

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

In the Matter of the Accusation Against:

**P & G PHARMACY INC., DBA
SUNSHINE CENTER PHARMACY;
THOMAS JOHN GARIBALDI,
Original Pharmacy Permit No. PHY 46165; and**

**THOMAS JOHN GARIBALDI,
Registered Pharmacist License No. RPH 30954,**

Respondents.

Agency Case No. 7241

OAH No. 2022120354

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Repeval 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 May 31, 2023.

It is so ORDERED on May 1, 2023.

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 written in a cursive style with a large initial "S" and "O".

Seung W. Oh, Pharm.D.
Board President

1 ROB BONTA
Attorney General of California
2 JOSHUA A. ROOM
Supervising Deputy Attorney General
3 CHRISTOPHER M. YOUNG
Deputy Attorney General
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Attorneys for Complainant
7

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

12 In the Matter of the Accusation Against:

13 **P & G PHARMACY INC., DBA**
14 **SUNSHINE CENTER PHARMACY;**
15 **THOMAS JOHN GARIBALDI**
1166 Mission Rd.,
South San Francisco, CA 94080

16 **Original Pharmacy Permit No. PHY 46165,**

17 **and**

18 **THOMAS JOHN GARIBALDI**
503 Santa Teresa
19 Millbrae, CA 94030

20 **Registered Pharmacist License No. RPH**
30954

21 Respondents.
22

Case No. 7241

OAH No. 2022120354

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER FOR PUBLIC
REPROVAL**

[Bus. & Prof. Code § 495]

23
24 In the interest of a prompt and speedy settlement of this matter, consistent with the public
25 interest and the responsibilities of the Board of Pharmacy of the Department of Consumer Affairs
26 (Board), the parties hereby agree to the following Stipulated Settlement and Disciplinary Order
27 for Public Repeval which will be submitted to the Board for approval and adoption as the final
28 disposition of the Accusation.

1 **PARTIES**

2 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy
3 (Board). She brought this action solely in her official capacity and is represented in this matter by
4 Rob Bonta, Attorney General of the State of California, by Christopher M. Young, Deputy
5 Attorney General.

6 2. Respondents P & G Pharmacy Inc., dba Sunshine Center Pharmacy, and Thomas
7 John Garibaldi (Respondents) are represented in this proceeding by attorney Natalia Mazina,
8 whose address is: Mazina Law, 100 Pine Street, Suite 1250, San Francisco, CA 94111-5235.

9 **JURISDICTION**

10 3. On or about June 30, 2003, the Board issued Original Permit No. PHY 46165 to P &
11 G Pharmacy Inc., dba Sunshine Center Pharmacy (Respondent Pharmacy). The Original Permit
12 was in full force and effect at all times relevant to the charges brought in Accusation No. 7241
13 and will expire on June 1, 2023, unless renewed.

14 4. On or about July 28, 1977, the Board of Pharmacy issued Registered Pharmacist
15 License Number RPH 30954 to Thomas John Garibaldi (Respondent Garibaldi). The Registered
16 Pharmacist License was in full force and effect at all times relevant to the charges brought herein
17 and will expire on August 31, 2023, unless renewed.

18 5. Accusation No. 7241 was filed before the Board and is currently pending against
19 Respondents. The Accusation and all other statutorily required documents were properly served
20 on Respondents on September 2, 2022. Respondents timely filed their Notice of Defense
21 contesting the Accusation. A copy of Accusation No. 7241 is attached as exhibit A and
22 incorporated herein by reference.

23 **ADVISEMENT AND WAIVERS**

24 6. Respondent Garibaldi has carefully read, fully discussed with counsel, and
25 understands the charges and allegations in Accusation No. 7241. Respondent Garibaldi has also
26 carefully read, fully discussed with counsel, and understands the effects of this Stipulated
27 Settlement and Disciplinary Order for Public Repeval.
28

1 or participation by Respondents or their counsel. By signing the stipulation, Respondents
2 understand and agree that they may not withdraw their agreement or seek to rescind the
3 stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this
4 stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public
5 Repeval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any
6 legal action between the parties, and the Board shall not be disqualified from further action by
7 having considered this matter.

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

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

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

21 **DISCIPLINARY ORDER**

22 IT IS HEREBY ORDERED that Original Permit No. PHY 46165, issued to Respondent P
23 & G Pharmacy Inc., dba Sunshine Center Pharmacy, and Pharmacist License No. RPH 30954,
24 issued to Thomas John Garibaldi, shall be publicly reprovved by the Board of Pharmacy under
25 Business and Professions Code section 495 in resolution of Accusation No. 7241, attached as
26 exhibit A.

27 ///

28 ///

1 **17. Definition: Respondent**

2 For the purposes of paragraph 17, “Respondent” shall refer to Respondent P & G
3 Pharmacy, Inc., dba Sunshine Center Pharmacy. All terms and conditions stated herein shall bind
4 and be applicable to the licensed premises and to all owners, managers, officers, administrators,
5 members, directors, trustees, associates, or partners thereof. For purposes of compliance with any
6 term or condition, any report, submission, filing, payment, or appearance required to be made by
7 Respondent to or before the Board or its designee shall be made by an owner or executive officer
8 with authority to act on behalf of and legally bind the licensed entity.

9 IT IS FURTHER HEREBY ORDERED that Respondent shall, within six (6) months of the
10 effective date of the Disciplinary Order, undergo an inspection by an external entity approved in
11 advance by the Board for this purpose, at its own expense, to perform an evaluation of the
12 operations of the pharmacy and implement the changes recommended by the consultant.

13 The consultant shall be a pharmacist licensed by and not on probation with the board, who
14 has been approved by the board or its designee to serve in this position. Respondent shall submit
15 the name of the proposed consultant to the board or its designee for approval within thirty (30)
16 days of the effective date of the decision. Assumption of any unauthorized supervision
17 responsibilities shall be considered a violation of probation.

18 A copy of the consultant’s report must be provided to the Board at the same time as it is
19 being provided to Respondent. The Board shall receive updates on implementation efforts by
20 Respondent. Failure to timely: submit a proposed entity to the Board for approval; undergo the
21 inspection; or provide the inspection report, shall be deemed unprofessional conduct and cause
22 for further discipline against Respondent.

23 **Full Compliance.** As a resolution of the charges in Accusation No. 7241, this stipulated
24 settlement is contingent upon Respondent’s full compliance with all conditions of this Decision
25 and Order. If Respondent fails to satisfy any of these conditions, such failure to comply
26 constitutes cause for discipline, including outright revocation, of Respondent’s Original
27 Pharmacy Permit No. PHY 46165. If Respondent violates any term and condition of this
28 Decision and Order, all of the charges and allegations contained in Accusation Number 7241 shall

1 be deemed to be true, correct, and admitted by Respondent for purposes of any disciplinary action
2 the Board may take if such occurs.

3 **18. Definition: Respondent**

4 For the purposes of paragraph 18, “Respondent” shall refer to Respondent Thomas John
5 Garibaldi, RPH.

6 **Coursework.** Within thirty (30) days of the effective date of this decision, Respondent
7 shall submit to the Board, for prior approval, an appropriate program of remedial education
8 related to pharmacy law and operations. The program of remedial education shall consist of at
9 least ten (10) hours, having 50% in-person training or live webinar online classes, which shall be
10 completed within one year of the effective date of this Decision and Order, at Respondent’s own
11 expense. All remedial education shall be in addition to, and shall not be credited toward,
12 continuing education (CE) courses used for license renewal purposes for pharmacists.

13 Failure to timely submit for approval or complete the approved remedial education shall be
14 considered a violation of this Decision and Order. Respondent’s license will not be renewed until
15 he satisfies this term, as required.

16 **Full Compliance.** As a resolution of the charges in Accusation No. 7241, this stipulated
17 settlement is contingent upon Respondent’s full compliance with all conditions of this Decision
18 and Order. If Respondent fails to satisfy any of these conditions, such failure to comply
19 constitutes cause for discipline, including outright revocation, of Respondent’s Pharmacist
20 License No. RPH 30954. If Respondent violates any term and condition of this Decision and
21 Order, all of the charges and allegations contained in Accusation Number 7241 shall be deemed
22 to be true, correct, and admitted by Respondent for purposes of any disciplinary action the Board
23 may take if such occurs.

24 **19. Cost Recovery.** No later than six (6) months from the effective date of the Decision
25 and Order, Respondents shall pay \$10,000 to the Board for its costs associated with the
26 investigation and enforcement of this matter pursuant to Business and Professions Code Section
27 125.3, jointly and severally. If Respondents fail to pay the Board costs as ordered, Respondents
28 shall not be allowed to renew their Original Permit and Pharmacist License until Respondents pay

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

3 **ACCEPTANCE**

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

9

10 DATED: _____
11 P & G PHARMACY INC., DBA SUNSHINE
12 CENTER PHARMACY; THOMAS JOHN
13 GARIBALDI, RPH
14 *Respondents*

15

16 I have read and fully discussed with Respondents P & G Pharmacy Inc., dba Sunshine
17 Center Pharmacy, and Thomas John Garibaldi, the terms and conditions and other matters
18 contained in the above Stipulated Settlement and Disciplinary Order for Public Repeval. I
19 approve its form and content.

20 DATED: _____
21 NATALIA MAZINA
22 *Attorney for Respondents*

23

24

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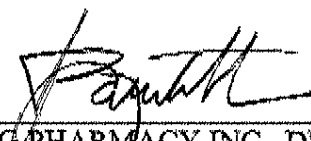
28

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

3 **ACCEPTANCE**

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

9
10 DATED: 03/20/2023



P & G PHARMACY INC., DBA SUNSHINE
CENTER PHARMACY; THOMAS JOHN
GARIBALDI, RPH
Respondents

11
12
13
14 I have read and fully discussed with Respondents P & G Pharmacy Inc., dba Sunshine
15 Center Pharmacy, and Thomas John Garibaldi, the terms and conditions and other matters
16 contained in the above Stipulated Settlement and Disciplinary Order for Public Repeval. I
17 approve its form and content.

18 DATED: March 21, 2023



NATALIA MAZINA
Attorney for Respondents

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ENDORSEMENT

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

DATED: March 24, 2023

Respectfully submitted,

ROB BONTA
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General

Christopher M. Young
CHRISTOPHER M. YOUNG
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 7241

1 ROB BONTA
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2 JOSHUA A. ROOM
Supervising Deputy Attorney General
3 CHRISTOPHER M. YOUNG
Deputy Attorney General
4 State Bar No. 238532
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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:

Case No. 7241

13 **P & G PHARMACY INC., DBA**
14 **SUNSHINE CENTER PHARMACY;**
15 **THOMAS JOHN GARIBALDI**
1166 Mission Rd.,
16 South San Francisco, CA 94080

ACCUSATION

17 **Original Pharmacy Permit No. PHY 46165,**

18 **and**

19 **THOMAS JOHN GARIBALDI**
503 Santa Teresa
20 Millbrae, CA 94030

21 **Registered Pharmacist License No. RPH**
30954

22 Respondents.

23
24 **PARTIES**

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

27 2. On or about June 30, 2003, the Board of Pharmacy issued Original Pharmacy Permit
28 Number PHY 46165 to P & G Pharmacy Inc., dba Sunshine Center Pharmacy; Thomas John

1 Garibaldi (Respondent Pharmacy). The Original Pharmacy Permit was in full force and effect at
2 all times relevant to the charges brought herein and will expire on June 1, 2023, unless renewed.

3 3. On or about July 28, 1977, the Board of Pharmacy issued Registered Pharmacist
4 License Number RPH 30954 to Thomas John Garibaldi (Respondent Garibaldi). The Registered
5 Pharmacist License was in full force and effect at all times relevant to the charges brought herein
6 and will expire on August 31, 2023, unless renewed.

7 JURISDICTION

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

11 5. Code section 4011 provides that the Board shall administer and enforce the Pharmacy
12 Law [Bus. & Prof. Code, § 4000 et seq.]. Further pursuant to Code section 4011, the Board also
13 administers and enforces the Uniform Controlled Substances Act.

14 6. Code section 4300, subdivision (a), provides that every license issued by the Board
15 may be suspended or revoked.

16 7. Code section 4300.1 provides that the expiration, cancellation, forfeiture, suspension,
17 or voluntary surrender of a license “shall not deprive the board of jurisdiction to commence or
18 proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to
19 render a decision suspending or revoking the license.”

20 8. Code section 4307 states:

21 (a) Any person who has been denied a license or whose license has been
22 revoked or is under suspension, or who has failed to renew his or her license while it
23 was under suspension, or who has been a manager, administrator, owner, member,
24 officer, director, associate, partner, or any other person with management or control
25 of any partnership, corporation, trust, firm, or association whose application for a
26 license has been denied or revoked, is under suspension or has been placed on
27 probation, and while acting as the manager, administrator, owner, member, officer,
28 director, associate, partner, or any other person with management or control had
knowledge of or knowingly participated in any conduct for which the license was
denied, revoked, suspended, or placed on probation, shall be prohibited from serving
as a manager, administrator, owner, member, officer, director, associate, partner, or in
any other position with management or control of a licensee as follows:

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

1 five years.

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

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

8 (c) The provisions of subdivision (a) may be alleged in any pleading filed
9 pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of
10 the Government Code. However, no order may be issued in that case except as to a
11 person who is named in the caption, as to whom the pleading alleges the applicability
12 of this section, and where the person has been given notice of the proceeding as
13 required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of
14 the Government Code. The authority to proceed as provided by this subdivision shall
15 be in addition to the board's authority to proceed under Section 4339 or any other
16 provision of law.

17 **STATUTORY PROVISIONS**

18 9. Code section 4059.5 states, in pertinent part:

19 (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous
20 devices may only be ordered by an entity licensed by the board and shall be delivered
21 to the licensed premises and signed for and received by a pharmacist. Where a
22 licensee is permitted to operate through a designated representative, or in the case of a
23 reverse distributor a designated representative-reverse distributor, that individual shall
24 sign for and receive the delivery.

25 ...

26 10. Code section 4113, subdivision (c), states that the "pharmacist-in-charge shall be
27 responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining
28 to the practice of pharmacy."

11 11. Code section 4301 states, in pertinent part:

12 The board shall take action against any holder of a license who is guilty of
13 unprofessional conduct or whose license has been issued by mistake. Unprofessional
14 conduct includes, but is not limited to, any of the following:

15 ...

16 (j) The violation of any of the statutes of this state, of any other state, or of the United
17 States regulating controlled substances and dangerous drugs.

18 ...

19 (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting
20 the violation of or conspiring to violate any provision or term of this chapter or of the

1 applicable federal and state laws and regulations governing pharmacy, including
2 regulations established by the board or by any other state or federal regulatory
3 agency.

4 ...

5 12. Business and Professions Code section 4306.5 states, in pertinent part:

6 Unprofessional conduct for a pharmacist may include any of the following:

7 (a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of
8 his or her education, training, or experience as a pharmacist, whether or not the act or
9 omission arises in the course of the practice of pharmacy or the ownership,
10 management, administration, or operation of a pharmacy or other entity licensed by
11 the board.

12 ...

13 **REGULATORY PROVISIONS**

14 13. California Code of Regulations, title 16, section 1707.5 states, in pertinent part:

15 ...

16 (d) The pharmacy shall have policies and procedures in place to help patients
17 with limited or no English proficiency understand the information on the label as
18 specified in subdivision (a) in the patient's language. The pharmacy's policies and
19 procedures shall be specified in writing and shall include, at minimum, the selected
20 means to identify the patient's language and to provide interpretive services and
21 translation services in the patient's language. The pharmacy shall, at minimum,
22 provide interpretive services in the patient's language, if interpretive services in such
23 language are available, during all hours that the pharmacy is open, either in person by
24 pharmacy staff or by use of a third-party interpretive service available by telephone at
25 or adjacent to the pharmacy counter.

26 ...

27 14. California Code of Regulations, title 16, section 1714 states, in pertinent part:

28 ...

(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures,
and equipment so that drugs are safely and properly prepared, maintained, secured
and distributed. The pharmacy shall be of sufficient size and unobstructed area to
accommodate the safe practice of pharmacy.

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and
orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and
insects, and properly lighted. The pharmacy shall be equipped with a sink with hot
and cold running water for pharmaceutical purposes.

...

///

1 15. California Code of Regulations, title 16, section 1735.2 states, in pertinent part:

2 ...

3 (e) A drug preparation shall not be compounded until the pharmacy has first prepared
4 a written master formula document that includes at least the following elements:

5 (1) Active ingredients to be used.

6 (2) Equipment to be used.

7 (3) The maximum allowable beyond use date for the preparation, and the
8 rationale or reference source justifying its determination.

9 (4) Inactive ingredients to be used.

10 (5) Specific and essential compounding steps used to prepare the drug.

11 (6) Quality reviews required at each step in preparation of the drug.

12 (7) Post-compounding process or procedures required, if any.

13 (8) Instructions for storage and handling of the compounded drug preparation.

14 ...

15 (k) Prior to allowing any drug product preparation to be compounded in a pharmacy,
16 the pharmacist-in-charge shall complete a self-assessment for compounding
17 pharmacies developed by the board (Incorporated by reference is "Community
18 Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form
19 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the
20 California Code of Regulations. That form contains a first section applicable to all
21 compounding, and a second section applicable to sterile injectable compounding. The
22 first section must be completed by the pharmacist-in-charge before any compounding
23 is performed in the pharmacy. The second section must be completed by the
24 pharmacist-in-charge before any sterile compounding is performed in the pharmacy.
25 The applicable sections of the self-assessment shall subsequently be completed before
26 July 1 of each odd-numbered year, within 30 days of the start date of a new
27 pharmacist-in-charge or change of location, and within 30 days of the issuance of a
28 new pharmacy license. The primary purpose of the self-assessment is to promote
compliance through self-examination and education.

...

16. California Code of Regulations, title 16, section 1735.3 states, in pertinent part:

(a) For each compounded drug preparation, pharmacy records shall include:

(1) The master formula document.

(2) A compounding log consisting of a single document containing all of the
following:

(A) Name and Strength of the compounded drug preparation.

1 (B) The date the drug preparation was compounded.

2 (C) The identity of any pharmacy personnel engaged in compounding the
3 drug preparation.

4 (D) The identity of the pharmacist reviewing the final drug preparation.

5 (E) The quantity of each ingredient used in compounding the drug
6 preparation.

7 (F) The manufacturer, expiration date and lot number of each component. If
8 the manufacturer name is demonstrably unavailable, the name of the supplier may
9 be substituted. If the manufacturer does not supply an expiration date for any
10 component, the records shall include the date of receipt of the component in the
11 pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.

12 (i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are
13 sterile preparations compounded in a single lot for administration within
14 seventy-two (72) hours to a patient in a health care facility licensed under
15 section 1250 of the Health and Safety Code and stored in accordance with
16 standards for "Redispensed CSPs" found in Chapter 797 of the United States
17 Pharmacopeia -- National Formulary (USP37-NF32) Through 2nd Supplement
18 (37th Revision, Effective December 1, 2014), hereby incorporated by reference.

19 (G) A pharmacy-assigned unique reference or lot number for the compounded
20 drug preparation.

21 (H) The beyond use date or beyond use date and time of the final compounded
22 drug preparation, expressed in the compounding document in a standard date and
23 time format.

24 (I) The final quantity or amount of drug preparation compounded for
25 dispensing.

26 (J) Documentation of quality reviews and required post-compounding process
27 and procedures.

28 ...

17. California Code of Regulations, title 16, section 1735.5 states:

22 (a) Any pharmacy engaged in compounding shall maintain written policies and
23 procedures for compounding that establishes procurement procedures, methodologies
24 for the formulation and compounding of drugs, facilities and equipment cleaning,
25 maintenance, operation, and other standard operating procedures related to
26 compounding. Any material failure to follow the pharmacy's written policies and
27 procedures shall constitute a basis for disciplinary action.

28 (b) The policies and procedures shall be reviewed and such review shall be
documented on an annual basis by the pharmacist-in-charge. The policies and
procedures shall be updated whenever changes in policies and procedures are
implemented.

(c) The policies and procedures shall include at least the following:

1 (1) Procedures for notifying staff assigned to compounding duties of any
changes in policies or procedures.

2 (2) A written plan for recall of a dispensed compounded drug preparation where
3 subsequent information demonstrates the potential for adverse effects with continued
4 use. The plan shall ensure that all affected doses can be accounted for during the
recall and shall provide steps to identify which patients received the affected lot or
compounded drug preparation(s).

5 (3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting
6 equipment used in compounding, and for training on these procedures as part of the
staff training and competency evaluation process.

7 (4) Procedures for evaluating, maintaining, certifying, cleaning, and
8 disinfecting the facility (physical plant) used for compounding, and for training on
these procedures as part of the staff training and competency evaluation process.

9 (5) Documentation of the methodology used to validate integrity, potency,
10 quality, and labeled strength of compounded drug preparations. The methodology
must be appropriate to compounded drug preparations.

11 (6) Documentation of the methodology and rationale or reference source used
12 to determine appropriate beyond use dates for compounded drug preparations.

13 (7) Dates and signatures reflecting all annual reviews of the policies and
procedures by the pharmacist-in-charge.

14 (8) Dates and signatures accompanying any revisions to the policies and
15 procedures approved by the pharmacist-in-charge.

16 (9) Policies and procedures for storage of compounded drug preparations in the
17 pharmacy and daily documentation of all room, refrigerator, and freezer temperatures
within the pharmacy.

18 (10) Policies and procedures regarding ensuring appropriate functioning of
19 refrigeration devices, monitoring refrigeration device temperatures, and actions to
take regarding any out of range temperature variations within the pharmacy.

20 (11) Policies and procedures for proper garbing when compounding with
hazardous products. This shall include when to utilize double shoe covers.

21
22 18. California Code of Regulations, title 16, section 1735.7 states:

23 (a) A pharmacy engaged in compounding shall maintain documentation
24 demonstrating that personnel involved in compounding have the skills and training
25 required to properly and accurately perform their assigned responsibilities and
26 documentation demonstrating that all personnel involved in compounding are trained
27 in all aspects of policies and procedures. This training shall include but is not limited
to support personnel (e.g. institutional environmental services, housekeeping),
28 maintenance staff, supervising pharmacist and all others whose jobs are related to the
compounding process.

(b) The pharmacy shall develop and maintain an on-going competency evaluation
process for pharmacy personnel involved in compounding, and shall maintain

1 documentation of any and all training related to compounding undertaken by
2 pharmacy personnel.

3 (c) Pharmacy personnel assigned to compounding duties shall demonstrate
4 knowledge about processes and procedures used in compounding prior to
5 compounding any drug preparation.

6 19. California Code of Regulations, title 16, section 1735.8 states:

7 (a) Any pharmacy engaged in compounding shall maintain, as part of its written
8 policies and procedures, a written quality assurance plan designed to monitor and
9 ensure the integrity, potency, quality, and labeled strength of compounded drug
10 preparations.

11 (b) The quality assurance plan shall include written procedures for verification,
12 monitoring, and review of the adequacy of the compounding processes and shall also
13 include written documentation of review of those processes by qualified pharmacy
14 personnel.

15 (c) The quality assurance plan shall include written standards for qualitative and
16 quantitative analysis of compounded drug preparations to ensure integrity, potency,
17 quality, and labeled strength, including the frequency of testing. All qualitative and
18 quantitative analysis reports for compounded drug preparations shall be retained by
19 the pharmacy and maintained along with the compounding log and master formula
20 document. The quality assurance plan shall include a schedule for routine testing and
21 analysis of specified compounded drug preparations to ensure integrity, potency,
22 quality, and labeled strength, on at least an annual basis.

23 (d) The quality assurance plan shall include a written procedure for scheduled action
24 in the event any compounded drug preparation is ever discovered to be outside
25 minimum standards for integrity, potency, quality, or labeled strength.

26 (e) The quality assurance plan shall include a written procedure for responding to out-
27 of-range temperature variations within the pharmacy and within patient care areas of
28 a hospital where furnished drug is returned for redispensing.

...

COST RECOVERY

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

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FACTUAL BACKGROUND

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2 21. A Board inspector conducted an inspection of Respondent Pharmacy, located in
3 South San Francisco, California, on August 24, 2021. The inspection occurred after the Board
4 received information from Amerisource Bergen, a pharmaceutical wholesaler, that dangerous
5 drugs and devices were potentially being signed for and received by non-pharmacist employees at
6 Respondent Pharmacy. Respondent Garibaldi, the Pharmacist in Charge and owner, was present
7 during the August 24, 2021, inspection. Several violations of the Pharmacy Law were found
8 during the inspection, as detailed below in paragraphs 22 through 25.

9 22. Respondent Pharmacy was not in a clean and orderly condition during the inspection.
10 Loose pills were scattered around Respondent Pharmacy, drugs were stored in cabinets along
11 with household items such as plastic sandwich bags, cotton balls, and aluminum foil. The sink at
12 Respondent Pharmacy was not used for pharmaceutical purposes only, as indicated by dish soap,
13 coffee mugs, a hand towel, and a sponge in or near the sink, along with the smell of coffee in the
14 sink. Moreover, at least 22 expired medications were found in the active inventory.

15 23. Respondent Garibaldi did not ensure that interpretive services were available to all
16 customers, and indicated to the Board inspector that he could only provide interpretive services to
17 customers who carried certain insurance plans that would reimburse for interpretive services.

18 24. The inspection revealed that, on at least 160 occasions, someone other than a
19 pharmacist signed for and received dangerous drugs or devices at Respondent Pharmacy.

20 25. Respondent Garibaldi denied that Respondent Pharmacy compounds medications,
21 although Garibaldi conceded at the inspection that he “mixed” creams for a few patients.
22 Respondent Garibaldi was apparently unaware that mixing two or more creams was considered
23 compounding. Respondent Garibaldi provided the Board inspector with the name of one patient,
24 RM, for whom Garibaldi compounded creams, and the inspector determined that, between July 1,
25 2018, and August 30, 2021, Respondent Pharmacy compounded nystatin/triamcinolone cream for
26 RM on at least 16 occasions. Respondent Garibaldi never prepared master formula documents,
27 filled out a Compounding Self-Assessment, or completed and maintained compounding logs for
28 RM’s compounded medications, or any other patient’s compounded medications. Respondent

1 Pharmacy likewise did not maintain compounding policies and procedures, did not have any
2 training records relating to compounding, and did not maintain a written quality assurance plan
3 for compounding. Respondent Pharmacy had no records of testing the compounds it had
4 prepared to ensure integrity, potency, quality, and/or labeled strength on at least an annual basis.

5 **FIRST CAUSE FOR DISCIPLINE**

6 (Respondents Pharmacy and Garibaldi: Operational Standards and Cleanliness)

7 26. Respondents Pharmacy and Garibaldi are subject to disciplinary action under Code
8 section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of
9 Regulations, section 1714, subdivisions (b) and (c), which require that a licensed pharmacy be
10 properly maintained and equipped. As described above in paragraphs 21-22, Respondent
11 Garibaldi failed to ensure Respondent Pharmacy was properly maintained, in that the pharmacy
12 was disorganized, cluttered, failed to have a sink dedicated to pharmaceutical use, and had
13 expired drugs in its active inventory.

14 **SECOND CAUSE FOR DISCIPLINE**

15 (Respondents Pharmacy and Garibaldi: Interpretive Services for All Customers)

16 27. Respondents Pharmacy and Garibaldi are subject to disciplinary action under Code
17 section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of
18 Regulations, section 1707.5, subdivision (d), which requires that a pharmacy have policies and
19 procedures in place to ensure patients with limited English proficiency have access to interpretive
20 services to help understand the information contained on prescription labels. As described above
21 in paragraph 23, Respondents failed to ensure policies were in place providing adequate
22 interpretive services for all customers.

23 **THIRD CAUSE FOR DISCIPLINE**

24 (Respondents Pharmacy and Garibaldi: Receipt of Dangerous Drugs and Devices)

25 28. Respondents Pharmacy and Garibaldi are subject to disciplinary action under Code
26 section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and section 4059.5,
27 subdivision (a), which requires that dangerous drugs and devices shall be signed for and/or
28 received only by a pharmacist. As described above in paragraph 24, Respondents failed to ensure

1 that all deliveries of dangerous drugs and devices were signed for and/or received by a
2 pharmacist.

3 **FOURTH CAUSE FOR DISCIPLINE**

4 (Respondents Pharmacy and Garibaldi: Failure to Follow Compounding Policies and Procedures)

5 29. Respondents Pharmacy and Garibaldi are subject to disciplinary action under Code
6 section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of
7 Regulations, section 1735.5, which requires that any pharmacy engaged in compounding shall
8 maintain written policies and procedures for compounding that cover specified topics pertinent to
9 compounding operations. As described above in paragraph 25, Respondents engaged in
10 compounding medications but failed to ensure that uniform policies and procedures applicable to
11 compounding were instituted at Respondent Pharmacy.

12 **FIFTH CAUSE FOR DISCIPLINE**

13 (Respondents Pharmacy and Garibaldi: Compounding Master Formula Requirements)

14 30. Respondents Pharmacy and Garibaldi are subject to disciplinary action under Code
15 section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of
16 Regulations, section 1735.2, subdivision (e), for failing to complete the required master formula
17 documents for compounded drugs as described above in paragraph 25.

18 **SIXTH CAUSE FOR DISCIPLINE**

19 (Respondents Pharmacy and Garibaldi: Recordkeeping for Compounded Drug Preparations)

20 31. Respondents Pharmacy and Garibaldi are subject to disciplinary action under Code
21 section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of
22 Regulations, section 1735.3, subdivision (a), for maintaining incomplete records of compounded
23 drugs prepared by Respondents as described above in paragraph 25.

24 **SEVENTH CAUSE FOR DISCIPLINE**

25 (Respondents Pharmacy and Garibaldi: Failure to Complete Self-Assessment)

26 32. Respondents Pharmacy and Garibaldi are subject to disciplinary action under Code
27 section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of
28 Regulations, section 1735.2, subdivisions (e) and/or (k), which require that Respondent Garibaldi

1 complete a compounding self-assessment prior to any compounding. The self-assessment was
2 not prepared, as described above in paragraph 25.

3 **EIGHTH CAUSE FOR DISCIPLINE**

4 (Respondents Pharmacy and Garibaldi: Training of Compounding Staff)

5 33. Respondents Pharmacy and Garibaldi are subject to disciplinary action under Code
6 section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of
7 Regulations, section 1735.7, subdivision (b), which requires that a pharmacy conducting
8 compounding have an ongoing competency evaluation process and training for compounding
9 staff. As described above in paragraph 25, Respondents did not have appropriate documentation
10 of ongoing compounding training.

11 **NINTH CAUSE FOR DISCIPLINE**

12 (Respondents Pharmacy and Garibaldi: Compounding Quality Assurance)

13 34. Respondents Pharmacy and Garibaldi are subject to disciplinary action under Code
14 section 4301, subdivisions (j) and/or (o), section 4113, subdivision (c), and California Code of
15 Regulations, section 1735.8, for failing to perform end-product testing of compounded drugs as
16 described above in paragraph 25.

17 **OTHER MATTERS**

18 35. Pursuant to Code section 4307, if discipline is imposed on Respondent Pharmacy
19 License Number PHY 46165, Respondent Pharmacy shall be prohibited from serving as a
20 manager, administrator, owner, member, officer, director, associate, or partner of a licensee for
21 five years if Respondent Pharmacy License Number PHY 46165 is placed on probation, or until
22 reinstatement if Respondent Pharmacy License Number PHY 46165 is revoked.

23 36. Pursuant to Code section 4307, if discipline is imposed on Respondent Pharmacy
24 License Number PHY 46165 issued to Respondent Pharmacy while Respondent Garibaldi was
25 the owner or manager, and had knowledge of or knowingly participated in any conduct for which
26 the licensee was disciplined, Respondent Garibaldi shall be prohibited from serving as a manager,
27 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
28

1 Respondent Pharmacy License Number PHY 46165 is placed on probation, or until reinstatement
2 if Respondent Pharmacy License Number PHY 46165 is revoked.

3 37. Pursuant to Code section 4307, if discipline is imposed on Respondent Garibaldi's
4 Pharmacist License Number RPH 30954, Respondent Garibaldi shall be prohibited from serving
5 as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee
6 for five years if License Number RPH 30954 is placed on probation, or until reinstatement if
7 License Number RPH 30954 is revoked.

8 **PRAYER**

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

11 1. Revoking or suspending Original Pharmacy Permit Number PHY 46165, issued to P
12 & G Pharmacy Inc., dba Sunshine Center Pharmacy (Respondent Pharmacy);

13 2. Revoking or suspending Registered Pharmacist License Number RPH 30954, issued
14 to Thomas John Garibaldi;

15 3. Prohibiting P & G Pharmacy Inc., dba Sunshine Center Pharmacy from serving as a
16 manager, administrator, owner, member, officer, director, associate, or partner of a licensee for
17 five years if Original Pharmacy Permit Number PHY 46165 is placed on probation, or until
18 reinstatement if Original Pharmacy Permit Number PHY 46165 is revoked.

19 4. Prohibiting Thomas John Garibaldi from serving as a manager, administrator, owner,
20 member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy
21 Permit Number PHY 46165 is placed on probation, or until reinstatement if Original Pharmacy
22 Permit Number PHY 46165 is revoked.

23 5. Prohibiting Thomas John Garibaldi from serving as a manager, administrator, owner,
24 member, officer, director, associate, or partner of a licensee for five years if Pharmacist License
25 Number RPH 30954 is placed on probation, or until reinstatement if Pharmacist License Number
26 RPH 30954 is revoked.

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6. Ordering Respondent Pharmacy and Respondent Garibaldi 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,

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

DATED: 8/31/2022

Signature on File
ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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