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

11 In the Matter of the Accusation Against:

Case No. 3167

12 **DONALD WEEKS, RPH**
833 S Main Street, A-137
13 Fallbrook, CA 92028

OAH No. 2010020553

SECOND AMENDED ACCUSATION

14 Original Pharmacist License No. RPH 38871

Hearing: Tuesday, November 30, 2010

15 Respondent.

16 Complainant alleges:

17 **PARTIES**

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

21 2. On or about August 23, 1984, the Board issued Original Pharmacist License No.
22 RPH 38871 to Respondent Donald Weeks, RPH. The license will expire on February 29, 2012,
23 unless renewed.

24 3. During all relevant times herein, Respondent was the Pharmacist-in-Charge (PIC)
25 of Fallbrook Pharmacy #2, located at 343 E Alvarado St., Suite C, Fallbrook, CA 92028.^{1/}

26
27 1. In 1994, the Board issued Original Pharmacy Permit Number PHY 39905 to Fallbrook
Pharmacy, Inc., aka Fallbrook Pharmacy #2, Tip Clements, President, Sandra Clements, Vice
28 President, and Richard Clements, Secretary. The Original Pharmacy permit was in full force and
(continued...)

JURISDICTION

1
2 4. This Accusation is brought before the Board, Department of Consumer Affairs,
3 under the authority of the following laws. All section references are to the Business and
4 Professions Code (Code) unless otherwise indicated.

5 5. Section 4300 of the Code provides that every license issued by the Board may be
6 suspended or revoked.

7 6. Section 4301 of the Code states in pertinent part that:

8 The board shall take action against any holder of a license who is guilty of
9 unprofessional conduct Unprofessional conduct shall include, but is not limited to,
10 any of the following:

11

12 (b) Incompetence

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14 (d) The clearly excessive furnishing of controlled substances in violation of
15 subdivision (a) of Section 11153 of the Health and Safety Code.

16

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

19

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

24

25 7. Section 4081 of the Code states in pertinent part that:

26 (a) All records of manufacture and of sale, acquisition, or disposition of
27 dangerous drugs or dangerous devices shall be at all times during business hours

28 effect at all times relevant to the charges brought herein. That license has since been revoked
outright, pursuant to a stipulated decision in Accusation Case # 3029.

1 open to inspection by authorized officers of the law, and shall be preserved for at
2 least three years from the date of making. A current inventory shall be kept by
3 every . . . pharmacy . . . holding a currently valid and unrevoked certificate,
4 license, permit, registration, or exemption under Division 2 (commencing with
5 Section 1200) of the Health and Safety Code or under Part 4 (commencing with
6 Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a
7 stock of dangerous drugs or dangerous devices.

8 (b) The owner, officer, and partner of any pharmacy, wholesaler, or
9 veterinary food-animal drug retailer shall be jointly responsible, with the
10 pharmacist-in-charge or exemptee, for maintaining the records and inventory
11 described in this section.
12

13 8. Code section 4332 provides in pertinent part that any person who "fails, neglects"
14 to maintain records required by Code section 4081 is guilty of a misdemeanor.

15 9. Code section 4113 states that in pertinent part that:
16

17 (b) The pharmacist-in-charge shall be responsible for a pharmacy's
18 compliance with all state and federal laws and regulations pertaining to the
19 practice of pharmacy.
20

21 10. Code section 4067, subdivision (a), states:
22

23 (a) No person or entity shall dispense or furnish, or cause to be dispensed
24 or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on
25 the Internet for delivery to any person in this state without a prescription issued
26 pursuant to a good faith prior examination of a human or animal for whom the
27 prescription is meant if the person or entity either knew or reasonably should have
28 known that the prescription was not issued pursuant to a good faith prior
examination of a human or animal, or if the person or entity did not act in
accordance with Section 1761 of Title 16 of the California Code of Regulations.

11. Code section 125.3 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.

1 12. Section 1718 of Title 16 of the California Code of Regulations (CCR) states:

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

5 The controlled substances inventories required by Title 21, CFR, Section
6 1304 shall be available for inspection upon request for at least 3 years after the date
7 of the inventory.

8 13. Section 1761 of Title 16 of the California Code of Regulations (CCR) states:

9 (a) No pharmacist shall compound or dispense any prescription which
10 contains any significant error, omission, irregularity, uncertainty, ambiguity or
11 alteration. Upon receipt of any such prescription, the pharmacist shall contact the
12 prescriber to obtain the information needed to validate the prescription.

13 (b) Even after conferring with the prescriber, a pharmacist shall not
14 compound or dispense a controlled substance prescription where the pharmacist
15 knows or has objective reason to know that said prescription was not issued for a
16 legitimate medical purpose.

17 14. Health & Safety (H&S) Code section 11153, subdivision (a) states:

18 (a) A prescription for a controlled substance shall only be issued for a
19 legitimate medical purpose by an individual practitioner acting in the usual course
20 of his or her professional practice. The responsibility for the proper prescribing and
21 dispensing of controlled substances is upon the prescribing practitioner, but a
22 corresponding responsibility rests with the pharmacist who fills the prescription.
23 Except as authorized by this division, the following are not legal prescriptions: (1)
24 an order purporting to be a prescription which is issued not in the usual course of
25 professional treatment or in legitimate and authorized research; or (2) an order for
26 an addict or habitual user of controlled substances, which is issued not in the course
27 of professional treatment or as part of an authorized narcotic treatment program, for
28 the purpose of providing the user with controlled substances, sufficient to keep him
 or her comfortable by maintaining customary use.

 15. Health & Safety (H&S) Code section 11208 provides that proof that the amount of
 controlled substances possessed or received by a defendant at any time in a lesser or greater
 amount than is accounted for by the records required by law is prima facie evidence of guilt.

 16. Title 21 of the Code of Federal Regulations (CFR) states, in pertinent part:

 a. 21 CFR section 1304.11(a) requires that a separate inventory be made for
 each registered location and each independent activity registered.

1 24. In 2004, Fallbrook entered into an Internet dispensing scheme involving
2 Fallbrook's pharmacies filling and dispensing mostly controlled substances (the vast majority of
3 which were hydrocodone with APAP, Vicodin, Vicodin ES and Norco) to patients from all over
4 the United States and all prescribed by a single physician in New Jersey, Dr. Phillip Mach. From
5 approximately July 2004 to May 2005, all exact dates unknown, Fallbrook, through Fallbrook
6 Pharmacy and FP#2 dispensed drugs to fill more than 5,831 prescriptions issued by Dr. Mach, of
7 which approximately 88 are known to be for California residents/addresses.

8 25. Both Fallbrook Pharmacy and FP#2 had separate computers. However, with
9 regard to at least the Dr. Mach prescriptions, while the prescriptions were filled in the downstairs
10 Fallbrook Pharmacy, they were input into the computer for FP#2 upstairs, for the legal and
11 appropriate use of which Respondent, as PIC, was also responsible.

12 26. On May 13, 2005, pursuant to a search warrant, the DEA seized, among other
13 things, both substantial amounts of hydrocodone with APAP from FP#2 and also two long narrow
14 boxes of blank prescriptions (estimated to be between 8,000 and 10,000 blanks) pre-stamped with
15 a signature stamp of Dr. Mach.

16 27. In Board case no. 3029, Fallbrook's corporate officers, on behalf of Fallbrook
17 Pharmacy and FP#2, admitted multiple violations of state and federal laws and regulations in
18 connection with Fallbrook Pharmacy and FP#2's violations concerning, among other things,
19 Fallbrook's Internet scheme. Both of the original pharmacy permits and the pharmacist permit of
20 Tip Clements have been revoked outright, effective April 9, 2008. (A true and correct copy of the
21 disciplinary order in that case is attached hereto and incorporated herein by reference for the
22 limited purpose of establishing the factual admissions therein.)

23 28. On August 31, 2006, Dr. Mach signed a Plea Agreement and Sentencing
24 Stipulation (Plea Agreement) in the matter of *United States of America v. Philip Mach*, U.S.
25 District Court, District of Minnesota, case no. 06-cr-302(1) MJD, in resolution of criminal
26 charges originally filed against him in the matter of *United States of America v. Philip Mach*, U.S.
27 District Court, District of New Jersey, case no. 06-cr-302 MJD, and subsequently transferred to
28 the U.S. District Court, District of Minnesota, arising out of his actions described in paragraphs

1 25—27, above. In that Plea Agreement, Dr. Mach admitted, agreed, and acknowledged “that
2 every prescription he issued for [his] customers was issued other than for a legitimate medical
3 purpose, that none was issued in the usual course of professional practice, and that the purported
4 prescriptions were in fact sham prescriptions;” and that he “knowingly and intentionally
5 conspired with others to dispense and distribute, and to cause to be dispenses and distributed,
6 prescription drugs that are controlled substances, other than for a legitimate medical purpose and
7 not in the usual course of professional practice.” Dr. Mach was convicted on his plea of guilty to
8 one count of conspiring to distribute controlled substances, in violation of Title 21, U.S. Code,
9 Section 846, conspiracy to violate Title 21, U.S. Code, Sections 841(a)(1) and 841(b)(1)(D), and
10 Title 21, Code of Federal Regulations, Section 1306.04; to one count of unlawful distribution and
11 dispensing of controlled substances in violation of Title 21, U.S. Code, Sections 841(a)(1) and
12 841(b)(1)(D); Title 18, U.S. Code, Section 2; and Title 21, Code of Federal Regulations, Section
13 1306.04; and to a single count of conspiracy to distribute and dispense controlled substances in
14 violation of Title 21, U.S. Code, Section 846. Dr. Mach also agreed to surrender to the DEA his
15 DEA registration to dispense controlled substances. On May 10, 2007, Dr. Mach was sentenced
16 by the U.S. District Court, District of Minnesota, to be imprisoned for 15 months at the Federal
17 reservation at Fort Dix, New Jersey; upon release from imprisonment to remain, on supervised
18 release for a term of three years; to undergo periodic drug testing, cooperate in the collection of
19 DNA, and participate in counseling and drug abuse programs; to not unlawfully possess or use
20 any controlled substance, firearm, ammunition, or dangerous device; to comply with standard
21 conditions of supervised release; and to pay \$100 to the Crime Victim’s Fund.

22 **FIRST CAUSE FOR DISCIPLINE**

23 **(Unprofessional Conduct: Failure to Make a Separate Inventory for FP#2)**

24 29. Respondent Weeks’ pharmacist license is subject to disciplinary action under
25 Code section 4301(o) in conjunction with 21 CFR section 1304.11(a) in that he, as PIC of FP#2,
26 failed to make any drug inventory for FP#2 separate from Fallbrook Pharmacy during all times
27 relevant herein, as is more particularly alleged above and incorporated herein by reference.
28

1 SECOND CAUSE FOR DISCIPLINE

2 (Unprofessional Conduct: Failure re Complete Accountability for Controlled Substances)

3 30. Respondent Weeks' pharmacist license is subject to disciplinary action under
4 Code section 4301(o) in conjunction with Code section 4113, CCR section 1718, and CFR
5 section 1304.11(c) in that he, as PIC of FP#2, failed to maintain or do the required DEA biennial
6 inventory for FP#2, as is more particularly alleged above and incorporated herein by reference.

7 THIRD CAUSE FOR DISCIPLINE

8 (Unprofessional Conduct: General Unprofessional Conduct: Simple Negligence)

9 31. Respondent Weeks' pharmacist license is subject to disciplinary action for
10 unprofessional conduct under Code section 4301 for negligence, as follows:

11 32. As the PIC of FP#2, Respondent had the duty to assure that FP#2 was not
12 violating any state or federal law concerning the practice of pharmacy. Under the circumstances,
13 that duty included his duty to know if, and to what extent, his pharmacy was involved in
14 Fallbrook's Internet dispensing scheme, as more particularly alleged above and set forth in the
15 disciplinary order in Case No. 3029, incorporated herein by reference.

16 33. Respondent permitted FP#2's computer to be used in conjunction with
17 Fallbrook's Internet dispensing scheme. Also, at least as of May 13, 2005, FP#2 was the
18 repository for significant quantities of hydrocodone with APAP. That drug was most often filled
19 and dispensed by Fallbrook using Dr. Mach prescriptions and was rarely, if ever, one of the
20 controlled substances that FP#2 filled and dispensed in large quantities in its regular business.
21 Moreover, the many thousands of blank prescriptions pre-stamped with Dr. Mach's signature
22 were discovered in FP#2, not Fallbrook Pharmacy downstairs.

23 34. Respondent knew, or in the exercise of reasonable care should have known, that
24 FP#2 was being used as part of the Fallbrook Internet dispensing scheme. He failed in his duty to
25 investigate and insure that the scheme did not violate state and federal law concerning the practice
26 of pharmacy.

1 FOURTH CAUSE FOR DISCIPLINE

2 (Unprofessional Conduct: Incompetence)

3 35. Respondent Weeks' pharmacist license is subject to disciplinary action for
4 unprofessional conduct under Code section 4301(b) for incompetence, as follows:

5 36. As the PIC of FP#2, Respondent had the duty to assure that FP#2 was not
6 violating any state or federal law concerning the practice of pharmacy. Under the circumstances,
7 that duty included his duty to know if, and to what extent, his pharmacy was involved in
8 Fallbrook's Internet dispensing scheme, as more particularly alleged above and set forth in the
9 disciplinary order in Case No. 3029.

10 37. Respondent permitted FP#2's computer to be used in conjunction with
11 Fallbrook's Internet dispensing scheme. Also, at least as of May 13, 2005, FP#2 was the
12 repository for significant quantities of hydrocodone with APAP. That drug was most often filled
13 and dispensed by Fallbrook using Dr. Mach prescriptions and was rarely, if ever, one of the
14 controlled substances that FP#2 filled and dispensed in large quantities in its regular business.
15 Moreover, the many thousands of blank prescriptions pre-stamped with Dr. Mach's signature
16 were discovered in FP#2, not Fallbrook Pharmacy downstairs.

17 38. In allowing FP#2 to be used as part of the Fallbrook Internet dispensing scheme
18 that violated state and federal law concerning the practice of pharmacy, Respondent demonstrated
19 that he lacked the requisite knowledge, ability, or skill of a competent PIC to practice pharmacy
20 within the standard of care governing pharmacists.

21 FIFTH CAUSE FOR DISCIPLINE

22 (Unprofessional Conduct: Clearly Excessive Furnishing of Controlled Substances)

23 39. Respondent Weeks' pharmacist license is subject to disciplinary action under
24 Code section 4301(d), in conjunction with H&S Code section 11153(a), for the clearly excessive
25 furnishing of controlled substances as follows:

26 40. As the PIC of FP#2, Respondent had the duty to assure that FP#2 was not
27 violating any state or federal law concerning the practice of pharmacy. Under the circumstances,
28 that included his duty to know if, and to what extent, his pharmacy was involved in Fallbrook's

1 Internet dispensing scheme, as more particularly alleged above and set forth in the disciplinary
2 order in Case No. 3029.

3 41. Respondent permitted FP#2's computer to be used in conjunction with
4 Fallbrook's Internet dispensing scheme. Also, at least as of May 13, 2005, FP#2 was the
5 repository for significant quantities of hydrocodone with APAP. That drug was most often filled
6 and dispensed by Fallbrook using Dr. Mach prescriptions and was rarely, if ever, one of the
7 controlled substances that FP#2 filled and dispensed in large quantities in its regular business.
8 Moreover, the many thousands of blank prescriptions pre-stamped with Dr. Mach's signature
9 were discovered in FP#2, not Fallbrook Pharmacy downstairs.

10 42. In allowing FP#2 to be used as part of the Fallbrook Internet dispensing scheme,
11 Respondent furnished clearly excessive amounts of controlled substances for patients with no
12 legitimate medical need in violation of H&S Code section 11153(a), as is more particularly
13 alleged above and incorporated herein by reference.

14 SIXTH CAUSE FOR DISCIPLINE

15 (Unprofessional Conduct: Violation of Governing Statutes and Regulations)

16 43. Respondent Weeks' pharmacist license is subject to disciplinary action under
17 Code sections 4081(a) and (b), and 4301(j) and (o) for violating the laws, statutes, and regulations
18 of the state of California, as follows:

19 a. Under Code section 4067(a), by dispensing or furnishing, or causing to be
20 dispensed or furnished, dangerous drugs on the Internet for delivery to persons in this state
21 without a prescription issued pursuant to a good faith prior examination of a human for whom the
22 prescription is meant, as more particularly alleged above and incorporated herein by reference.

23 b. Under 16 CCR section 1761, by compounding or dispensing prescriptions
24 containing significant errors, omissions, irregularities, uncertainties, ambiguities or alterations,
25 without contacting the prescriber to obtain the information needed to validate the prescription, or
26 alternatively, even after conferring with the prescriber, compounding or dispensing controlled
27 substance prescriptions where Respondent knew or had objective reason to know that said
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1 prescriptions were not issued for a legitimate medical purpose, as more particularly alleged above
2 and incorporated herein by reference.

3 PRAYER

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

6 1. Revoking or suspending Original Pharmacist License Number RPH 38871, issued
7 to Donald Weeks, RPH;

8 2. Ordering Donald Weeks, RPH to pay the Board of Pharmacy the reasonable costs
9 of the investigation and enforcement of this case, pursuant to Business and Professions Code
10 section 125.3;

11 3. Taking such other and further action as deemed necessary and proper.

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14 DATED: November 22, 2010

for A. Michael German
VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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