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

In the Matter of the Accusation Against: **PROFESSIONAL COMPOUNDING CENTERS OF AMERICA, LTD., DBA PROFESSIONAL COMPOUNDING CENTERS OF AMERICA** **L. DAVID SPARKS, PRESIDENT** **DEAN J. KING, VICE PRESIDENT** **FABIAN V. ZACCARDO, AKA FABIAN ZACCARDO, VICE PRESIDENT AND DESIGNATED REPRESENTATIVE IN CHARGE** **LAWSON KLOESEL, SECRETARY** **9901 South Wilcrest Drive** **Houston, TX 77099** **Out of State Distributor License No. OSD 3279** **and** **FABIAN V. ZACCARDO** **AKA FABIAN ZACCARDO** **11802 Sendera Lane** **Richmond, TX 77407** **Designated Representative License No. EXC 18242** Respondents.	Case No. 5962 **A C C U S A T I O N**

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Complainant alleges:

PARTIES

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

2. On or about May 19, 1997, the Board issued Out of State Distributor License Number OSD 3279 to Professional Compounding Centers of America, LTD. (Respondent PCCA), doing business as (dba) Professional Compounding Centers of America. On or about May 19, 1997, L. David Sparks became the President, Dean J. King became the Vice President, and Lawson Kloesel became the Secretary. On or about March 9, 2005, Fabian Zaccardo, also known as (aka) Fabian V. Zaccardo (Respondent Zaccardo) became the Vice President and on or about August 15, 2005, Respondent Zaccardo became the Designated Representative In Charge. The Out of State Distributor License was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2017, unless renewed.

3. On or about August 15, 2005, the Board issued Designated Representative Certificate number EXC 18242 to Fabian V. Zaccardo, aka Fabian Zaccardo (Respondent Zaccardo). The Designated Representative Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2017, unless renewed.

JURISDICTION

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

STATUTORY PROVISIONS – BUSINESS AND PROFESSIONS CODE

5. Section 4300 of the Code states in pertinent part:

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

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

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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."

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

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

. . .

"(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.

. . .

"(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..."

8. Code section 4161 states in pertinent part:

"(a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.

. . .

"(j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws governing wholesalers..."

9. Code section 4169 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..."

10. Code section 4304 states:

"The board may deny, revoke, or suspend any license issued pursuant to Section 4161 for any violation of this chapter or for any violation of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code."

HEALTH AND SAFETY CODE

11. Health and Safety Code section 110290 states:

In determining whether the labeling or advertisement of a food, drug, device, or cosmetic is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account. The extent that the labeling or advertising fails to reveal facts concerning the food, drug, device, or cosmetic or consequences of customary use of the food, drug, device, or cosmetic shall also be considered.

12. Health and Safety Code section 111330 states that "[a]ny drug or device is misbranded if its labeling is false or misleading in any particular."

13. Health and Safety Code section 111335 provides that any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290.)

14. Health and Safety Code section 111375 states in pertinent part:

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

. . .

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

15. Health and Safety Code section 111400 provides that 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.

16. Health and Safety Code section 111440 provides that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

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17. Health and Safety Code section 111450 provides that it is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

18. Health and Safety Code section 111550 provides, in pertinent part:

"No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:

"(a) It is one of the following:

"(1) A new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355).

"(b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended . . ."

FEDERAL STATUTES

19. Section 201, subdivision (p), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. section 321, subdivision (p), states, in pertinent part:

> The term "new drug" means--
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> (1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof . . .
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> (2) Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

20. Title 21, United States Code, section 352, states in pertinent part:

A Drug or device shall be deemed to be misbranded—

(f) Directions for use and warnings on label

> Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph,

as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

21. Section 505, subdivision (a), of the Act (21 U.S.C. section 355, subdivision (a)), states, in pertinent part, that ". . . [n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."

DRUG CLASSIFICATIONS

22. Domperidone is an anti-dopaminergic drug that acts as an antiemetic and a prokinetic agent. It is a dangerous drug under Code section 4022. Domperidone is not currently a legally marketed human drug and is not approved for sale in the United States. The U.S. Food and Drug Administration ("FDA") has determined that any products containing domperidone are unapproved new drugs and misbranded. Consequently, any product containing domperidone violates the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301, et seq.; "the Act"). Domperidone is available for use in the treatment of certain gastrointestinal disorders, but only if an Investigational New Drug Application ("IND") is submitted to and approved by the FDA.

BACKGROUND

23. On or about February 27, 2004, the Wall Street Journal published an article titled "As Druggists Mix Customized Brews, FDA Raises Alarm." Respondent PCCA's CEO and President Dave Sparks is quoted as saying "That drug (domperidone) is available in every lactation center, and the FDA is not doing anything about it."

24. On or about June 7, 2004, the FDA issued a Talk Paper entitled, "FDA Warns against Women Using Unapproved Drug, Domperidone, to Increase Milk Production", warning breastfeeding women not to use the product because of safety concerns. The FDA stated that although domperidone was approved in several countries outside the U.S. to treat certain gastric

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disorders, it is not approved in any country, including the U.S., for enhancing breast milk production in lactating women and it is not approved in the U.S. for any purpose.[1]

25. In June 2004, the FDA issued a warning letter to Respondent PCCA warning Respondent PCCA to cease distributing the active pharmaceutical ingredient (API) domperidone and conveying the FDA's public health concerns in regards to domperidone.

26. On or about June 15, 2006, the U.S. Marshals Service and the FDA executed a seizure warrant at Respondent PCCA's facility and seized over 300 bottles/vials of various size consisting of four (4) bulk APIs, including domperidone, which were intended to be sold to pharmacies for use in compounding human drug products.

27. On or about April 14, 2015, the Board issued a Subscriber Alert[2], stating that domperidone is not approved by the FDA for any use in humans in the U.S. The Board also stated that the FDA currently permits patients 12 years of age and older with various gastrointestinal conditions that are refractory to standard therapy to be treated with domperidone through an Expanded Access Program, that physicians who are interested in obtaining expanded access for domperidone must submit an IND, and that currently, no pharmacies in California[3] are authorized to compound domperidone under the Expanded Access program.

28. On August 18, 2015, Board of Pharmacy Inspector C. A. received wholesale records from Respondent PCCA which show that from August 17, 2012, to August 17, 2015, Respondent PCCA sold at least 518 grams of domperidone to at least 113 pharmacies on at least 475 separate invoiced dates.

29. From August 15, 2015, to November 20, 2015, the Board conducted investigations on the use of domperidone in compounding pharmacies in California. During that time, Inspector

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[1] The FDA stated that there were several published reports and case studies of cardiac arrhythmias, cardiac arrest, and sudden death in patients receiving an IV form of domperidone, which had been withdrawn from marketing in a number of countries. Further, in several countries where the oral form of domperidone continued to be marketed, labels for the product contained specific warnings against use of domperidone by breastfeeding women.

[2] All pharmacists are required to subscribe to the Board's Subscriber Alert email blasts.

[3] As of March 2015, only Dougherty's Pharmacy located in Dallas, Texas, is approved to compound domperidone pursuant to an investigational new drug (IND) application.

C. A. received information from six (6) other pharmacies that Respondents continued to sell domperidone to pharmacies, the domperidone sold by Respondents was not marked that it was not approved for human use, and Respondents continued to keep a master formula for compounding domperidone for human use available for its members.

FIRST CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and

Federal and State Laws Governing Pharmacy)

30. Respondents PCCA and Zaccardo are subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), and section 4304, in that Respondents violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.), and federal and state laws governing pharmacy, as follows:

a. On and between August 17, 2012, and August 17, 2015, Respondents introduced or delivered for introduction into interstate commerce the drug domperidone by selling, shipping, or providing at least 518 grams of domperidone to at least 113 pharmacies on at least 475 separate invoiced dates. The 113 pharmacies then compounded and dispensed domperidone to patients when, in fact, there was no investigational new drug application ("IND") for domperidone approved by the FDA, in violation of 21 U.S.C. section 355, subdivision (a).

b. On and between August 17, 2012, and August 17, 2015, Respondents sold, delivered, or gave away the drug domperidone when, in fact, there was no IND for domperidone approved by the FDA, in violation of Health and Safety Code section 111550.

SECOND CAUSE FOR DISCIPLINE

(Sold Misbranded Drugs)

31. Respondents PCCA and Zaccardo are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (j), and Code section 4304 for violating statutes regulating controlled substances and dangerous drugs, in that Respondents sold misbranded drugs, as defined by Health & Safety Code sections 110290, 111330, 111400, and United States Code, title 21, section 352(f), in violation of Health and Safety Code section

111440, and 111450. The circumstances are that in and between August 17, 2012, and August 17, 2015, Respondents sold at least 518 grams of the dangerous drug domperidone to at least 113 pharmacies on at least 475 separate invoiced dates. Respondents failed to notify their consumers that domperidone is not approved for human use.

THIRD CAUSE FOR DISCIPLINE

(Dishonest or Deceitful Acts)

32. Respondents PCCA and Zaccardo ares subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (f), and section 4304, for committing dishonest or deceitful acts. The circumstances are that despite numerous warnings from the FDA and the California State Board of Pharmacy, in and between August 17, 2012, and August 17, 2015, Respondents sold at least 518 grams of misbranded domperidone to at least 113 pharmacies on at least 475 separate invoiced dates. Respondents misled their consumers to believe that domperidone was acceptable and approved for human use when in fact it was not, as set forth in paragraph 29, above.

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 Out of State Distributor License Number OSD 3279, issued to Professional Compounding Centers of America, LTD., dba Professional Compounding Centers of America;

2. Revoking or suspending Designated Representative Certificate number EXC 18242, issued to Fabian Zaccardo aka Fabian V. Zaccardo;

3. Ordering Professional Compounding Centers of America, LTD., dba Professional Compounding Centers of America and Fabian Zaccardo aka Fabian V. Zaccardo 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,

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

DATED: 3/22/17

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

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