

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

In the Matter of the Accusation Against:

Case No. 6172

**SAN MARCOS PHARMACY INC. DBA
SANTA MARIA PHARMACY
Michael Soliman, Owner
16279 Paramount Blvd., Unit G
Paramount, CA 90723
Pharmacy Permit No. PHY 53623**

OAH No. 2019021105

**GEORGE RAAFAT FAKHRY HENIN
8400 Edinger Avenue, #Z208
Huntington Beach, CA 92647
Original Pharmacist License No. RPH 70281**

Respondents.

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 January 23, 2020.

It is so ORDERED on December 24, 2019.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Greg Lippe
Board President

1 XAVIER BECERRA
Attorney General of California
2 THOMAS L. RINALDI
Supervising Deputy Attorney General
3 CRISTINA FELIX
Deputy Attorney General
4 State Bar No. 195663
300 So. Spring Street, Suite 1702
5 Los Angeles, CA 90013
Telephone: (213) 269-6321
6 Facsimile: (916) 731-2126
E-mail: Cristina.Felix@doj.ca.gov
7 *Attorneys for Complainant*

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

12 In the Matter of the Accusation Against:

13 **SAN MARCOS PHARMACY, INC. DBA**
SANTA MARIA PHARMACY, MICHAEL
14 **SOLIMAN**
15 **16279 Paramount Blvd., Unit G**
Paramount, CA 90723

16 **Permit No. PHY 53623,**

17 **and**

18 **GEORGE RAAFAT FAKHRY HENIN**
8400 Edinger Ave, #Z208
19 **Huntington Beach, CA 92647**

20 **Pharmacist License No. RPH 70281**

21 Respondents.

Case No. 6172

OAH No. 2019021105

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER FOR PUBLIC
REPROVAL AS TO GEORGE
RAAFAAT FAKHRY HENIN ONLY

[Bus. & Prof. Code § 495]

22
23 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
24 entitled proceedings that the following matters are true:

25 ///

26 ///

27 ///

1 **PARTIES**

2 1. Anne Sodergren (Complainant) is the Interim Executive Officer of the Board of
3 Pharmacy (Board). She brought this action solely in her official capacity and is represented in
4 this matter by Xavier Becerra, Attorney General of the State of California, by Cristina Felix,
5 Deputy Attorney General.

6 2. Respondent George Raafat Fakhry Henin (Respondent) is represented in this
7 proceeding by attorney Armond Marcarian, Esq., whose address is: 31255 Cedar Valley Drive,
8 Ste 301, Westlake Village, CA 91362.

9 **JURISDICTION**

10 3. On or about December 2, 2013, the Board issued Original Pharmacist License
11 Number RPH 70281 to Respondent. The License was in full force and effect at all times relevant
12 to the charges brought herein and will expire on September 30, 2019. Respondent has been the
13 Pharmacist-in-Charge at San Marcos Pharmacy Inc. dba Santa Maria Pharmacy since June 15,
14 2015.

15 4. First Amended Accusation No. 6172 was filed before the Board and is currently
16 pending against Respondent. The First Amended Accusation and all other statutorily required
17 documents were properly served on Respondent on September 4, 2019. Respondent timely filed
18 his Notice of Defense. A copy of First Amended Accusation No. 6172 is attached as exhibit A
19 and incorporated herein by reference.

20 **ADVISEMENT AND WAIVERS**

21 5. Respondent has carefully read, fully discussed with counsel, and understands the
22 charges and allegations in First Amended Accusation No. 6172. Respondent has also carefully
23 read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and
24 Disciplinary Order for Public Reproval.

25 6. Respondent is fully aware of his legal rights in this matter, including the right to a
26 hearing on the charges and allegations in the First Amended Accusation; the right to be
27 represented by counsel at his own expense; the right to confront and cross-examine the witnesses
28 against him; the right to present evidence and to testify on his own behalf; the right to the

1 issuance of subpoenas to compel the attendance of witnesses and the production of documents;
2 the right to reconsideration and court review of an adverse decision; and all other rights accorded
3 by the California Administrative Procedure Act and other applicable laws.

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

6 **CULPABILITY**

7 8. Respondent understands and agrees that the charges and allegations in First
8 Amended Accusation No. 6172, if proven at a hearing, constitute cause for imposing discipline
9 upon his Original Pharmacist License.

10 9. For the purpose of resolving the First Amended Accusation without the expense and
11 uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could
12 establish a factual basis for the charges in the First Amended Accusation, and that Respondent
13 hereby gives up his right to contest those charges.

14 10. Respondent agrees that his Original Pharmacist License is subject to discipline,
15 agrees to be bound by the Disciplinary Order below, and agrees that the Public Repeval Order
16 below shall be considered discipline.

17 **CONTINGENCY**

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

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

13. This Stipulated Settlement and Disciplinary Order for Public Reproval 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 for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. 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 the Original Pharmacist License No. RPH 70281 issued to Respondent George Raafat Fakhry Henin shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of First Amended Accusation No. 6172, attached as exhibit A.

Cost Recovery. Respondent shall pay \$2750.00 to the Board for its costs associated with the investigation and enforcement of this matter. Respondent shall be permitted to pay these costs in a payment plan approved by the Board. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew his Original Pharmacist License until Respondent pays costs in full.

///

///

///

1 **Remedial Education.** Within sixty (60) days of the effective date of this decision,
2 Respondent shall submit to the board or its designee, for prior approval, an appropriate program
3 of remedial education related to (1) pharmacy operations and (2) non-sterile compounding. The
4 program of remedial education shall consist of least five (5) hours of pharmacy operations and at
5 least five (5) hours of non-sterile compounding, for a total of ten (10) hours of continuing
6 education. At least 50% of the education hours must be in-person training. All remedial
7 education shall be in addition to, and shall not be credited toward, continuing education (CE)
8 courses used for license renewal purposes for pharmacists.

9 Following the completion of each course, the board or its designee may require the
10 Respondent, at Respondent's own expense, to take an approved examination to test the
11 respondent's knowledge of the course(s). If the respondent does not achieve a passing score on
12 the examination that course shall not count towards satisfaction of this term. Respondent shall
13 take another course approved by the board in the same subject area.

14 Within one year of this decision, such remedial education shall be completed and written
15 proof thereof, in a form acceptable to the Board, shall be provided to the Board or its designee.
16 Failure to timely submit for approval or complete the approved remedial education may subject
17 Respondent's license to discipline.

18 **Drug Diversion and Abuse Training.** Within one (1) year of the effective date of this
19 decision, and at respondent owner's expense, Respondent shall complete the continuing education
20 course offered jointly by the Board and DEA entitled "Prescription Drug Abuse and Diversion-
21 What a Pharmacist Needs to Know." This course shall be in addition to, and shall not be credited
22 toward, continuing education (CE) courses used for license renewal purposes. Respondent shall
23 not be allowed to renew his license until completed as specified herein.

24 ///

25 ///

26 ///

27 ///

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Repeval and have fully discussed it with my attorney, Armond Marcarian, Esq. I understand the stipulation and the effect it will have on my Original Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order for Public Repeval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

GEORGE RAAFAT FAKHRY HENIN
Respondent

I have read and fully discussed with Respondent George Raafat Fakhry Henin the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Repeval. I approve its form and content.

DATED: _____

September 27, 2019


ARMOND MARCARIAN, ESQ.
Attorney for Respondent

///

///

///

///

///

///

///

///

///

///

///

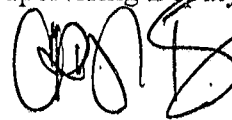
ENDORSEMENT

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

DATED: SEPT 27, 2019

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
THOMAS L. RINALDI
Supervising Deputy Attorney General



CRISTINA FELIX
Deputy Attorney General
Attorneys for Complainant

LA2017604594
53767475_3.docx

Exhibit A

First Amended Accusation No. 6172

1 XAVIER BECERRA
Attorney General of California
2 THOMAS L. RINALDI
Supervising Deputy Attorney General
3 CRISTINA FELIX
Deputy Attorney General
4 State Bar No. 195663
300 So. Spring Street, Suite 1702
5 Los Angeles, CA 90013
Telephone: (213) 897-2455
6 Facsimile: (213) 897-2804
Attorneys for Complainant

7
8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

10 In the Matter of the Accusation Against:

Case No. 6172

11 **SAN MARCOS PHARMACY INC. DBA**
12 **SANTA MARIA PHARMACY**
13 **Michael Soliman, Owner**
14 **16279 Paramount Blvd., Unit G**
Paramount, CA 90723
Pharmacy Permit No. PHY 53623

FIRST AMENDED ACCUSATION

15 **GEORGE RAAFAT FAKHRY HENIN**
16 **8400 Edinger Avenue, #Z208**
Huntington Beach, CA 92647
17 **Original Pharmacist License No. RPH 70281**

18 Respondents.

19 Complainant alleges:

20 **PARTIES**

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

24 2. On or about June 15, 2015, the Board issued Permit Number PHY 53623 to San
25 Marcos Pharmacy Inc. dba Santa Maria Pharmacy (Respondent Santa Maria Pharmacy), Michael
26 Soliman was President and owner since June 15, 2015. The Permit was in full force and effect at
27 all times relevant to the charges brought herein and will expire on June 1, 2020, unless renewed.
28

George Raafat Rakhry Henin (Respondent Henin) has been the Pharmacist-in Charge since June 15, 2015.

3. On or about December 2, 2013, the Board issued Original Pharmacist License Number RPH 70281 to Respondent Henin. The License was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2019.

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.

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, in pertinent part:

"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 procured by fraud or misrepresentation or is 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.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

1 . . .

2 (q) Engaging in any conduct that subverts or attempts to subvert an investigation of the
3 board.

4 . . .”

5 8. Section 4081 of the Code states, in pertinent part:

6 “(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of
7 dangerous drugs or dangerous devices shall be at all times during business hours open to
8 inspection by authorized officers of the law, and shall be preserved for at least three years from
9 the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-
10 party logistics provider, pharmacy, veterinary food-animal drug retailer, physician, dentist,
11 podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a
12 currently valid and unrevoked certificate, license, permit, registration, or exemption under
13 Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4
14 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who
15 maintains a stock of dangerous drugs or dangerous devices.

16 (b) The owner, officer, and partner of a pharmacy, wholesaler, . . . shall be jointly
17 responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-
18 charge for maintaining the records and inventory described in this section.

19 . . .”

20 9. Section 4105, subdivision (a), of the Code states:

21 “All records or other documentation of the acquisition and disposition of dangerous drugs
22 and dangerous devices by any entity licensed by the board shall be retained on the licensed
23 premises in a readily retrievable form.”

24 10. Section 4113 of the Code states:

25 “(a) Every pharmacy shall designate a pharmacist-in-charge and within 30 days thereof,
26 shall notify the board in writing of the identity and license number of that pharmacist and the date
27 he or she was designated.

28 . . .

1 (c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all
2 state and federal laws and regulations pertaining to the practice of pharmacy."

3 11. Section 4307 of the Code states:

4 "(a) Any person who has been denied a license or whose license has been revoked or is
5 under suspension, or who has failed to renew his or her license while it was under suspension, or
6 who has been a manager, administrator, owner, member, officer, director, associate, partner, or
7 any other person with management or control of any partnership, corporation, trust, firm, or
8 association whose application for a license has been denied or revoked, is under suspension or has
9 been placed on probation, and while acting as the manager, administrator, owner, member,
10 officer, director, associate, partner, or any other person with management or control had
11 knowledge of or knowingly participated in any conduct for which the license was denied,
12 revoked, suspended, or placed on probation, shall be prohibited from serving as a manager,
13 administrator, owner, member, officer, director, associate, partner, or in any other position with
14 management or control of a licensee as follows:

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

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

19 (b) "Manager, administrator, owner, member, officer, director, associate, partner, or any
20 other person with management or control of a license" as used in this section and Section 4308,
21 may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

22 (c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to
23 Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code.
24 However, no order may be issued in that case except as to a person who is named in the caption,
25 as to whom the pleading alleges the applicability of this section, and where the person has been
26 given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part
27 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision
28

1 shall be in addition to the board's authority to proceed under Section 4339 or any other provision
2 of law."

3 12. Health and Safety Code Section 111335 states: "Any drug or device is misbranded if
4 its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with
5 Section 110290)."

6 13. Health and Safety Code Section 111440 states: "It is unlawful for any person to
7 manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

8 **REGULATORY PROVISIONS**

9 14. California Code of Regulations, title 16, section 1735.3, states:

10 "(a) For each compounded drug product, pharmacy records shall include:

11 (1) The master formula record.

12 (2) The date the drug product was compounded.

13 (3) The identity of the pharmacy personnel who compounded the drug product.

14 (4) The identity of the pharmacist reviewing the final drug product.

15 (5) The quantity of each component used in compounding the drug product.

16 (6) The manufacturer, expiration date and lot number of each component. If the
17 manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.
18 Exempt from the requirements in this paragraph are sterile products compounded on a one-time
19 basis for administration within seventy-two (72) hours and stored in accordance with standards
20 for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia--National
21 Formulary (USP-NF) (35th Revision, Effective May I, 2012), hereby incorporated by reference,
22 to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

23 (7) A pharmacy assigned reference or lot number for the compounded drug product.

24 (8) The expiration date of the final compounded drug product.

25 (9) The quantity or amount of drug product compounded.

26 (b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of
27 chemicals, bulk drug substances, drug products, and components used in compounding.

28 (c) Chemicals, bulk drug substances, drug products, and components used to compound

1 drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain
2 any available certificates of purity or analysis for chemicals, bulk drug substances, drug products,
3 and components used in compounding. Certificates of purity or analysis are not required for drug
4 products that are approved by the Food and Drug Administration.

5 (d) Pharmacies shall maintain and retain all records required by this article in the pharmacy
6 in a readily retrievable form for at least three years from the date the record was created."

7 15. California Code of Regulations, title 16, section 1735.4, states:

8 "(a) In addition to the labeling information required under Business and Professions Code
9 section 4076, the label of a compounded drug product shall contain the generic name(s) of the
10 principal active ingredient(s).

11 (b) A statement that the drug has been compounded by the pharmacy shall be included on
12 the container or on the receipt provided to the patient.

13 (c) Drug products compounded into unit-dose containers that are too small or otherwise
14 impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the
15 name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy
16 reference or lot number, and expiration date"

17 16. California Code of Regulations, title 16, section 1735.8, subdivision (c) states:

18 "The quality assurance plan shall include written standards for qualitative and quantitative
19 integrity, potency, quality, and labeled strength analysis of compounded drug products. All
20 qualitative and quantitative analysis reports for compounded drug products shall be retained by
21 the pharmacy and collated with the compounding record and master formula."

22 **COST RECOVERY PROVISION**

23 17. Section 125.3 provides, in pertinent part, that the Board may request the
24 administrative law judge to direct a licensee found to have committed a violation or violations of
25 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
26 enforcement of the case.

27 ///

28 ///

RELEVANT FACTS

18. On October 6, 2016, Inspector Yamada inspected Respondent Santa Maria Pharmacy. Respondent Henin was present, and was the pharmacist-in charge. At the back of the pharmacy, an area appeared to be a non-sterile compounding area. Cabinets located in this area contained unlabeled or improperly labeled compounded preparations, including a large unlabeled bowl containing a creamy substance, covered in plastic. There were also multiple jars of topical compounds and some of the jars were labeled with preparation names and expiration dates. However, none of the preparations were labeled with a pharmacy reference number or a lot number.

19. Inspector Yamada selected two compounded preparations located at the compounding area, tramadol/baclofen and flurbiprofen/GABA. The compounding worksheets for these two preparations were not found in the compounding binders that were located in the compounding area and Respondent Henin was unable to locate the hardcopy worksheets during the inspection. Respondent Henin confirmed that Marcos Soliman, the pharmacist-in-charge of Santa Maria Pharmacy, Inc. dba Santa Maria Community Pharmacy (SMCP), a pharmacy located in El Monte, handled all the compounding at Respondent Santa Maria Pharmacy and came to the pharmacy about once a week.

20. When questioned during the inspection about the use of a reverse distributor, Respondent Henin informed the inspector that the pharmacy's reverse distributor was RX Reverse Distributors. When requested, however, Respondent Henin was unable to locate any documents confirming the shipment of dangerous drugs from Respondent Santa Maria Pharmacy to RX Reverse Distributors. When questioned, Respondent Henin also stated that Marcos Soliman handled all the drug returns and that he was not provided information by the owners of Respondent Santa Maria Pharmacy, and that he was blocked from access to the records.

21. When questioned during the inspection about expired drugs, Respondent Henin also advised the inspector that expired drugs were sent to SMCP and that pharmacy should have all the records. When requested, however, Respondent Henin was not able to produce a copy of the

1 drug transfer records for the drugs that were allegedly transferred to SMCP from Respondent
2 Santa Maria Pharmacy.

3 22. During the inspection, the inspector found two boxes containing IV fluids and one
4 box containing IV administration sets in the middle of the floor by the front entrance to the
5 dispensing area. When requested, however, Respondent Henin was unable to locate an inventory
6 of any drug shipments from Respondent Santa Maria Pharmacy to RX Reverse Distributors.

7 23. At approximately 12:30 p.m., Marcos Soliman arrived at the pharmacy and confirmed
8 that he was the only compounding staff member at Respondent Santa Maria, that the compounded
9 preparations the inspector found at Respondent Santa Maria Pharmacy were not properly labeled,
10 and that the worksheets were possibly not completed for these compounds. Marcos Soliman
11 stated that he was unable to locate the documentation for the compounds at that time.

12 24. Marcos Soliman advised the inspector that he checked the weights for his
13 preparations as part of his quality assurance process and had not sent out any compounded
14 preparations for testing. Respondent Santa Maria Pharmacy did not have any records of
15 quantitative and qualitative analysis for compounded preparations they prepared at Respondent
16 Santa Maria Pharmacy.

17 25. The inspector requested, but did not receive, the compounding record for the
18 triamcinolone/nystatin cream previously found in an inspection of another pharmacy, SMCP, on
19 September 30, 2016. The jar of compounded triamcinolone/nystatin cream she found at SMCP
20 was labeled as being prepared by Respondent Santa Maria Pharmacy, had a lot number of
21 8152016, and an expiration date of February 2017. When the inspector questioned Marcos
22 Soliman regarding compounds found at SMCP, Marcos Soliman stated that the compounds found
23 at SMCP were sent there for destruction, were for demonstration for students, and the compounds
24 were not for dispensing. Marcos Soliman advised that he could not produce transfer records at
25 the time of the inspection as he had to go through boxes and it would take hours to do so.

26 26. Respondent Henin provided the inspector a compounding worksheet for one of the
27 requested compounded preparations over an hour after she requested the worksheet. When
28 questioned by the inspector as to whether the worksheets were received from someone else by

1 email, Respondent Henin stated that the worksheet was maintained in the computer. However, he
2 was unable to locate it for her on the computer when requested to do so, and advised the inspector
3 that Ms. Villarreal printed it out for him. Ms. Villarreal advised the inspector that Marcos Soliman
4 instructed her to print out the worksheet which was on the computer desktop. However, she was
5 unable to locate the worksheet on the desktop when instructed to do so by the inspector. After
6 searching emails in the inbox, emails with attachments for compounding records for the two
7 compounding preparations prepared in an Excel format were found. However, the worksheets
8 Respondent Henin provided the inspector varied from the worksheets in the email as follows: 1)
9 Respondent Henin's worksheets were not in excel format, 2) the ingredients listed were different,
10 with different lot numbers and expiration dates, 3) Respondent's worksheets contained the name
11 "Alma" as the technician and the emailed worksheets had "Cynthia" as the technician.

12 Contradicting his earlier statement, Respondent Henin then admitted that he was unable to locate
13 the compounding worksheet for the items the inspector requested so he requested them from
14 SMCP and they were emailed to him and then Ms. Villarreal printed the worksheets for him.

15 27. At the end of the inspection on October 6, 2016, Inspector Yamada issued notices of
16 non-compliance and requested that Respondent Henin provide certain documentation within
17 fourteen (14) and twenty-one (21) days.

18 28. On November 4, 2016, an attorney submitted some of the requested documents on
19 behalf of Respondent Santa Maria Pharmacy, including worksheets for vitamin D3. The
20 worksheets provided had lines for "Verifying Pharmacist Initial" and "Compounder Initial" with
21 hand written initials printed on both spaces which appeared to be those of Marcos Soliman. (The
22 worksheets the inspector found during her inspection had lines for "pharmacist" and "technician"
23 with the names of the individuals as "Marcos S" and "Cynthia.")

24 29. On November 8, 2016, the board inspector informed Respondent Henin and
25 Respondent San Maria Pharmacy's attorney that certain requested documents had not been
26 received and should be provided within seventy-two (72) hours. However, the documents were
27 not received until after a written notice of non-compliance for subverting an investigation was
28 issued on November 18, 2016.

30. On February 16, 2017, Marcos Soliman emailed the Board inspector compounding worksheets, including for Diclo 3%/Lido5%; Clindamycin1%; Benzoyl Peroxide 10%; Diclofenac 3%; Acyclovir 5%; Econazole 1.5%; Lidocaine 5%; Urea 30%; Floucinolone and Erythromycin 3%. The worksheets were in the same format as those the inspector reviewed at the inspection except for a few changes, including that the worksheets had lines for “Verifying Pharmacist Initial” and “Compounder Initial” with handwritten initials printed next to the verifying pharmacist initials. The hand written initials appeared to be made by Marcos Soliman.

FIRST CAUSE FOR DISCIPLINE

(Failure to Label Compounded Preparations)

(Respondent Santa Maria Pharmacy and Respondent Henin)

31. Respondent Santa Maria Pharmacy and Respondent Henin are subject to disciplinary action under Code of Regulations, title 16, section 1753.4, subdivision (c), in that, on October 6, 2016, a Board inspection revealed that Respondent Santa Maria Pharmacy’s compounded preparations were not properly labeled with the expiration date and/or pharmacy assigned reference number of the compounded preparation as follows, as set forth in paragraphs 18 through 19, and 23, which is incorporated herein:

Compound Name	Expiration Date	Lot #/Ref #
Dicio 3%/ Lido 5%	None	None
Clindamycin 1 %	1/17	None
Benzoyl Peroxide 10%	4/17	None
Diclofenac 3%	None	None
Acyclovir 5%	3/17	None
Econazole 1.5%	1/17	None
Lidocaine Oint.	None	None
Urea 30%	None	None
Fluocinolone	None	None

Erythromycin 3%	4/17	None
Tramadol 15%/ Baclo 5%/ GABA 10%	None	None

SECOND CAUSE FOR DISCIPLINE

(Possession of Misbranded Drugs)

(Respondent Santa Maria Pharmacy, Respondent Henin)

32. Respondents Santa Maria Pharmacy and Respondent Henin are subject to disciplinary action under Health and Safety Code sections 111335 and 111440 in that, on October 6, 2016, a Board inspection revealed that Respondent Santa Maria Pharmacy was in possession of misbranded compounded preparations as they did not contain the expiration date and/or pharmacy assigned reference number, as set forth in paragraphs 18 through 19, 23 and 31, which are incorporated herein.

THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Compounding Drug Products)

(Respondent Santa Maria Pharmacy, Respondent Henin)

33. Respondents Santa Maria Pharmacy and Respondent Henin are subject to disciplinary action under California Code of Regulations, title 16, section 1735.3, subdivisions (a)-(d) in that, on September 30, 2016, at a Board inspection of another pharmacy (SMCP), the inspector found at least one jar of compounded triamcinolone/nystatin cream labeled as being prepared by Respondent Santa Maria Pharmacy. The compounded preparation was labeled with lot number 8152016 and an expiration date of February 2017. On October 6, 2016, during an inspection of Respondent Santa Maria Pharmacy, the compounding record for the triamcinolone/nystatin cream was requested but not provided, as set forth in paragraph 25, which is incorporated herein.

///

///

///

///

///

FOURTH CAUSE FOR DISCIPLINE

(Failure to Conduct Compounding Quality Assurance)

(Respondent Santa Maria Pharmacy, Respondent Henin)

34. Respondents Santa Maria Pharmacy and Respondent Henin are subject to disciplinary action under California Code of Regulations, title 16, section 1735.8, subdivision (c), in that, on October 6, 2016, a Board inspection revealed that Respondent Santa Maria Pharmacy did not conduct any qualitative and quantitative analysis on any compounded preparation, as set forth in paragraph 24, which is incorporated herein.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional conduct: False Compounding Records and Worksheets)

(Respondent Santa Maria Pharmacy, Respondent Henin)

35. Respondents Santa Maria Pharmacy and Respondent Henin are subject to disciplinary action under section 4301, subdivisions (f) and (g), in that, on October 6, 2016, Respondent Henin, pharmacist-in-charge, provided falsified compounding records to a Board inspector for tramadol 20%/baclofen 5%/ lipoderm 5% and flurbiprofen 10%/ gabapentin 10%/lidocaine 5% lipo. The compounding worksheets for Vitamin D3 400 IU 1ml droppers and triamcinolone creams provided to the Board inspector on November 4, 2016 were also falsified. In addition, the compounding worksheets for Diclo 3%/ Lido 5%; Clindamycin 1%; Benzoyl Peroxide 10%; Diclofenac 3%; Acyclovir 5%; Econazole 1.5%; Lidocaine 5%; Urea 30%; Floucinolone; and Erythromycin 3% provided to the inspector on February 16, 2017 were falsified. Complainant refers to, and by this reference, incorporates the allegations set forth above in paragraphs 26 through 30, inclusive, as though set forth fully.

///

///

///

///

///

///

1 **SIXTH CAUSE FOR DISCIPLINE**

2 **(Subverting Investigation: Records)**

3 **(Respondent Santa Maria Pharmacy, Respondent Henin)**

4 36. Respondents Santa Maria Pharmacy and Respondent Henin are subject to disciplinary
5 action under section 4301, subdivision (q), in that they failed to provide a copy of documents and
6 information requested by a Board inspector on October 6, 2016 until after a written notice of non-
7 compliance and subverting an investigation was issued on November 18, 2016, as set forth in
8 paragraphs 27 and 29, which are incorporated herein.

9 **SEVENTH CAUSE FOR DISCIPLINE**

10 **(Failure to Maintain Records)**

11 **(Respondent Santa Maria Pharmacy, Respondent Henin)**

12 37. Respondents Santa Maria Pharmacy and Respondent Henin are subject to disciplinary
13 action under sections 4081, subdivisions (a) and (b), and 4105, subdivision (a), in that during a
14 Board inspection on October 6, 2016, they were unable to produce any records of disposition for
15 dangerous drugs sent to another pharmacy, SMCP, for the alleged purposes of return or
16 destruction of the products and were unable to produce the records of acquisition for two boxes of
17 intravenous fluid solution and one box of intravenous administration sets, as set forth in
18 paragraphs 18 through 22, and 25 which are incorporated herein.

19 **OWNERSHIP PROHIBITION**

20 38. As set forth above, section 4307, subdivision (a), provides, in pertinent part, that any
21 person whose license has been revoked or is under suspension shall be prohibited from serving as
22 a manager, administrator, owner, member, officer, director, associate or partner of a licensee.

23 39. Pursuant to section 4307, if Michael Soliman had knowledge of, or knowingly
24 participated in, any conduct for which Pharmacy Permit PHY 53623 was revoked, suspended or
25 placed on probation, while acting as administrator, owner, officer, director, or any other person
26 with management or control of San Marcos Pharmacy Inc. dba Santa Maria Pharmacy, he shall be
27 prohibited from serving as administrator, owner, member, officer, director, associate, or partner
28 of a licensee for five years if Pharmacy Permit Number PHY 53623 is placed on probation, or

1 until Pharmacy Permit Number PHY 53623 is reinstated if Pharmacy Permit Number PHY 53623
2 is revoked.

3 **DISCIPLINE CONSIDERATIONS**

4 40. To determine the degree of discipline, if any, to be imposed on Respondent Henin,
5 Complainant alleges that on or about December 7, 2016, in a prior action, the Board issued
6 Citation Number C1 2016 72897 and ordered Respondent to pay a total of \$1,000.00 in fines.
7 The fines were imposed for violations of Code of Regulations, title 16, sections 1716 and 1761,
8 for filling erroneous prescriptions. That Citation is now final and is incorporated by reference as
9 if fully set forth.

10 **PRAYER**

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

13 1. Revoking or suspending Permit Number PHY 53623, issued to San Marcos Pharmacy
14 dba Santa Maria Pharmacy; Michael Soliman, Owner;

15 2. Revoking or suspending Pharmacist License No. RPH 70281 issued to George
16 Raafat Fakhry Henin;

17 3. Prohibiting Michael Soliman from serving as a manager, administrator, owner,
18 member, officer, director, associate, partner, or in any other position with management or control
19 of a licensee, for five years if Pharmacy Permit Number PHY 53623 is placed on probation, or
20 until Pharmacy Permit Number PHY 53623 is reinstated if Pharmacy Permit Number PHY 53623
21 is revoked;

22 4. Ordering San Marcos Pharmacy dba Santa Maria Pharmacy and George Raafat
23 Fakhry Henin to pay the Board of Pharmacy the reasonable costs of the investigation and
24 enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

25 ///

26 ///

27 ///

28 ///

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

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

DATED: September 3, 2019



ANNE SODERGREN
Interim Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

LA2017604595
53710028.docx