

**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
210 16th Avenue
Santa Cruz, CA 95062**

Pharmacist License No. RPH 36789

**AKIRA AOYAMA
608 San Miguel Avenue
Salinas, CA 93901**

Pharmacist License No. RPH 24477

Respondents.

Case No. 5077

OAH No. 2014120239

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER – AS TO
DAVID MARK SMITH ONLY**

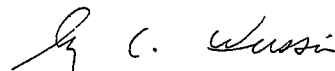
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary 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 May 20, 2015.

It is so ORDERED on May 6, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

STAN C. WEISSER, Board President

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8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
10 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

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Sterile Compounding License No. LSC
15 **99382**

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER – AS TO
DAVID MARK SMITH ONLY

16 **DAVID MARK SMITH**
17 **210 16th Avenue**
Santa Cruz, CA 95062

18 **Pharmacist License No. RPH 36789**

19 **AKIRA AOYAMA**
20 **608 San Miguel Avenue**
Salinas, CA 93901

21 **Pharmacist License No. RPH 24477**

22 Respondents.

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

25 PARTIES

26 1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.
27 She brought this action solely in her official capacity and is represented in this matter by Kamala
28

1 D. Harris, Attorney General of the State of California, by Char Sachson, Deputy Attorney
2 General.

3 2. Respondent David Mark Smith ("Respondent Smith") is represented in this
4 proceeding by attorney Tony J. Park, Pharm.D., J.D., whose address is: 2855 Michelle Drive,
5 Suite 180, Irvine, CA 92606-1027.

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

9 JURISDICTION

10 4. Accusation No. 5077 was filed before the Board of Pharmacy ("Board"), Department
11 of Consumer Affairs, and is currently pending against Respondent Smith. The Accusation and all
12 other statutorily required documents were properly served on Respondent on August 19, 2014.
13 Respondent Smith timely filed his Notice of Defense contesting the Accusation.

14 5. A copy of Accusation No. 5077 is attached as Exhibit A and incorporated herein by
15 reference.

16 ADVISEMENT AND WAIVERS

17 6. Respondent Smith has carefully read, fully discussed with counsel, and understands
18 the charges and allegations in Accusation No. 5077. Respondent Smith has also carefully read,
19 fully discussed with counsel, and understands the effects of this Stipulated Settlement and
20 Disciplinary Order.

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

28

1 Respondent shall report any of the following occurrences to the board, in writing, within
2 seventy-two (72) hours of such occurrence:

- 3 • an arrest or issuance of a criminal complaint for violation of any provision of the
4 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
5 substances laws
- 6 • a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
7 criminal complaint, information or indictment
- 8 • a conviction of any crime
- 9 • discipline, citation, or other administrative action filed by any state or federal agency
10 which involves respondent's pharmacist license or which is related to the practice of
11 pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging
12 for any drug, device or controlled substance.

13 Failure to timely report such occurrence shall be considered a violation of probation.

14 3. Report to the Board

15 Respondent shall report to the board quarterly, on a schedule as directed by the board or its
16 designee. The report shall be made either in person or in writing, as directed. Among other
17 requirements, respondent shall state in each report under penalty of perjury whether there has
18 been compliance with all the terms and conditions of probation. Failure to submit timely reports
19 in a form as directed shall be considered a violation of probation. Any period(s) of delinquency
20 in submission of reports as directed may be added to the total period of probation. Moreover, if
21 the final probation report is not made as directed, probation shall be automatically extended until
22 such time as the final report is made and accepted by the board.

23 4. Interview with the Board

24 Upon receipt of reasonable prior notice, respondent shall appear in person for interviews
25 with the board or its designee, at such intervals and locations as are determined by the board or its
26 designee. Failure to appear for any scheduled interview without prior notification to board staff,
27 or failure to appear for two (2) or more scheduled interviews with the board or its designee during
28 the period of probation, shall be considered a violation of probation.

1 5. **Cooperate with Board Staff**

2 Respondent shall cooperate with the board's inspection program and with the board's
3 monitoring and investigation of respondent's compliance with the terms and conditions of his
4 probation. Failure to cooperate shall be considered a violation of probation.

5 6. **Continuing Education**

6 Respondent shall provide evidence of efforts to maintain skill and knowledge as a
7 pharmacist as directed by the board or its designee.

8 7. **Notice to Employers**

9 During the period of probation, respondent shall notify all present and prospective
10 employers of the decision in case number 5077 and the terms, conditions and restrictions imposed
11 on respondent by the decision, as follows:

12 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
13 respondent undertaking any new employment, respondent shall cause his direct supervisor,
14 pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's
15 tenure of employment) and owner to report to the board in writing acknowledging that the listed
16 individual(s) has/have read the decision in case number 5077, and terms and conditions imposed
17 thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s)
18 submit timely acknowledgment(s) to the board.

19 If respondent works for or is employed by or through a pharmacy employment service,
20 respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity
21 licensed by the board of the terms and conditions of the decision in case number 5077 in advance
22 of the respondent commencing work at each licensed entity. A record of this notification must be
23 provided to the board upon request.

24 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen
25 (15) days of respondent undertaking any new employment by or through a pharmacy employment
26 service, respondent shall cause his direct supervisor with the pharmacy employment service to
27 report to the board in writing acknowledging that they has read the decision in case number 5077

28

1 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure
2 that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

3 Failure to timely notify present or prospective employer(s) or to cause that/those
4 employer(s) to submit timely acknowledgments to the board shall be considered a violation of
5 probation.

6 "Employment" within the meaning of this provision shall include any full-time,
7 part-time, temporary, relief or pharmacy management service as a pharmacist or any
8 position for which a pharmacist license is a requirement or criterion for employment,
9 whether the respondent is an employee, independent contractor or volunteer.

10 **8. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as**
11 **Designated Representative-in-Charge, or Serving as a Consultant**

12 During the period of probation, respondent shall not supervise any intern pharmacist, be the
13 pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board
14 nor serve as a consultant unless otherwise specified in this order. Assumption of any such
15 unauthorized supervision responsibilities shall be considered a violation of probation.

16 **9. Reimbursement of Board Costs**

17 As a condition precedent to successful completion of probation, respondent Smith shall pay
18 to the board its costs of investigation and prosecution in the amount of \$12,988.50. Respondent
19 Smith shall make said payments pursuant to a plan approved by the Board. There shall be no
20 deviation from this schedule absent prior written approval by the board or its designee. Failure to
21 pay costs by the deadline(s) as directed shall be considered a violation of probation.

22 The filing of bankruptcy by respondent shall not relieve respondent of his responsibility to
23 reimburse the board its costs of investigation and prosecution.

24 Respondent Smith shall be jointly and severally liable for payment of costs of
25 investigation and prosecution with Respondent A&O Specialty Pharmacy.

26 **10. Probation Monitoring Costs**

27 Respondent shall pay any costs associated with probation monitoring as determined by the
28 board each and every year of probation. Such costs shall be payable to the board on a schedule as

1 directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall
2 be considered a violation of probation.

3 **11. Status of License**

4 Respondent shall, at all times while on probation, maintain an active, current license with
5 the board, including any period during which suspension or probation is tolled. Failure to
6 maintain an active, current license shall be considered a violation of probation.

7 If respondent's license expires or is cancelled by operation of law or otherwise at any time
8 during the period of probation, including any extensions thereof due to tolling or otherwise, upon
9 renewal or reapplication respondent's license shall be subject to all terms and conditions of this
10 probation not previously satisfied.

11 **12. License Surrender While on Probation/Suspension**

12 Following the effective date of this decision, should respondent cease practice due to
13 retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,
14 respondent may tender his license to the board for surrender. The board or its designee shall have
15 the discretion whether to grant the request for surrender or take any other action it deems
16 appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent
17 will no longer be subject to the terms and conditions of probation. This surrender constitutes a
18 record of discipline and shall become a part of the respondent's license history with the board.

19 Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to
20 the board within ten (10) days of notification by the board that the surrender is accepted.

21 Respondent may not reapply for any license from the board for three (3) years from the effective
22 date of the surrender. Respondent shall meet all requirements applicable to the license sought as
23 of the date the application for that license is submitted to the board, including any outstanding
24 costs.

25 **13. Notification of a Change in Name, Residence Address, Mailing Address or**
26 **Employment**

27 Respondent shall notify the board in writing within ten (10) days of any change of
28 employment. Said notification shall include the reasons for leaving, the address of the new

1 employer, the name of the supervisor and owner, and the work schedule if known. Respondent
2 shall further notify the board in writing within ten (10) days of a change in name, residence
3 address, mailing address, or phone number.

4 Failure to timely notify the board of any change in employer(s), name(s), address(es), or
5 phone number(s) shall be considered a violation of probation.

6 14. Tolling of Probation

7 Except during periods of suspension, respondent shall, at all times while on probation, be
8 employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any
9 month during which this minimum is not met shall toll the period of probation, i.e., the period of
10 probation shall be extended by one month for each month during which this minimum is not met.
11 During any such period of tolling of probation, respondent must nonetheless comply with all
12 terms and conditions of probation.

13 Should respondent, regardless of residency, for any reason (including vacation) cease
14 practicing as a pharmacist for a minimum of 40 hours per calendar month in California,
15 respondent must notify the board in writing within ten (10) days of the cessation of practice, and
16 must further notify the board in writing within ten (10) days of the resumption of practice. Any
17 failure to provide such notification(s) shall be considered a violation of probation.

18 It is a violation of probation for respondent's probation to remain tolled pursuant to the
19 provisions of this condition for a total period, counting consecutive and non-consecutive months,
20 exceeding thirty-six (36) months.

21 "Cessation of practice" means any calendar month during which respondent is
22 not practicing for at least 40 hours as a pharmacist, as defined by Business and
23 Professions Code section 4000 et seq. "Resumption of practice" means any calendar
24 month during which respondent is practicing for at least 40 hours as a pharmacist, as
25 defined by Business and Professions Code section 4000 et seq.

26 15. Violation of Probation

27 If respondent has not complied with any term or condition of probation, the board shall
28 have continuing jurisdiction over respondent, and probation shall automatically be extended, until

1 all terms and conditions have been satisfied or the board has taken other action as deemed
2 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and
3 to impose the penalty that was stayed.

4 If respondent violates probation in any respect, the board, after giving respondent notice
5 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that
6 was stayed. Notice and opportunity to be heard are not required for those provisions stating that a
7 violation thereof may lead to automatic termination of the stay and/or revocation of the license. If
8 a petition to revoke probation or an accusation is filed against respondent during probation, the
9 board shall have continuing jurisdiction and the period of probation shall be automatically
10 extended until the petition to revoke probation or accusation is heard and decided.

11 **16. Completion of Probation**

12 Upon written notice by the board or its designee indicating successful completion of
13 probation, respondent's license will be fully restored.

14 **17. Remedial Education**

15 Within sixty (60) days of the effective date of this decision, respondent shall submit to the
16 board or its designee, for prior approval, an appropriate program of remedial education related to
17 pharmacy operations and sterile compounding. The program of remedial education shall consist
18 of at least ten (10) hours a year for the first three (3) years of probation, at respondent's own
19 expense. All remedial education shall be in addition to, and shall not be credited toward,
20 continuing education (CE) courses used for license renewal purposes.

21 Failure to timely submit or complete the approved remedial education shall be considered a
22 violation of probation. The period of probation will be automatically extended until such
23 remedial education is successfully completed and written proof, in a form acceptable to the board,
24 is provided to the board or its designee.

25 Following the completion of each course, the board or its designee may require the
26 respondent, at his own expense, to take an approved examination to test the respondent's
27 knowledge of the course. If the respondent does not achieve a passing score on the examination,
28 this failure shall be considered a violation of probation. Any such examination failure shall

1 require respondent to take another course approved by the board in the same subject area.

2 **18. No Ownership of Licensed Premises**

3 Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a
4 manager, administrator, member, officer, director, trustee, associate, or partner of any additional
5 business, firm, partnership, or corporation licensed by the board. If respondent currently owns or
6 has any legal or beneficial interest in, or serves as a manager, administrator, member, officer,
7 director, trustee, associate, or partner of any business, firm, partnership, or corporation currently
8 or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold
9 that interest, but only to the extent of that position or interest as of the effective date of this
10 decision. Violation of this restriction shall be considered a violation of probation.

11 **19. Consultant for Owner or Pharmacist-In-Charge**

12 During the period of probation, respondent shall not supervise any intern pharmacist or
13 serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-
14 charge. However, if, at any time during the period of probation, respondent serves as a
15 pharmacist-in-charge, respondent shall retain an independent consultant at his own expense who
16 shall be responsible for reviewing pharmacy operations on a monthly basis (this may be reduced
17 to quarterly reviews by a Board designee) for compliance by respondent with state and federal
18 laws and regulations governing the practice of pharmacy and for compliance by respondent with
19 the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and
20 not on probation with the board and whose name shall be submitted to the board or its designee,
21 for prior approval, within thirty (30) days of the effective date of this decision. Respondent shall
22 not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he is not
23 the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the
24 consultant shall be considered a violation of probation.

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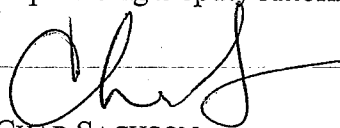
ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated: 4/8/15

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
FRANK H. PACOE
Supervising Deputy Attorney General



CHAR SACHSON
Deputy Attorney General
Attorneys for Complainant

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41237484.doc

Exhibit A

Accusation No. 5077

1 KAMALA D. HARRIS
Attorney General of California
2 FRANK H. PACOE
Supervising Deputy Attorney General
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ACCUSATION

14 **Pharmacy License No. PHY 47448**
15 **Sterile Compounding License No. LSC 99382**

16 **DAVID MARK SMITH**
17 **536 Abbott Street**
18 **Salinas, CA 93901**

19 **Pharmacist License No. RPH 36789**

20 **AKIRA AOYAMA**
21 **608 San Miguel Avenue**
22 **Salinas, CA 93901**

23 **Pharmacist License No. RPH 24477**

24 Respondents.

25 Complainant alleges:

26 PARTIES

27 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
28 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

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

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

7 4. On or about November 3, 1981, the Board of Pharmacy issued Pharmacist License
8 Number RPH 36789 to David Mark Smith (Respondent Smith). The Pharmacist License was in
9 full force and effect at all times relevant to the charges brought herein and will expire on June 30,
10 2015, unless renewed.

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

15 JURISDICTION

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

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

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

24 9. Code section 4300.1 provides that the expiration, cancellation, forfeiture, or
25 suspension of a board-issued license by operation of law or by order or decision of the board or a
26 court of law, the placement of a license on a retired status, or the voluntary surrender of a license
27 by a licensee shall not deprive the board of jurisdiction to commence or proceed with any
28

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

3 STATUTORY AND REGULATORY PROVISIONS

4 10. Section 4300 of the Code states:

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

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

9 "(1) Suspending judgment.

10 "(2) Placing him or her upon probation.

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

12 "(4) Revoking his or her license.

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

15 ..."

16 11. Section 4301 of the Code states:

17 "The board shall take action against any holder of a license who is guilty of unprofessional
18 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

19 Unprofessional conduct shall include, but is not limited to, any of the following:

20 ...

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

24 ...

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

27 ...

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 ...

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

25 ..."

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

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

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

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

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

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

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

9 "(c) placing the product into a container;

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

11 "(e) packaging and repackaging."

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

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

20 COST RECOVERY

21 24. Section 125.3 of the Code states, in pertinent part, that the Board may request the
22 administrative law judge to direct a licentiate found to have committed a violation or violations of
23 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
24 enforcement of the case.

25 CONTROLLED SUBSTANCES/DANGEROUS DRUGS

26 25. Section 4022 of the Code states

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

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

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

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

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

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

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

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

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

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

20 32. Itraconazole/mupirocin/tac/xylitol nasal spray is a dangerous drug per Code section
21 4022, and is used for allergic fungal sinusitis.

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

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

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

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

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

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

5 Respondent A&O, Pharmacy License No. PHY 47488

6 FIRST CAUSE FOR DISCIPLINE

7 (EXCEEDED ALLOWABLE PHARMACIST TO TECHNICIAN RATIO)

8 39. Respondent A&O is subject to disciplinary action under Code sections 4115(f)(1),
9 4301(j) and/or (o), and/or California Code of Regulations, title 16, section 1793.2, in that it
10 exceeded the allowable pharmacist to technician ratio. During a routine inspection on December
11 3, 2012, three pharmacy technicians at A&O Specialty Pharmacy were observed performing
12 technician duties such as counting, pouring and mixing pharmaceuticals, while only one
13 pharmacist, David Mark Smith, was on duty.

14 SECOND CAUSE FOR DISCIPLINE

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

17 40. Respondent A&O is subject to disciplinary action under Code sections 4059.5(a) and
18 4301(j) and/or (o), and/or Health and Safety Code section 11209(a), in that from January 11, 2011
19 to December 2012, deliveries of dangerous drugs and/or Schedule II-IV controlled substances,
20 from Amerisource Bergen Drug Co. to A&O Speciality Pharmacy were signed for and received
21 by non-pharmacists.

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

23 THIRD CAUSE FOR DISCIPLINE

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

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

1 patients from A&O Specialty Pharmacy without being quarantined to conduct sterility and/or
2 pyrogen¹ testing.

3 a. From August 29, 2011 to January 12, 2012, Tri-Mix 20 mg/0.67 mg/6.6 mcg
4 injectable solution (lot 08192011@14) was compounded with stock solutions of prostaglandin
5 500 mcg/ml (lot 07272011) and papaverine/phentolamine 30mg/1mg/ml (lot 08192011) which
6 were never tested for sterility and pyrogens prior to being dispensed.

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

12 c. From July 27, 2012 to November 8, 2012, prostaglandin 500 mcg/ml (lot
13 07132012@8, lot 07122012@8) and phentolamine 10mg/ml (lot 06182012@2), stock solutions
14 made from non-sterile active pharmaceutical ingredients that were not tested for sterility and
15 pyrogens, were used to compound Tri-Mix 30mg/6mg/60mcg (lot 10292012@8), Tri-Mix 22.5
16 mg/0.83mg/8.33mcg (lot 07302012@5, lot 11082012@18), Tri-Mix 30mg/2mc/10mcg (lot
17 10102012@1), and were dispensed to different patients.

18 d. From February 14, 2012 to December 17, 2012, multiple batches of
19 hydroxocobalamine injectable, including 5mg/ml (lot 04022012@4, lot 07092012@15 and lot
20 12172012@12), 10mg/ml (lot 02142012@3 and lot 04202012@14, and 25mg/ml (lot
21 08312012@15 and lot 11292012@12), compounded from non-sterile ingredients were not
22 quarantined for end-product testing for sterility and endotoxins prior to being dispensed.

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28 ¹ A thermostable bacterial toxin.

1 FOURTH CAUSE FOR DISCIPLINE

2 (USE OF INGREDIENTS PAST THEIR BEYOND USE DATES)

3 42. Respondent A&O is subject to disciplinary action under Code sections 4169(a)(4),
4 and/or 4301(j) and/or (o), and/or California Code of Regulations, title 16, sections 1735.2 and
5 1735.2(h) in that it used compounded stock solutions past their beyond use dates to compound
6 injectable products.

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

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

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

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

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

24 FIFTH CAUSE FOR DISCIPLINE

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

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

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

3	Compounded Products Name/Strength	Lot Number	Date Made	Labeled BUD
4	Diltiazem/lidocaine/ntg/hydrocortisone 2/2/0.3/2% ointment	04122012@4	4/12/2012	4/7/2013
5	Progesterone vaginal 100 mg capsules	04182012@7	4/7/2012	4/13/2013
6	Nifedipine/gabapentin/bupivacaine 0.3/3/0.75 7 ointment	05252012@16	5/25/2012	5/20/2013
8	Nifedipine/lidocaine 0.3/2% ointment	07052012@4	07/05/2012	6/5/2013
9	Lidocaine/priilocaine/tetracaine 5/5/2% dental 10 gel	08072012@4	08/07/2012	4/30/2013
11	Diltiazem/lidocaine/hydrocortisone 2/2/2% 11 ointment	08152012@5 12102012@15	8/15/2012	8/10/2013 12/5/2013
12	Progesterone cream 10% versabase	09052012@5	9/5/2012	8/31/2013
13	Liothyribube (T3) 37.5mcg capsules S.R.	10102012@3	10/10/2012	10/5/2013
14	Lidocaine HCL 5% ointment	11302012@7	11/3/2012	11/20/2014
15	Diltiazem/lidocaine/hydrocortisone 2/2/2% 16 ointment	1210/2012@5	12/10/2012	12/5/2013
17	Diltiazem 2% ointment	12142012@4	12/14/2012	12/9/2013
18	Testosterone versabase 0.5% cream	12172012@15	12/17/2012	10/24/2013 or 12/12/2013
19				
20	Diltiazem/lidocaine 2/2% ointment	12202012@6	12/20/2012	12/15/2013
21	Progesterone SR 150 mg capsules	01022013@18	1/2/2013	12/28/2013
22	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 compounded 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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1 a. From August 29, 2011 to January 12, 2012, Tri-Mix 20mg/0.67mg/6.6mcg
2 injectable solution (lot 08192011@14) was compounded with stock solutions of prostaglandin
3 500mcg/ml (lot 07272011) and papaverine/phentolamine 30mg/1mg/ml (lot 08192011) which
4 were never tested for sterility and pyrogens prior to being dispensed.

5 b. Phentolamine 10mg/ml (lot 05242012@15), a solution made from non-sterile
6 active pharmaceutical ingredients that were never tested for sterility and pyrogens, was used to
7 compound Tri-Mix 30mg/6mg/50mcg/ml (lot 06242012@10) and was dispensed to a patient on
8 June 4, 2012 and August 8, 2012, and to compound Tri-Mix 15mg/5mg/2mcg (lot
9 06042012@11) which was dispensed to a patient on June 2, 2012.

10 c. From July 27, 2012 to November 8, 2012, prostaglandin 500 mcg/ml (lot
11 07132012@8), lot 07122012@8), and phentolamine 10mg/ml (lot 06182012@2), stock solutions
12 made from non-sterile active pharmaceutical ingredients that were not tested for sterility and
13 pyrogens, were used to compound Tri-Mix 30mg/6mg/60mcg (lot 10292012@8), Tri-Mix
14 22.5mg/0.83mg/8.33mcg (lot 07302012@5, lot 11082012), Tri-Mix 30mg/2mc/10mcg (lot
15 10102012@1), and were dispensed to different patients.

16 d. From February 14, 2012 to December 17, 2012, multiple batches of
17 hydroxocobalamine injectable, including 5mg/ml (lot 04022012@4, 07092012@15 and lot
18 12172012@12), 10mg/ml (lot 0212012@3 and lot 04202012@14), and 25mg/ml (lot
19 08312012@15 and lot 11292012@12) compounded from non-sterile ingredients were not
20 quarantined for end-product testing for sterility and endotoxin prior to being dispensed.

21 FOURTEENTH CAUSE FOR DISCIPLINE

22 (USE OF INGREDIENTS PAST THEIR BEYOND USE DATES)

23 52. Respondent Smith is subject to disciplinary action under Code sections 4169(a)(4),
24 4301(j) and/or (o), and/or California Code of Regulations, title 16, sections 1735.2 and 1735.2(h)
25 in that, on the following dates, while Respondent Smith was the pharmacist in charge, A&O
26 Specialty Pharmacy used compounded stock solutions past their beyond use dates to compound
27 injectable products:
28

1 a. From May 18, 2012 to August 8, 2012, prostaglandin 500 mcg/ml (lot
2 07272011@15), a stock solution made from non-sterile ingredients, with a beyond use date of
3 January 23, 2012, was used to compound different strengths of Tri-Mix products that were then
4 dispensed to different patients.

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

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

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

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

18 FIFTEENTH CAUSE FOR DISCIPLINE

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

21 53. Respondent Smith is subject to disciplinary action under Code sections 4301(j) and/or
22 (o), and/or California Code of Regulations, title 16, sections 1735.2 and 1735.2(h), in that during
23 an inspection that took place on January 13, 2013, the following compounded products were
24 discovered at A&O Specialty Pharmacy with assigned and labeled beyond use dates exceeding
25 180 days in the active inventory:

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

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

1 01112013@3). The lot number of the stock solution was not accurately recorded on the
2 compounding worksheets of the final products.

3 b. From April 2, 2012 to December 17, 2012, a stock solution of acetic acid 10%
4 (lot 02142012) was used as one fo the ingredients to compound different batches of
5 hydroxocobalamine, including 1mg/ml (lot 04272012@4, lot 08302012@4), 5mg/ml (lot
6 04022012@4, lot 07092012@15, 12172012@12, lot 12172012@17), 10mg/ml (lot
7 04202012@14) and 25mg/ml (lot 08312012@15(. The lot number of the stock solution was not
8 accurately recorded on the compounding worksheets of the final products.

9 SEVENTEENTH CAUSE FOR DISCIPLINE

10 (FAILURE TO DISINFECT)

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

16 EIGHTEENTH CAUSE FOR DISCIPLINE

17 (DISPENSING OF MISBRANDED PRODUCTS)

18 56. Respondent Smith is subject to disciplinary action under Code sections 4169(a)(3)
19 and/or 4301(j) and/or (o), in that A&O Specialty Pharmacy dispensed misbranded products. On
20 unknown dates in 2012 and 2013, while Respondent Smith was the pharmacist in charge, A&O
21 Specialty Pharmacy compounded and dispensed different strengths of hydroxocobalamin
22 injection products at 1mg/ml, 5mg/ml, 10mg/ml and 25mg/ml, but labeled the products as being
23 manufactured by Watson Laboratories Inc. and labeled the products with a National Drug Code of
24 00591-28880-30, that was specific for hydroxocobalamin 1mg/ml manufactured by Watson
25 Laboratores, Inc.

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1 NINETEENTH CAUSE FOR DISCIPLINE

2 (FRAUDULENT BILLING)

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

10 DISCIPLINE CONSIDERATIONS

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

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

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

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

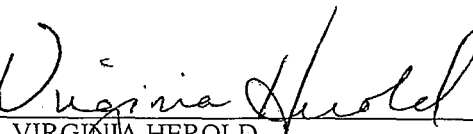
1 for permitting staff to work unsupervised where dangerous drugs were stored. That Citation is
2 now final and is incorporated by reference as if fully set forth.

3
4 PRAYER

5 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
6 and that following the hearing, the Board of Pharmacy issue a decision:

- 7 1. Revoking or suspending Pharmacy License Number PHY 47448, issued to A&O
8 Specialty Pharmacy;
- 9 2. Revoking or suspending Sterile Compounding License Number LSC 99283, issued to
10 A&O Specialty Pharmacy;
- 11 3. Revoking or suspending Pharmacist License Number RPH 36789, issued to David
12 Mark Smith;
- 13 4. Revoking or suspending Pharmacist License Number RPH 24477, issued to Akira
14 Aoyama;
- 15 5. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the
16 investigation and enforcement of this case, pursuant to Business and Professions Code section
17 125.3;
- 18 6. Taking such other and further action as deemed necessary and proper.

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20
21 DATED: 8/8/14



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

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