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

In the Matter of the Accusation Against**:** **AMER RX, INC. DBA AGE WELL, AMRO SHAKKER AMER, PRESIDENT AND OWNER** **191 W. Burton Mesa Blvd., Ste. A** **Lompoc, CA 93436** **Permit No. PHY 49116,** **AMRO SHAKKER AMER, PHARMACIST-IN-CHARGE** **147 Century** **Arroyo Grande, CA 93420** **Pharmacist License No. RPH 56570,** **and** **SAMI BORAIE** **237 Town Center West #123** **Santa Maria, CA 93458** **Pharmacist License No. RPH 69985** Respondent.	Case No. 5972 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about September 12, 2008, the Board of Pharmacy issued Permit Number PHY 49116 to Amer Rx, Inc. dba Age Well, Amro Shakker Amer, President and Owner (Respondent Age Well). The Permit expired on May 31, 2016, has not been renewed, and is currently cancelled.

3. On or about November 30, 2004, the Board of Pharmacy issued Pharmacist License Number RPH 56570 to Amro Shakker Amer, Pharmacist-in-Charge (Respondent Amer). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2018, unless renewed.

4. On or about October 11, 2013, the Board of Pharmacy issued Pharmacist License Number RPH 69985 to Sami Boraie (Respondent Boraie). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2019, unless renewed.

JURISDICTION

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

6. Section 4300.1 of the Code states:

"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 PROVISIONS

7. 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."

8. Section 4169 of the Code states in pertinent part:

"(a) A person or entity shall 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."

9. 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.

". . .

"(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

10. 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 issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

". . .

"(j) The violation of any of the statutes of this state, of 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."

11. Health and Safety Code section 111335 states:

"Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

12. Health and Safety Code section 111375 states:

"Any drug or device is misbranded unless its labeling bears all of the following information:

"(a) Adequate directions for use.

"(b) Such adequate warnings against use in pathological conditions or by children where its use may be dangerous to health.

"(c) Adequate warning against unsafe dosage or methods or duration of administration or application.

"Warnings shall be in a manner and form as are necessary for the protection of users.

"If the department determines that any requirement of subdivision (a), as applied to any drug or device, is not necessary for the protection of the public health, the department may adopt regulations exempting the drug or device from these requirements.

"Any drug or device exempted under Section 502(f) of the federal act (21 U.S.C. Sec. 352(f)) is exempt from the requirement of this section. The department, however, may adopt any

regulation including a drug or device within, or excluding a drug or device from the requirements of this section, whether or not the inclusion or exclusion of the drug or device is in accord with the federal act."

13. Health and Safety Code section 111400 states:

"Any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling."

14. Health and Safety Code section 111440 states:

"It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

COST RECOVERY

15. 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.

FACTUAL BACKGROUND

16. Domperidone is an anti-dopaminergic drug which acts as an antiemetic and a prokinetic agent. It is used in some countries for the treatment of gastroparesis; however, domperidone is not FDA-approved for use in humans in the United States due to significant health and safety concerns including the potential for sudden death, cardiac arrest, and cardiac arrhythmias. The FDA has warned breastfeeding women in particular not to use products containing domperidone due to its associated risks and propensity to be excreted in breast milk. Domperidone can only be obtained in the United States through an Expanded Access Program by submitting an investigational new drug application for the treatment of gastroesophageal reflux disease with upper gastrointestinal symptoms or gastroparesis in patients greater than 12 years old who have failed standard therapies. Currently, no pharmacies are authorized to compound domperidone.

17. Despite these prohibitions on the use of domperidone and products containing domperidone, between March 19, 2015 and May 18, 2015, Respondent Age Well compounded

domperidone 10mg capsules from the unapproved drug domperidone and dispensed seven (7) domperidone prescriptions, totaling 885 capsules, to two (2) patients. Six (6) of the prescriptions were dispensed by Respondent Amer and one (1) was dispensed by Respondent Boraie. In illegally dispensing these capsules, Respondents failed to notify consumers of the risks associated with the drug or of its unapproved status with the FDA. Respondent Age Well continued to dispense domperidone after issuance of a warning by the Board on April 14, 2015.

FIRST CAUSE FOR DISCIPLINE

(Unlawful Manufacturing and Sale of Misbranded Drugs)

18. Respondent Age Well is subject to disciplinary action under section 4301, subdivision (j), of the Code in conjunction with sections 111440, 111400, and 111375 of the Health and Safety Code in that Respondent violated state law regulating dangerous drugs by manufacturing, selling, delivering, holding, and/or offering for sale misbranded drugs. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 16 and 17, inclusive, as though set forth fully herein.

SECOND CAUSE FOR DISCIPLINE

(Prohibited Acts: Selling Misbranded Drugs)

19. Respondent Age Well is subject to disciplinary action under section 4301, subdivision (o), of the Code in conjunction with section 4169, subdivision (a)(3), of the Code in that Respondent violated the California Pharmacy Law by purchasing, trading, selling and/or transferring drugs that Respondent knew or reasonably should have known were misbranded. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 16 and 17, inclusive, as though set forth fully herein.

THIRD CAUSE FOR DISCIPLINE

(Unlawful Manufacturing and Sale of Misbranded Drugs)

20. Respondent Amer is subject to disciplinary action under section 4301, subdivision (j), of the Code in conjunction with sections 111440, 111400, and 111375 of the Health and Safety Code in that Respondent violated state law regulating dangerous drugs by manufacturing, selling, delivering, holding, and/or offering for sale misbranded drugs. Complainant refers to, and by this

reference incorporates, the allegations set forth above in paragraphs 16 and 17, inclusive, as though set forth fully herein.

FOURTH CAUSE FOR DISCIPLINE

(Prohibited Acts: Selling Misbranded Drugs)

21. Respondent Amer is subject to disciplinary action under section 4301, subdivision (o), of the Code in conjunction with section 4169, subdivision (a)(3), of the Code in that Respondent violated the California Pharmacy Law by purchasing, trading, selling and/or transferring drugs that Respondent knew or reasonably should have known were misbranded. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 16 and 17, inclusive, as though set forth fully herein.

FIFTH CAUSE FOR DISCIPLINE

(Unlawful Manufacturing and Sale of Misbranded Drugs)

22. Respondent Boraie is subject to disciplinary action under section 4301, subdivision (j), of the Code in conjunction with sections 111440, 111400, and 111375 of the Health and Safety Code in that Respondent violated state law regulating dangerous drugs by manufacturing, selling, delivering, holding, and/or offering for sale misbranded drugs. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 16 and 17, inclusive, as though set forth fully herein.

SIXTH CAUSE FOR DISCIPLINE

(Prohibited Acts: Selling Misbranded Drugs)

23. Respondent Boraie is subject to disciplinary action under section 4301, subdivision (o), of the Code in conjunction with section 4169, subdivision (a)(3), of the Code in that Respondent violated the California Pharmacy Law by purchasing, trading, selling and/or transferring drugs that Respondent knew or reasonably should have known were misbranded. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 16 and 17, inclusive, as though set forth fully herein.

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DISCIPLINE CONSIDERATIONS

24. To determine the degree of discipline, if any, to be imposed on Respondent Age Well, Complainant alleges that on or about April 26, 2016, in a prior action, the Board of Pharmacy issued Citation Number CI 2015 66762 and ordered Respondent Age Well to pay a fine of $1,000.00. That Citation is now final and is incorporated by reference as if fully set forth.

25. To determine the degree of discipline, if any, to be imposed on Respondent Amer, Complainant alleges that on or about April 26, 2016, in a prior action, the Board of Pharmacy issued Citation Number CI 2015 70092 and ordered Respondent Amer to pay a fine of $2,000.00. 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 Permit Number PHY 49116, issued to Amer Rx, Inc. dba Age Well, Amro Shakker Amer, President and Owner;

2. Revoking or suspending Pharmacist License Number RPH 56570, issued to Amro Shakker Amer, Pharmacist-in-Charge;

3. Revoking or suspending Pharmacist License Number RPH 69985, issued to Sami Boraie;

4. Ordering Amer Rx, Inc. dba Age Well, Amro Shakker Amer, President and Owner, Amro Shakker Amer, Pharmacist-in-Charge, and Sami Boraie to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 6/30/17

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

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