

**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 ZACCARDO, VICE PRESIDENT AND DESIGNATED
REPRESENTATIVE IN CHARGE,
LAWSON KLOESEL, SECRETARY,
Out of State Distributor License No. OSD 3279;**

and

**FABIAN V. ZACCARDO,
Designated Representative Certificate No. EXC 18242,**

Respondents

Agency Case No. 6852

OAH No. 2020090495

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reprimand 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 November 30, 2022.

It is so ORDERED on October 31, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

A handwritten signature in black ink, appearing to read "Seung W. Oh". The signature is fluid and cursive, with the first name "Seung" and last name "Oh" clearly visible.

Seung W. Oh, Pharm.D.
Board President

1 ROB BONTA
Attorney General of California
2 KAREN R. DENVIR
Supervising Deputy Attorney General
3 STEPHANIE ALAMO-LATIF
Deputy Attorney General
4 State Bar No. 283580
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Sacramento, CA 94244-2550
6 Telephone: (916) 210-6112
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7 E-mail: Stephanie.AlamoLatif@doj.ca.gov
Attorneys for Complainant
8

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

13 In the Matter of the Accusation Against:

14 **PROFESSIONAL COMPOUNDING**
15 **CENTERS OF AMERICA, LTD.,**
16 **DBA PROFESSIONAL COMPOUNDING**
17 **CENTERS OF AMERICA**
18 **L. DAVID SPARKS, PRESIDENT**
19 **DEAN J. KING, VICE PRESIDENT**
20 **FABIAN ZACCARDO, VICE PRESIDENT**
21 **AND DESIGNATED REPRESENTATIVE**
22 **IN CHARGE**
23 **LAWSON KLOESEL, SECRETARY**
24 **9901 South Wilcrest Drive**
25 **Houston, TX 77099**

26 **Out of State Distributer License No. OSD**
27 **3279**

28 **and**

FABIAN V. ZACCARDO
11802 Sedera Lane
Richmond, TX 77407

Designated Representative Certificate No.
EXC 18242

Respondents.

Case No. 6852

OAH No. 2020090495

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER FOR PUBLIC
REPROVAL - FABIAN V. ZACCARDO
ONLY

[Bus. & Prof. Code § 495]

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

3 **PARTIES**

4 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy
5 (Board), Department of Consumer Affairs. She brought this action solely in her official capacity
6 and is represented in this matter by Rob Bonta, Attorney General of the State of California, by
7 Stephanie Alamo-Latif, Deputy Attorney General.

8 2. Professional Compounding Centers of America LTD dba Professional Compounding
9 Centers of America; L. David Parks, President (Respondent PCCA) and Fabian V. Zaccardo
10 (Respondent Zaccardo) are represented in this proceeding by attorney Sweta Patel, whose address
11 is: 1981 North Broadway, Suite 220, Walnut Creek, CA 94596-3877.

12 **JURISDICTION**

13 3. On or about May 19, 1997, the Board issued Out of State Distributer License No.
14 OSD 3279 to Respondent PCCA. The Out of State Distributer License was in full force and
15 effect at all times relevant to the charges brought in Accusation No. 6852 and will expire on May
16 1, 2023, unless renewed.

17 4. On or about August 15, 2005, the Board issued Designated Representative Certificate
18 Number EXC 18242 to Respondent Zaccardo. The Designated Representative in Charge
19 Certificate was in full force and effect at all times relevant to the charges brought herein and will
20 expire on August 1, 2023, unless renewed.

21 5. Accusation No. 6852 was filed before the Board and is currently pending against
22 Respondent. The Accusation and all other statutorily required documents were properly served
23 on Respondents on May 29, 2020. Respondent Zaccardo timely filed his Notice of Defense
24 contesting the Accusation. A copy of Accusation No. 6852 is attached as exhibit A and
25 incorporated herein by reference.

26 **ADVISEMENT AND WAIVERS**

27 6. Respondent Zaccardo has carefully read, fully discussed with counsel, and
28 understands the charges and allegations in Accusation No. 6852. Respondent has also carefully

1 read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and
2 Disciplinary Order for Public Reapproval.

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

10 8. Respondent Zaccardo voluntarily, knowingly, and intelligently waives and gives up
11 each and every right set forth above.

12 **CULPABILITY**

13 9. Respondent Zaccardo agrees that the charges and allegations in Accusation No. 6852,
14 if proven at hearing, constitutes cause for imposing discipline on his Designated Representative
15 Certificate.

16 10. For purposes of resolving the Accusation without the expense and uncertainty of
17 further proceedings, Respondent Zaccardo agrees, at a hearing, Complainant could establish a
18 factual basis for the charges and allegations in the Accusation, and that Respondent Zaccardo
19 hereby gives up his right to contest those charges.

20 11. Respondent Zaccardo agrees that his Designated Representative Certificate is subject
21 to discipline and it agrees to be bound by the Disciplinary Order below.

22 **CONTINGENCY**

23 12. This stipulation shall be subject to approval by the Board. Respondent Zaccardo
24 understands and agrees that counsel for Complainant and the staff of the Board may communicate
25 directly with the Board regarding this stipulation and settlement, without notice to or participation
26 by Respondent or its counsel. By signing the stipulation, Respondent Zaccardo understands and
27 agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time
28 the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision

1 and Order, the Stipulated Settlement and Disciplinary Order for Public Reapproval shall be of no
2 force or effect, except for this paragraph, it shall be inadmissible in any legal action between the
3 parties, and the Board shall not be disqualified from further action by having considered this
4 matter.

5 13. The parties understand and agree that Portable Document Format (PDF), facsimile
6 and/or electronic copies of this Stipulated Settlement and Disciplinary Order for Public Reapproval,
7 including PDF, facsimile and/or electronic signatures thereto, shall have the same force and effect
8 as the originals.

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

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

19 **DISCIPLINARY ORDER**

20 IT IS HEREBY ORDERED that Designated Representative Certificate Number EXC
21 18242 issued to Respondent Fabian V. Zaccardo shall be publicly reprovved by the Board of
22 Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 6852
23 as to Respondent Zaccardo only, attached as exhibit A.

24 **1. Cost Recovery.** Respondent Zaccardo shall pay \$8,418.96 to the Board for its costs
25 associated with the investigation and enforcement of this matter pursuant to Business and
26 Professions Code Section 125.3. Respondent Zaccardo shall be permitted to pay these costs in a
27 payment plan approved by the Board. If Respondent Zaccardo fails to pay the Board costs as
28 ordered, Respondent Zaccardo shall not be allowed to renew his Designated Representative

Certificate until Respondent Zaccardo pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

2. Ethics Course. Within sixty (60) calendar days of the effective date of this decision, Respondent Zaccardo shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee that complies with Title 16 California Code of Regulations section 1773.5. Respondent Zaccardo shall provide proof of enrollment upon request. Within five (5) days of completion, Respondent Zaccardo shall submit a copy of the certificate of completion to the board or its designee. Failure to timely enroll in an approved ethics course, or to successfully complete it before six months from the effective date of the Decision, or to timely submit proof of completion to the Board or its designee, shall be considered a failure to comply with the conditions of this stipulated settlement.

4. Full Compliance. As a resolution of the charges in Accusation No. 6852, this stipulated settlement is contingent upon Respondent Zaccardo's full compliance with all conditions of this Order. If Respondent Zaccardo fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Designated Representative Certificate Number EXC 18242.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval, and have fully discussed it with our attorney, Sweta H. Patel. I understand the stipulation and the effect it will have on my Designated Representative Certificate Number EXC 18242. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED:

FABIAN V. ZACCARDO
Respondent

1 Certificate until Respondent Zaccardo pays costs in full. In addition, the Board may enforce this
2 order for payment of its costs in any appropriate court, in addition to any other rights the Board
3 may have.

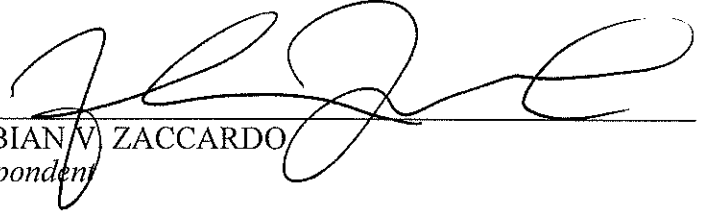
4 **2. Ethics Course.** Within sixty (60) calendar days of the effective date of this decision,
5 Respondent Zaccardo shall enroll in a course in ethics, at respondent's expense, approved in
6 advance by the board or its designee that complies with Title 16 California Code of Regulations
7 section 1773.5. Respondent Zaccardo shall provide proof of enrollment upon request. Within five
8 (5) days of completion, Respondent Zaccardo shall submit a copy of the certificate of completion
9 to the board or its designee. Failure to timely enroll in an approved ethics course, or to
10 successfully complete it before six months from the effective date of the Decision, or to timely
11 submit proof of completion to the Board or its designee, shall be considered a failure to comply
12 with the conditions of this stipulated settlement.

13 **4. Full Compliance.** As a resolution of the charges in Accusation No. 6852, this
14 stipulated settlement is contingent upon Respondent Zaccardo's full compliance with all
15 conditions of this Order. If Respondent Zaccardo fails to satisfy any of these conditions, such
16 failure to comply constitutes cause for discipline, including outright revocation, of Respondent's
17 Designated Representative Certificate Number EXC 18242.

18 **ACCEPTANCE**

19 I have carefully read the above Stipulated Settlement and Disciplinary Order for Public
20 Reproval, and have fully discussed it with our attorney, Sweta H. Patel. I understand the
21 stipulation and the effect it will have on my Designated Representative Certificate Number EXC
22 18242. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval
23 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the
24 Board of Pharmacy.

25 DATED: 8/15/2022

26 
FABIAN V. ZACCARDO
27 Respondent
28

1 I have read and fully discussed with Respondent Zaccardo the terms and conditions and
2 other matters contained in the above Stipulated Settlement and Disciplinary Order for Public
3 Reapproval. I approve its form and content.

4 DATED: _____

SWETA H. PATEL
Attorney for Respondent

6
7 **ENDORSEMENT**

8 The foregoing Stipulated Settlement and Disciplinary Order for Public Reapproval is hereby
9 respectfully submitted for consideration by the Board of Pharmacy of the Department of
10 Consumer Affairs.

11 DATED: _____

Respectfully submitted,


13 ROB BONTA
Attorney General of California
14 KAREN R. DENVIR
Supervising Deputy Attorney General

16 STEPHANIE ALAMO-LATIF
Deputy Attorney General
17 *Attorneys for Complainant*

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2 other matters contained in the above Stipulated Settlement and Disciplinary Order for Public
3 Reapproval. I approve its form and content.

4 DATED: 8/15/2022


SWETA H. PATEL
Attorney for Respondent

6
7 **ENDORSEMENT**

8 The foregoing Stipulated Settlement and Disciplinary Order for Public Reapproval is hereby
9 respectfully submitted for consideration by the Board of Pharmacy of the Department of
10 Consumer Affairs.

11 DATED: _____

Respectfully submitted,

12
13 ROB BONTA
Attorney General of California
14 KAREN R. DENVIR
Supervising Deputy Attorney General

15
16 STEPHANIE ALAMO-LATIF
Deputy Attorney General
17 *Attorneys for Complainant*
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1 I have read and fully discussed with Respondent Zaccardo the terms and conditions and
2 other matters contained in the above Stipulated Settlement and Disciplinary Order for Public
3 Reapproval. I approve its form and content.

4 DATED: _____

SWETA H. PATEL
Attorney for Respondent

6
7 **ENDORSEMENT**

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9 respectfully submitted for consideration by the Board of Pharmacy of the Department of
10 Consumer Affairs.

11 DATED: 8/15/2022
12 _____

Respectfully submitted,

13 ROB BONTA
Attorney General of California
14 KAREN R. DENVIR
Supervising Deputy Attorney General

15 

16 STEPHANIE ALAMO-LATIF
17 Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 6852

1 XAVIER BECERRA
Attorney General of California
2 KENT D. HARRIS
Supervising Deputy Attorney General
3 STEPHANIE ALAMO-LATIF
Deputy Attorney General
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5 P.O. Box 944255
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7 E-mail: Stephanie.AlamoLatif@doj.ca.gov
Attorneys for Complainant

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

13 In the Matter of the Accusation Against:

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14 **PROFESSIONAL COMPOUNDING CENTERS**
15 **OF AMERICA, LTD.,**
16 **DBA PROFESSIONAL COMPOUNDING**
17 **CENTERS OF AMERICA**
18 **L. DAVID SPARKS, PRESIDENT**
19 **DEAN J. KING, VICE PRESIDENT**
20 **FABIAN ZACCARDO, VICE PRESIDENT AND**
21 **DESIGNATED REPRESENTATIVE IN**
22 **CHARGE**
23 **LAWSON KLOESEL, SECRETARY**
24 **9901 South Wilcrest Drive**
25 **Houston, TX 77099**

ACCUSATION

26 **Out of State Distributer License No. OSD 3279**

27 **and**

28 **FABIAN V. ZACCARDO**
11802 Sedera Lane
Richmond, TX 77407

Designated Representative License No. EXC 18242

Respondents.

1
2 **PARTIES**

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

5 2. On or about May 19, 1997, the Board issued Out of State Distributer License Number
6 OSD 3279 to Professional Compounding Centers of America, LTD (Respondent PCCA) doing
7 business as (dba) Professional Compounding Centers of America. On or about May 19, 1997, L.
8 David Sparks became the President, Dean J. King became the Vice President and Lawson Kloesel
9 became the Secretary. On or about March 9, 2005, Fabian V. Zaccardo (Respondent Zaccardo)
10 became the Vice President and on or about August 15, 2005, Respondent Zaccardo became the
11 Designated Representative in Charge. The Out of State Distributer License was in full force and
12 effect at all times relevant to the charges brought herein and will expire on May 1, 2021, unless
13 renewed.

14 3. On or about August 15, 2005, the Board issued Designated Representative Certificate
15 Number EXC 18242 to Respondent Fabian V. Zaccardo. The Designated Representative in
16 Charge Certificate was in full force and effect at all times relevant to the charges brought herein
17 and will expire on August 1, 2020, unless renewed.

18 **JURISDICTION**

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

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

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

23 ...

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

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 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 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. Section 4307 of the Code states, in pertinent part:

“(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had

1 knowledge of or knowingly participated in any conduct for which the license was denied,
2 revoked, suspended, or placed on probation, shall be prohibited from serving as a manager,
3 administrator, owner, member, officer, director, associate, partner, or in any other position with
4 management or control of a licensee as follows:

5 (1) Where a probationary license is issued or where an existing license is placed on
6 probation, this prohibition shall remain in effect for a period not to exceed five years.

7 (2) Where the license is denied or revoked, the prohibition shall continue until the license is
8 issued or reinstated.

9 ...

10
11 9. Section 4022 of the Code states:

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

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

16 10. Section 4061 of the Code states, in pertinent part:

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

21 ...

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

24 11. Section 4169 of the Code states, in pertinent part:

25 (a) A person or entity shall not do any of the following:

26 ...

27 \\\

28 \\\

1 (2) Purchase, sell, or transfer dangerous drugs that the person knew or reasonably should
2 have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of
3 Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

4 12. Section 4304 of the Code states:

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

8 13. Health and Safety Code section 111250 states:

9 Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or
10 decomposed substance.

11 14. Health and Safety Code section 111295 states:

12 It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or
13 device that is adulterated.

14 **FEDERAL STATUTES**

15 15. 21 U.S. Code section 321 states, in pertinent part:

16 (ff) The term “dietary supplement” –

17 (1) Means a product (other than tobacco) intended to supplement the diet that bears or
18 contains one or more of the following dietary ingredients:

19 (A) a vitamin;

20 (B) a mineral;

21 (C) an herb or other botanical;

22 (D) an amino acid;

23 (E) a dietary substance for use by man to supplement the diet by increasing the total
24 dietary intake; or

25 (F) a concrete, metabolite, constituent, extract, or combination of any ingredient
26 described in clause (A), (B), (C), (D), or (E);

27 (2) Means a product that –

28 \\\

1 (A)(i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this
2 title; or

3 (ii) complies with section 350(c)(1)(B)(ii) of this title

4 (B) is not represented for use as a conventional food or as a sole item of a meal or the
5 diet; and

6 (C) is labeled as a dietary supplement; and

7 (3) does-

8 (A) Include an article that is approved as a new drug under section 355 of this title or
9 licensed as a biologic under section 262 of title 42 and was, prior to such approval, certification,
10 or license, marketed as a dietary supplement or as a food unless the Secretary has issued a
11 regulation, after notice and comment, finding that the article, when used as or in a dietary
12 supplement under the conditions of use and dosages set forth in the labeling for such dietary
13 supplement, is unlawful under section 342(f) of this title; and

14 (B) not include-

15 (i) an article that is approved as a new drug under section 355 of this title,
16 certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262
17 of title 42, or

18 (ii) an article authorized for investigation as a new drug, antibiotic, or
19 biological for which substantial clinical investigations have been instituted and for which the
20 existence of such investigations has been made public, which was not before such approval,
21 certification, licensing, or authorization marketed as a dietary supplement or as a food unless the
22 Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding
23 that the article would be unlawful under this chapter.

24 Except for purposes of paragraph (g) and section 350f of this title, a dietary supplement
25 shall be deemed to be a food within the meaning of this chapter.

26 16. 21 U.S. Code section 350 states, in pertinent part:

27 (c) Definitions

28 \\\

1 (1) For purposes of this section, the term “food to which this section applies” means a
2 food for humans which is a food for special dietary use-

3 (A) which is or contains any natural or synthetic vitamin or mineral, and

4 (B) which-

5 (i) is intended for ingestion in table, capsule, powder, softgel, gelcap, or
6 liquid form, or

7 (ii) if not intended for ingestion in such a form, is not represented as
8 conventional food and is not represented for use as a sole item of a meal or of the diet.

9 **COST RECOVERY**

10 17. Section 125.3 of the Code states, in pertinent part, that the Board may request the
11 administrative law judge to direct a licensee found to have committed a violation or violations of
12 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
13 enforcement of the case.

14 **DEFINITIONS**

15 18. An **endotoxin** is a heat-stable toxin associated with the outer membranes of certain
16 gram-negative bacteria, including *Burcella*, *Neisseria*, and *Vibrio* species. Endotoxins are not
17 secreted but are released only when the cells are disrupted. In large quantities they produce
18 hemorrhagic shock and severe diarrhea; smaller amounts cause fever, altered resistance to
19 bacterial infection, leukopenia followed by leukocytosis, and numerous other biologic effects.

20 **FACTUAL ALLEGATIONS**

21 19. On or about January 10, 2019, the Board received a report of adverse drug reactions
22 (ADR) to a non-sterile to sterile compound of glutathione.

23 20. The Board initiated an investigation, which found that pharmacies were using L-
24 glutathione, a dietary supplement graded bulk, to compound sterile drug preparations. L-
25 glutathione is not an active pharmaceutical ingredient (API).

26 21. According to Respondent PCCA’s website, “At PCCA, we’re proud of what we do –
27 helping pharmacists and prescribers create personalized medicine that makes a difference in
28 patients’ lives. That’s why we provide more products, more education and more support than any

1 other compounding organization. We're committed to helping you and your business shine
2 through our culture of innovation and quality, of success and celebration, of caring and sharing.
3 We've made it our business to support compounding pharmacists every step of the way..."

4 22. On the top of Respondents' web page, there is a link to "buy products" which directs
5 the consumer to a link to purchase PCCA branded products. This includes dietary supplements
6 and API. A search for glutathione yields Part 30-4835GM which is labeled "for use in dietary
7 supplements."

8 23. A second link for "membership" provides additional information including but not
9 limited to Clinical Support Team, Formulations, Innovation, Education and Marketing Resources.
10 Respondent's web page states "PCCA members rely on the expertise and experience of PCCA's
11 Clinical Support Team, consisting of more than 30 pharmacists, chemists and PhDs on call 24/7
12 to answer even the most challenging clinical questions. Complex formulas, difficult patients
13 triage cases, calculation questions – we have you covered..." "PCCA's FormulaPlus program
14 utilizes rigorous, stability-indicating methods to extend beyond-use dates on over 120 of our
15 member's favorite formulas..."

16 24. PCCA promised compounding pharmacies and Pharmacists that by becoming
17 members they will provide them answers to their compounding questions, marketing resources
18 and master formulas with extended beyond use dates (FormulaPlus).

19 25. PCCA provided a master formula (formula #9839 and #6461) to pharmacies and
20 pharmacists, including but not limited to ICP, which explained how to make a non-sterile to
21 sterile preparation, which required use of a PCCA product. The product which was required was
22 "Glutathione (L) reduced USP" sold by PCCA under part 30-4835 and labeled as "use in dietary
23 supplements." PCCA also provided a FormulaPlus (formula #9839 and #6461) which stated that
24 if the pharmacies followed PCCA master formula and used their chemicals they could assign a 90
25 day beyond use date to a non-sterile to sterile product made with a dietary supplement.

26 26. Testing was performed of the L-glutathione. The Certification of analysis showed
27 levels of contaminants, including filth, putrid, or decomposed substances.

28 \\\

1 **FIRST CAUSE FOR DISCIPLINE**

2 **(Dishonesty, Fraud, Deceit, or Corruption)**

3 27. Respondents PCCA and Zaccardo are subject to disciplinary action under Code
4 sections 4301, subdivision (f) and 4304, in that Respondents engaged in acts constituting
5 dishonesty, fraud, deceit, or corruption. The circumstances are as more fully set forth above in
6 paragraphs 18 through 25 and as follows:

7 a. Respondents supplied dishonest information to pharmacies in the State of California,
8 including but not limited to ICP. Respondent's master formula and formula plus for formula
9 numbers 9839 and 6461, represented that a pharmacy was able to compound a non-sterile to
10 sterile drug preparation and assign a 90 day beyond use date when made with a chemical which
11 was intended for use in dietary supplements, namely "Glutathione (L) reduced USP", sold by
12 PCCA under part 30-4835. In fact, L-glutathione is not an active pharmaceutical ingredient
13 (API).

14 **SECOND CAUSE FOR DISCIPLINE**

15 **(Violations of the Pharmacy Law and Federal and State Laws Governing Pharmacy)**

16 28. Respondents PCCA and Zaccardo are subject to disciplinary action under Code
17 sections 4301, subdivision (o) and 4304, for unprofessional conduct, in that Respondents violated,
18 or attempted to violate, directly or indirectly, or assisted in or abetted the violation of or conspired
19 to violate federal and state laws and regulations governing pharmacy, as follows:

20 a. As set forth more fully above in paragraphs 18 through 26, Respondents supplied
21 dishonest, deceitful and corrupt master formulas to pharmacies in California, including but not
22 limited to ICP, to compound adulterated non-sterile to sterile preparations using a dietary
23 supplement sold by PCCA, "Glutathione (L) reduced USP". Respondents aided and abetted
24 pharmacies in California, including but not limited to ICP, in manufacturing adulterated
25 compounded sterile preparations. Respondents' acts violate Code section 4169, subdivision (a)
26 and Health and Safety Code section 111295.

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1 **DISCIPLINE CONSIDERATIONS**

2 29. To determine the degree of discipline to be imposed on Respondents, if any,
3 Complainant alleges that in a prior disciplinary action entitled, “*In the Matter of the Accusation*
4 *Against: Professional Compounding Centers of America, LTD., doing business as Professional*
5 *Compounding Centers of America, and Fabian V. Zaccardo*”, effective on or about February 15,
6 2018, Respondent Zaccardo was Publically Reproved and Respondent PCCA’s license was
7 revoked, the revocation stayed, and Respondent PCCA was placed on probation for one year with
8 terms and conditions. The acts that led to the discipline of Respondents were violations of Code
9 sections 4301, subdivision (o) and section 4303, by violating 21 U.S.C. section 355 and Health
10 and Safety Code section 111550 (compounding, dispensing and selling new drug when no IND);
11 violation of Code sections 4301, subdivision (j), Code section 4304, Health and Safety Code
12 sections 110290, 111330, 111400, and 21 U.S.C. section 352(f) (sold misbranded drugs); and
13 Code section 4301, subdivision (f) and Code section 4304 (dishonest acts).

14 **OTHER MATTERS**

15 30. Pursuant to Code section 4307, if discipline is imposed on Out of State Distributer
16 License Number OSD 3279, issued to Professional Compounding Centers of America, LTD
17 doing business as Professional Compounding Centers of America, it shall be prohibited from
18 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
19 license for five years if Out of State Distributer License Number OSD 3279 is placed on
20 probation or until Out of State Distributer License Number OSD 3279 is reinstated if it is
21 revoked.

22 31. Pursuant to Code section 4307, if discipline is imposed on Out of State Distributer
23 License Number OSD 3279, issued to Professional Compounding Centers of America, LTD
24 doing business as Professional Compounding Centers of America, while Fabian V. Zaccardo was
25 a manager, administrator, owner, member, officer, director, associate, partner, or any other person
26 with management or control of Respondent PCCA, and had knowledge of or knowingly
27 participated in any conduct for which the license is disciplined, Fabian V. Zaccardo shall be
28 prohibited from serving as a manager, administrator, owner, member, officer, director, associate,

1 or partner of a license for five years if Out of State Distributer License Number OSD 3279 is
2 placed on probation or until Out of State Distributer License Number OSD 3279 is reinstated if it
3 is revoked.

4 **PRAYER**

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

7 1. Revoking or suspending Out of State Distributer License Number OSD 3279, issued
8 to Professional Compounding Centers of America, LTD., dba Professional Compounding Centers
9 of America;

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

12 3. Prohibiting Professional Compounding Centers of America, LTD. from serving as a
13 manager, administrator, owner, member, officer, director, associate, or partner of a licensee for
14 five years if Out of State Distributer License Number OSD 3279 is placed on probation or until
15 Out of State Distributer License Number OSD 3279 is reinstated if it is revoked;

16 4. Prohibiting Fabian V. Zaccardo from serving as a manager, administrator, owner,
17 member, officer, director, associate, or partner of a licensee for five years if Out of State
18 Distributer License Number OSD 3279 is placed on probation or until Out of State Distributer
19 License Number OSD 3279 is reinstated if it is revoked;

20 5. Ordering Professional Compounding Centers of America, LTD., dba Professional
21 Compounding Centers of America and Fabian V. Zaccardo, to pay the Board of Pharmacy the
22 reasonable costs of the investigation and enforcement of this case, pursuant to Business and
23 Professions Code section 125.3; and,

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1 6. Taking such other and further action as deemed necessary and proper.
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4 DATED: May 26, 2020
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ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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