in 2012 and 2013, Respondent A&O compounded and dispensed different strengths of hydroxocobalamin injection products at 1mg/ml, 5 mg/ml, 10mg/ml and 25mg/ml, but labeled the products as being manufactured by Watson Laboratories Inc. and labeled the products with a National Drug Code of 00591-2888-30 that was specific for hydroxocobalamine 1mg/ml manufactured by Watson Laboratories Inc.

NINTH CAUSE FOR DISCIPLINE

(FRAUDULENT BILLING)

47. Respondent A&O is subject to disciplinary action under sections 4301(f), (j) and/or (o), in that it committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption. On unknown dates in 2012 and 2013, Respondent A&O billed insurance companies with Watson Laboratories Inc.'s product National Drug Code, 00591-2888-30, that was specific for Watson manufactured hydroxocobalamin injectable solution 1mg/ml, for the dispensing of different strengths of hydroxocobalamin injection products compouned at A&O Specialty Pharmacy.

Respondent Aoyama, Pharmacist License No. RPH 24477

TENTH CAUSE FOR DISCIPLINE

(DELIVERIES OF DANGEROUS DRUGS SIGNED FOR AND RECEIVED BY NON-PHARMACIST)

48. Respondent Ayoama is subject to disciplinary action under Code sections 4113(c), 4059.5(a) and/or 4301(j) and/or (o), and/or Health and Safety Code section 11209(a), in that from January 11, 2011 to May 13, 2011, deliveries of dangerous drugs and/or Schedule II-IV controlled substances, from Amerisource Bergen Drug Co. (WLS4383) to A&O Speciality Pharmacy were signed for and received by non-pharmacists.

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Respondent Smith, Pharmacy License No. 36789

ELEVENTH CAUSE FOR DISCIPLINE

(EXCEEDED ALLOWABLE PHARMACIST TO TECHNICIAN RATIO)

49. Respondent Smith is subject to disciplinary action under Code sections 4115(f)(1), 4301(j) and/or (o), and/or California Code of Regulations, title 16, section 1793.2, in that it exceeded the allowable pharmacist to technician ratio. During a routine inspection on December 3, 2012, at A&O Specialty Pharmacy, three technicians were observed performing technician duties such as counting, pouring and mixing pharmaceuticals, while only one pharmacist, Respondent Smith (the pharmacist in charge), was on duty.

TWELFTH CAUSE FOR DISCIPLINE

(DELIVERIES OF DANGEROUS DRUGS SIGNED FOR AND RECEIVED BY NON-PHARMACIST)

50. Respondent Smith is subject to disciplinary action under Code sections 4059.5(a) and/or 4301(j) and/or (o), and/or Health and Safety Code section 11209(a), in that from May 14, 2011 to December 3, 2012, deliveries of dangerous drugs and/or Schedule II-IV controlled substances, from Amerisource Bergen Drug Co. (WLS4383) to A&O Specialty Pharmacy were signed for and received by non-pharmacists.

THIRTEENTH CAUSE FOR DISCIPLINE

(FAILURE TO QUARANTINE BATCH-PRODUCED STERILE INJECTABLE DRUGS FOR END PRODUCT TESTING)

51. Respondent Smith is subject to disciplinary action under Code sections 4301(j) and/or (o), and/or California Code of Regulations, title 16, section 1751.7(c), in that sterile injectable products compounded from one or more non-sterile ingredients were dispensed to multiple patients from A&O Specialty Pharmacy without being quarantined to conduct sterility and/or pyrogen testing. The following sterile injectable products compounded from one or more non-sterile ingredients were dispensed to multiple patients from A&O Specialty Pharmacy, without being quarantined to conduct sterility and/or pyrogen testing:

a. From August 29, 2011 to January 12, 2012, Tri-Mix 20mg/0.67mg/6.6mcg injectable solution (lot 08192011@14) was compounded with stock solutions of prostaglandin 500mcg/ml (lot 07272011) and papaverine/phentolamine 30mg/1mg/ml (lot 08192011) which were never tested for sterility and pyrogens prior to being dispensed.

b. Phentolamine 10mg/ml (lot 05242012@15), a solution made from non-sterile active pharmaceutical ingredients that were never tested for sterility and pyrogens, was used to compound Tri-Mix 30mg/6mg/50mcg/ml (lot 06242012@10) and was dispensed to a patient on June 4, 2012 and August 8, 2012, and to compound Tri-Mix 15mg/5mg/2mcg (lot 06042012@11) which was dispensed to a patient on June 2, 2012.

c. From July 27, 2012 to November 8, 2012, prostaglandin 500 mcg/ml (lot 07132012@8), lot 07122012@8), and phentolamine 10mg/ml (lot 06182012@2), stock solutions made from non-sterile active pharmaceutical ingredients that were not tested for sterility and pyrogens, were used to compound Tri-Mix 30mg/6mg/60mcg (lot 10292012@8), Tri-Mix 22.5mg/0.83mg/8.33mcg (lot 07302012@5, lot 11082012), Tri-Mix 30mg/2mc/10mcg (lot 10102012@1), and were dispensed to different patients.

d. From Febuary 14, 2012 to December 17, 2012, multiple batches of hydroxocobalamine injectable, including 5mg/ml (lot 04022012@4, 07092012@15 and lot 12172012@12), 10mg/ml (lot 0212012@3 and lot 04202012@14), and 25mg/ml (lot 08312012@15 and lot 11292012@12) compounded from non-sterile ingredients were not quarantined for end-product testing for sterility and endotoxin prior to being dispensed.

FOURTEENTH CAUSE FOR DISCIPLINE

(USE OF INGREDIENTS PAST THEIR BEYOND USE DATES)

52. Respondent Smith is subject to disciplinary action under Code sections 4169(a)(4), 4301(j) and/or (o), and/or California Code of Regulations, title 16, sections 1735.2 and 1735.2(h) in that, on the following dates, while Respondent Smith was the pharmacist in charge, A&O Specialty Pharmacy used compounded stock solutions past their beyond use dates to compound injectable products:

a. From May 18, 2012 to August 8, 2012, prostaglandin 500 mcg/ml (lot 07272011@15), a stock solution made from non-sterile ingredients, with a beyond use date of January 23, 2012, was used to compound different strengths of Tri-Mix products that were then dispensed to different patients.

b. From July 16, 2012 to December 28, 2012, several products were compounded with a stock solution, benzalkonium chloride 1% (lot 01302012@18), which bore a beyond use date of April 29, 2012.

c. From February 14, 2012 to April 2, 2012, two batches of compounded hydroxocobalamine were assigned beyond use dates of May 14, 2012 and July 1, 2012, which exceeded the beyond use date of April 14, 2012 of one of its ingredients, a stock solution, acetic acid 10% (lot 02142012).

d. From April 20, 2012 to December 17, 2012, multiple batches of hydroxocobalamine injectable products were compounded with a stock solution, acetic acid 10% (lot 02142012), which bore a beyond use date of April 14, 2012.

e. From August 31, 2012 to November 30, 2012, three lots of ophthalmic solution were compounded with a stock solution, benzalkonium chloride 10%, which bore a beyond use date of August 19, 2012.

FIFTEENTH CAUSE FOR DISCIPLINE

(COMPOUNDED DRUG PRODUCTS WITH BEYOND USE DATES EXCEEDING 180 DAYS)

53. Respondent Smith is subject to disciplinary action under Code sections 4301(j) and/or (o), and/or California Code of Regulations, title 16, sections 1735.2 and 1735.2(h), in that during an inspection that took place on January 13, 2013, the following compounded products were discovered at A&O Specialty Pharmacy with assigned and labeled beyond use dates exceeding 180 days in the active inventory:

Compounded Products Name/Strength	**Lot Number**	**Date Made**	**Labeled BUD**
Diltiazem/lidocaine/ntg/hydrocortisone 2/2/0.3/2% ointment	041222012@4	4/12/2012	4/7/2013
Progesterone vaginal 100mg capsules	04182012@7	4/7/2012	4/13/2013

Nifedipine/gabapentin/bupivacaine 0.3/3/0.75% ointment	05252012@16	5/25/2012	5/20/2013
Nifedipine/lidocaine0.3/2% ointment	07052012@4	8/7/2012	6/5/2013
Lidocaine/prilocaine/tetracaine 5/5/2% dental gel	08072012@4	8/7/2012	4/30/2013
Diltiazem/lodocaine/hydrocortisone 2/2/2% ointment	08152012@10 12/10/2012@15	8/15/2012	8/10/2013 12/5/2013
Progesterone cream 10% versabase	09052012@5	9/5/2012	8/31/2013
Liothyribube (T3) 37.5 mcg capsules S.R.	10102012@3	10/10/2012	10/5/2013
Lidocaine HCL 5% ointment	11302012@7	11/3/2012	11/20/2014
Diltiazem/lidocaine/hydrocortisone 2/2/2% ointment	12102012@5	12/10/2012	12/5/2013
Diltiazem 2% ointment	12142012@4	12/14/2012	12/9/2013
Testosterone versabase 0.5% cream	12172012@15	12/17/2012	10/24/2013 or 12/12/2013
Progesterone cream 15% versabase	12192012@9	12/19/2012	10/24/2013 or 12/14/2013
Diltiazem/lidocaine 2/2% ointment	12202012@6	12/20/2012	12/15/2013
Progesterone SR 150 mg capsules	01022013@18	1/2/2013	12/28/2013

SIXTEENTH CAUSE FOR DISCIPLINE

(FAILURE TO MAINTAIN ACCURATE LOT NUMBERS FOR RECORDS OF COMPOUNDED DRUG PRODUCTS)

54. Respondent Smith is subject to disciplinary action under Code sections 4301(j) and/or (o), and/or California Code of Regulations, title 16, sections 1735.3 and 1735.3(a)(6), in that A&O Specialty Pharmacy failed to maintain accurate lot numbers of records of compounded drug products as follows:

a. From July 16, 2012 to January 11, 2013, a stock solution of benzalkonium chloride 1% (lot 01302012@18) was used as one of the ingredients to compound several drug products, including EDTA Dental 17% solution (lot 07162012@11), and intraconazole/mupirocin/tac/xylitol 0.2/0.2/0.03/02% nasal spray (lot 12202012@11 and lot

01112013@3). The lot number of the stock solution was not accurately recorded on the compounding worksheets of the final products.

b. From April 2, 2012 to December 17, 2012, a stock solution of acetic acid 10% (lot 02142012) was used as one fo the ingredients to compound different batches of hydroxocobalamine, including 1mg/ml (lot 04272012@4, lot 08302012@4), 5mg/ml (lot 04022012@4, lot 07092012@15, 12172012@12, lot 12172012@17), 10mg/ml (lot 04202012@14) and 25mg/ml (lot 08312012@15(. The lot number of the stock solution was not accurately recorded on the compounding worksheets of the final products.

SEVENTEENTH CAUSE FOR DISCIPLINE

(FAILURE TO DISINFECT)

55. Respondent Smith is subject to disciplinary action under Code sections 4301(j) and (o), and California Code of Regulations, title 16, sections 1751.4 and 1751.4(d), failing to disinfect weekly. On February 14, 2013, a review of the cleaning log during an inspection at A&O Specialty Pharmacy indicated the walls, ceiling and storage units in the cleanroom where sterile injectable drug products were compounded, were not disinfected weekly.

EIGHTEENTH CAUSE FOR DISCIPLINE

(DISPENSING OF MISBRANDED PRODUCTS)

56. Respondent Smith is subject to disciplinary action under Code sections 4169(a)(3) and/or 4301(j) and/or (o), in that A&O Specialty Pharmacy dispensed misbranded products. On unknown dates in 2012 and 2013, while Respondent Smith was the pharmacist in charge, A&O Specialty Pharmacy compounded and dispensed different strengths of hydroxocobalamin injection products at 1mg/ml, 5mg/ml, 10mg/ml and 25mg/ml, but labeled the products as being manufactured by Watson Laboratories Inc. and labeled the products with a National Drug Code of 00591-28880-30, that was specific for hydroxocobalamin 1mg/ml manufactured by Watson Laboratores, Inc.

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NINETEENTH CAUSE FOR DISCIPLINE

(FRAUDULENT BILLING)

57. Respondent Smith is subject to disciplinary action under Code sections 4301(f), (j) and/or (o), in that he committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption. On unknown dates in 2012 and 2013, while Respondent Smith was the pharmacist in charge, A&O Specialty Pharmacy billed insurance companies with Watson Laboratories Inc.'s product National Drug Code, 00491-2888-30, that was specific for Watson manufactured hydroxocobalamin injectable solution 1mg/ml, for the dispensing of different strengths of hydroxocobalamin injection products compounded at A&O Specialty Pharmacy.

DISCIPLINE CONSIDERATIONS

58. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that on or about April 14, 2011, in a prior action, the Board of Pharmacy issued Citation Number CI 2010 47968 to Respondent Aoyama and ordered him to pay a $3,500.00 fine for compounding drugs from expired ingredients. That Citation is now final and is incorporated by reference as if fully set forth.

59. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that on or about April 14, 2011, in a prior action, the Board of Pharmacy issued Citation Number CI 2010 46099 to Respondent A&O and ordered it to pay a $3,500.00 fine for compounding drugs from expired ingredients. That Citation is now final and is incorporated by reference as if fully set forth.

60. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that on or about October 25, 2013, in a prior action, the Board of Pharmacy issued Citation Number CI 2013 58405 to Respondent Smith and ordered him to pay a $500.00 fine for permitting staff to work unsupervised where dangerous drugs were stored. That Citation is now final and is incorporated by reference as if fully set forth.

61. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that on or about October 25, 2013, in a prior action, the Board of Pharmacy issued Citation Number CI 2012 55360 to Respondent A&O and ordered it to pay a $500.00 fine

for permitting staff to work unsupervised where dangerous drugs were stored. That Citation is now final and is incorporated by reference as if fully set forth.

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 License Number PHY 47448, issued to A&O Specialty Pharmacy;

2. Revoking or suspending Sterile Compounding License Number LSC 99283, issued to A&O Specialty Pharmacy;

3. Revoking or suspending Pharmacist License Number RPH 36789, issued to David Mark Smith;

4. Revoking or suspending Pharmacist License Number RPH 24477, issued to Akira Aoyama;

5. Ordering Respondents 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;

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

DATED: 8/8/14

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

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