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** **DEANJ. 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** **and** **FABIAN V. ZACCARDO** **AKA FABIAN ZACCARDO** **11802 Sedera Lane** **Richmond, TX 77407** **Designated Representative License No. EXC 18242** Respondents.	Case No. 5962 OAH No. 2017060382 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER** **As to Professional Compounding Centers of America, Ltd., DBA Professional Compounding Centers of America 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 at 5:00 p.m. on February 15, 2018.

It is so ORDERED on January 16, 2018.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

XAVIER BECERRA
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BEFORE THE
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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 OAH No. 2017060382 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER** **As to Professional Compounding Centers of America, LTD., DBA Professional Compounding Centers of America Only**

IT IS HEREBY STIPULATED AND AGREED by and between Professional Compounding Centers of America, LTD. (Respondent PCCA), doing business as (dba)

Professional Compounding Centers of America, and the Board of Pharmacy that the following matters are true:

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, 2018, 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, 2018, unless renewed.

4. Respondent PCCA is represented is represented in this proceeding by attorney Jonathan Allan Klein, whose address is: Klein, Hockel, Iezza & Patel, P.C., 455 Market Street, Suite 1480, San Francisco, CA 94104.

JURISDICTION

1. Accusation No. 5962 was filed before the Board, and is currently pending against Respondent PCCA. The Accusation and all other statutorily required documents were properly served on Respondent PCCA on April 3, 2017. Respondent PCCA timely filed its Notice of Defense contesting the Accusation.

2. A copy of Accusation No. 5962 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

3. Respondent PCCA has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5962. Respondent PCCA has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

4. Respondent PCCA is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

5. Respondent PCCA voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

6. Respondent PCCA understands and agrees that the charges and allegations in Accusation No. 5962, if proven at a hearing, constitute cause for imposing discipline upon its Out of State Distributor License.

7. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent PCCA hereby gives up its right to contest the charges and allegations in Accusation No. 5962.

8. Respondent PCCA agrees that its Out of State Distributor License is subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

RESERVATION

9. The admissions made by Respondent herein are only for the purposes of this proceeding, or any other proceedings in which the Board of Pharmacy or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

CONTINGENCY

10. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

11. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

12. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

13. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Out of State Distributor License No. OSD 3279 issued to Respondent Professional Compounding Centers of America, LTD., dba Professional Compounding Centers of America is revoked. However, the revocation is stayed and Respondent PCCA is placed on probation for one (1) year on the following terms and conditions.

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1. **Obey All Laws**

Respondent owner shall obey all state and federal laws and regulations.

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

- ☐ an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- ☐ a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- ☐ a conviction of any crime
- ☐ discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's Out of State Distributor license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

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

2. **Report to the Board**

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

3. **Interview with the Board**

Upon receipt of reasonable prior notice, respondent owner shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to

board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

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

5. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondent owner shall pay to the board its costs of investigation and prosecution in the amount of $5,555.50. Respondent owner shall make said payment within sixty (60) days of the effective date of this decision unless otherwise agreed to in writing by the Board or its designee. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

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

6. **Probation Monitoring Costs**

Respondent owner shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. **Status of License**

Respondent owner shall, at all times while on probation, maintain current licensure with the board. If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

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

8. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should respondent owner discontinue business, respondent owner may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

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Respondent owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. **Notice to Employees**

Respondent owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent owner shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. **Owners and Officers: Knowledge of the Law**

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. **Posted Notice of Probation**

Respondent owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient,

customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. **Violation of Probation**

If a respondent owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent license, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

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

13. **Completion of Probation**

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

14. **Ethics Course for Officers**

Within sixty (60) calendar days of the effective date of this decision, respondent's officers shall each enroll in a course in ethics related to the regulations governing and/or requirements of a wholesaler, at their or respondent PCCA's expense, approved in advance in writing by the board or its designee. Failure to initiate the courses during the first six (6) months of probation, and complete them within the year of probation, is a violation of probation.

Respondent PCCA shall submit each certificate of completion to the board or its designee within five days after each individual completes the course.

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15. **Inspection by Verified-Accredited Wholesale Distributors (VAWD) Program**

Within six (6) months of the effective date of this decision, respondent shall arrange for and submit to an inspection by the Verified-Accredited Wholesale Distributors (VAWD) Program through the National Association of Boards of Pharmacy (NABP). The inspection report issued by VAWD must be submitted to the Board within three (3) days of the inspection. Respondents have indicated they have an inspection report completed in June 2017, which the Board will accept to satisfy this term and condition of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Sweta Patel. I understand the stipulation and the effect it will have on my Out of State Distributor License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 11/17/2017

PROFESSIONAL COMPOUNDING CENTERS OF AMERICA, LTD., DBA PROFESSIONAL COMPOUNDING CENTERS OF AMERICA

By: FABIAN ZACCARDO, COO
(Print name and title of officer)
Respondent

I have read and fully discussed with Respondent Professional Compounding Centers of America, LTD., dba Professional Compounding Centers of America the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 11/20/2017

SWETA PATEL
Attorney for Respondent

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ENDORSEMENT

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

Dated: November 20, 2017

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
JANICE K. LACHMAN
Supervising Deputy Attorney General

KRISTINA T. JARVIS
Deputy Attorney General
Attorneys for Complainant

Exhibit A

Accusation No. 5962

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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--
>
> (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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