

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

In the Matter of the Accusation Against:

**JOHN VINCENT CASTALDO
19958 Chaparral Circle
Penn Valley, California 95946**

**Original Pharmacist License No. RPH
31324,**

Case No. 5605
OAH No. 2016050394

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER**

Respondent.

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on December 22, 2016.

It is so ORDERED on November 22, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

1 KAMALA D. HARRIS
Attorney General of California
2 DIANN SOKOLOFF
Supervising Deputy Attorney General
3 GREGORY TUSS
Deputy Attorney General
4 State Bar No. 200659
1515 Clay Street, 20th Floor
5 P.O. Box 70550
Oakland, CA 94612-0550
6 Telephone: (510) 622-2143
Facsimile: (510) 622-2270
7 *Attorneys for Complainant*

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 **JOHN VINCENT CASTALDO**
19958 Chaparral Circle
Penn Valley, California 95946

14 **Original Pharmacist License No. RPH**
15 **31324,**

16 Respondent.

Case No. 5605
OAH No. 2016050394

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER

17
18 IT IS STIPULATED AND AGREED by and between the parties to the above-entitled
19 proceedings that the following matters are true:

20 **PARTIES**

21 1. Complainant Virginia Herold is the Executive Officer of the Board of Pharmacy
22 (board), Department of Consumer Affairs. She brought this action solely in her official capacity
23 and is represented in this matter by Kamala D. Harris, Attorney General of the State of California,
24 and by Gregory Tuss, Deputy Attorney General.

25 2. Respondent John Vincent Castaldo is represented in this proceeding by attorney Craig
26 O'Loughlin, whose address is Two North Central Avenue, Phoenix, AZ 85004

27 3. On August 8, 1977, the board issued Original Pharmacist License No. RPH 31324 to
28 respondent. This original pharmacist license was in full force and effect at all times relevant to

1 the charges brought in this accusation and will expire on December 31, 2016, unless renewed.

2 **JURISDICTION**

3 4. Accusation No. 5605 was filed before the board and is currently pending against
4 respondent. The accusation and all other statutorily required documents were properly served on
5 respondent on January 21, 2016. Respondent timely filed his notice of defense contesting the
6 accusation.

7 5. A copy of Accusation No. 5605 is attached as exhibit 1 and incorporated by
8 reference.

9 **ADVISEMENT AND WAIVERS**

10 6. Respondent has carefully read, fully discussed with counsel, and understands the
11 charges and allegations in Accusation No. 5605. Respondent has also carefully read, fully
12 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
13 Order.

14 7. Respondent is fully aware of his legal rights in this matter, including the right to a
15 hearing on the charges and allegations in the accusation; the right to confront and cross-examine
16 the witnesses against him; the right to present evidence and to testify on his own behalf; the right
17 to the issuance of subpoenas to compel the attendance of witnesses and the production of
18 documents; the right to reconsideration and court review of an adverse decision; and all other
19 rights accorded by the California Administrative Procedure Act and other applicable laws.

20 8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and
21 every right set forth above.

22 **CULPABILITY**

23 9. Respondent admits the truth of each and every charge and allegation in Accusation
24 No. 5605.

25 10. Respondent agrees that his Original Pharmacist License No. RPH 31324 is subject to
26 discipline and it agrees to be bound by the board's probationary terms as set forth in the
27 Disciplinary Order below.

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

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

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

2. Report to the Board

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

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

///

4. Cooperate with Board Staff

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

5. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in Accusation No. 5605 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause their direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in Accusation No. 5605, and terms and conditions imposed by it. It shall be respondent's responsibility to ensure that their employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify their direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in Accusation No. 5605 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause their direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that they has read the decision in case number 5605 and the terms and conditions imposed by it. It shall be respondent's responsibility to ensure that

1 his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

2 Failure to timely notify present or prospective employer(s) or to cause that/those
3 employer(s) to submit timely acknowledgments to the board shall be considered a violation of
4 probation.

5 "Employment" within the meaning of this provision shall include any full-time, part-time,
6 temporary, relief or pharmacy management service as a pharmacist or any position for which a
7 pharmacist license is a requirement or criterion for employment, whether the respondent is an
8 employee, independent contractor or volunteer.

9 **7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as**
10 **Designated Representative-in-Charge, or Serving as a Consultant**

11 During the period of probation, respondent shall not supervise any intern pharmacist, be the
12 pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board,
13 nor serve as a consultant unless otherwise specified in this order. Assumption of any such
14 unauthorized supervision responsibilities shall be considered a violation of probation.

15 **8. Reimbursement of Board Costs**

16 As a condition precedent to successful completion of probation, respondent shall pay to the
17 board its costs of investigation and prosecution in the amount of \$10,766.75. Respondent is
18 responsible for these costs jointly and severally with respondents Safeway, Inc., Karen Lyn Muir,
19 and Christine Moheb Stephanos who are also named in Accusation No. 5605. Respondent shall
20 be permitted to pay these costs in a payment plan approved by the board or its designee, with
21 payments to be completed no later than one month prior to the end of the probation term.

22 There shall be no deviation from this schedule absent prior written approval by the board or
23 its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of
24 probation.

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

27 **9. Probation Monitoring Costs**

28 Respondent shall pay any costs associated with probation monitoring as determined by the

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

10. Status of License

Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

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

11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board. Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

12. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. This notification shall include the reasons for leaving, the address of the new

1 employer, the name of the supervisor and owner, and the work schedule if known. Respondent
2 shall further notify the board in writing within ten (10) days of a change in name, residence
3 address, mailing address, or phone number.

4 Failure to timely notify the board of any change in employer(s), name(s), address(es), or
5 phone number(s) shall be considered a violation of probation.

6 **13. Tolling of Probation**

7 Except during periods of suspension, respondent shall, at all times while on probation, be
8 employed as a pharmacist in California for a minimum of 30 hours per calendar month. Any
9 month during which this minimum is not met shall toll the period of probation, i.e., the period of
10 probation shall be extended by one month for each month during which this minimum is not met.
11 During any such period of tolling of probation, respondent must nonetheless comply with all
12 terms and conditions of probation.

13 Should respondent, regardless of residency, for any reason (including vacation) cease
14 practicing as a pharmacist for a minimum of 30 hours per calendar month in California,
15 respondent must notify the board in writing within ten (10) days of the cessation of practice, and
16 must further notify the board in writing within ten (10) days of the resumption of practice. Any
17 failure to provide such notification(s) shall be considered a violation of probation.

18 It is a violation of probation for respondent's probation to remain tolled pursuant to the
19 provisions of this condition for a total period, counting consecutive and non-consecutive months,
20 exceeding thirty-six (36) months.

21 "Cessation of practice" means any calendar month during which respondent is not
22 practicing as a pharmacist for at least 30 hours, as defined by Business and Professions Code
23 section 4000 et seq. "Resumption of practice" means any calendar month during which
24 respondent is practicing as a pharmacist for at least 30 hours as a pharmacist as defined by
25 Business and Professions Code section 4000 et seq.

26 **14. Violation of Probation**

27 If respondent has not complied with any term or condition of probation, the board shall
28 have continuing jurisdiction over respondent and probation shall automatically be extended until

1 all terms and conditions have been satisfied or the board has taken other action as deemed
2 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and
3 to impose the penalty that was stayed.

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

11 **15. Completion of Probation**

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

14 **16. Remedial Education**

15 Within sixty (60) days of the effective date of this decision, respondent shall submit to the
16 board or its designee, for prior approval, an appropriate program of remedial education related to
17 compounding. The program of remedial education shall consist of at least 10 hours, which shall
18 be completed within 18 months at respondent's own expense. All remedial education shall be in
19 addition to, and shall not be credited toward, continuing education (CE) courses used for license
20 renewal purposes.

21 Failure to timely submit or complete the approved remedial education shall be considered a
22 violation of probation. The period of probation will be automatically extended until such
23 remedial education is successfully completed and written proof, in a form acceptable to the board,
24 is provided to the board or its designee.

25 Following the completion of each course, the board or its designee may require the
26 respondent, at their own expense, to take an approved examination to test the respondent's
27 knowledge of the course. If the respondent does not achieve a passing score on the examination,
28 this failure shall be considered a violation of probation. Any such examination failure shall

1 require respondent to take another course approved by the board in the same subject area.

2 **ACCEPTANCE**

3 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
4 discussed it with my attorney, Craig O'Loughlin. I understand the stipulation and the effect it will
5 have on my Original Pharmacist License No. RPH 31324. I enter into this Stipulated Settlement
6 and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the
7 Decision and Order of the Board of Pharmacy.

8
9 DATED: _____

10 **JOHN VINCENT CASTALDO**
Respondent

11 I have read and fully discussed with respondent John Vincent Castaldo the terms and
12 conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.
13 I approve its form and content.

14 DATED: _____

15 **CRAIG O'LOUGHLIN**
Attorney for Respondent

16
17 **ENDORSEMENT**

18 This Stipulated Settlement and Disciplinary Order is submitted for consideration by the
19 Board of Pharmacy.

20
21 Dated:

Respectfully submitted,

22 **KAMALA D. HARRIS**
Attorney General of California
23 **DIANN SOKOLOFF**
Supervising Deputy Attorney General

24
25 **GREGORY TUSS**
Deputy Attorney General
26 *Attorneys for Complainant*

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28 Castaldo Settlement.doc

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2 renewal purposes.

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4 violation of probation. The period of probation will be automatically extended until such
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6 is provided to the board or its designee.

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8 respondent, at their own expense, to take an approved examination to test the respondent's
9 knowledge of the course. If the respondent does not achieve a passing score on the examination,
10 this failure shall be considered a violation of probation. Any such examination failure shall
11 require respondent to take another course approved by the board in the same subject area.

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14 discussed it with my attorney, Craig O'Loughlin. I understand the stipulation and the effect it will
15 have on my Original Pharmacist License No. RPH 31324. I enter into this Stipulated Settlement
16 and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the
17 Decision and Order of the Board of Pharmacy.

18
19 DATED: 10/17/16


20 JOHN VINCENT CASTALDO
Respondent

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22 conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.
23 I approve its form and content.

24 DATED: 10/17/16


25 CRAIG O'LOUGHLIN
Attorney for Respondent

26 ///

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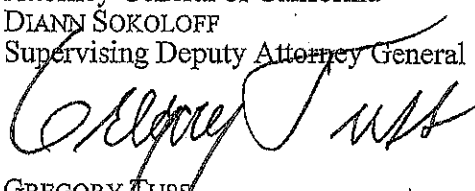
ENDORSEMENT

This Stipulated Settlement and Disciplinary Order is submitted for consideration by the Board of Pharmacy.

Dated: 10.17.16

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
DIANN SOKOLOFF
Supervising Deputy Attorney General


GREGORY TUSS
Deputy Attorney General
Attorneys for Complainant

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Exhibit 1

Accusation No. 5605

1 KAMALA D. HARRIS
Attorney General of California
2 DIANN SOKOLOFF
Supervising Deputy Attorney General
3 GREGORY TUSS
Deputy Attorney General
4 State Bar No. 200659
1515 Clay Street, 20th Floor
5 Post Office Box 70550
Oakland, California 94612-0550
6 Telephone: (510) 622-2143
Facsimile: (510) 622-2270
7 *Attorneys for Complainant*

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

11 In the Matter of the Accusation Against:

Case No. 5605

12 **SAFEWAY PHARMACY INC.**
d.b.a. Safeway Pharmacy #4905
13 6100 Hellyer Avenue, Suite 100
San Jose, California 95138

ACCUSATION

14 Original Permit No. PHY 52537
15 Original Permit No. PHY 53416,

16 **SAFEWAY PHARMACY INC.**
d.b.a. Safeway Pharmacy #4526
17 255 Second Street
Los Altos, California 94022

18 Original Permit No. PHY 51192,

19 **JOHN VINCENT CASTALDO**
20 23750 Hutchinson Road
Los Gatos, California 95033

21 Original Pharmacist License No. RPH 31324,

22 **KAREN LYN MUIR**
23 156 Dunsmuir Way
Menlo Park, California 94025

24 Original Pharmacist License No. RPH 39228,

25 and
26
27
28

1 **CHRISTINE MOHEB STEPHANOS**
2 **1845 Orangetree Lane**
3 **Mountain View, California 94040**

4 **Original Pharmacist License No. RPH 61981,**
5
6 **Respondents.**

7 Complainant Virginia Herold alleges:

8 **I. PARTIES**

9 1. Complainant brings this accusation solely in her official capacity as the Executive
10 Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

11 2. On December 3, 2014, the Board issued Original Permit No. PHY 52537 to
12 respondent Safeway Pharmacy Inc. (Safeway), d.b.a. Safeway Pharmacy #4905. Original Permit
13 No. PHY 52537 was cancelled on March 6, 2015. On February 27, 2015, the Board issued
14 Original Permit No. PHY 53416 to respondent Safeway Pharmacy #4905. Original Permit No.
15 PHY 53416 will expire on January 1, 2016, unless renewed.

16 3. On December 13, 2012, the Board issued Original Permit No. PHY 51192 to
17 respondent Safeway, d.b.a. Safeway Pharmacy #4526. Original Permit No. PHY 51192 was
18 cancelled on January 9, 2015.

19 4. On August 8, 1977, the Board issued Original Pharmacist License No. RPH 31324
20 to respondent John Vincent Castaldo. This original pharmacist license was in full force and effect
21 at all times relevant to the charges brought in this accusation and will expire on December 31,
22 2016, unless renewed.

23 5. On March 14, 1985, the Board issued Original Pharmacist License No.
24 RPH 39228 to respondent Karen Lyn Muir. This original pharmacist license was in full force and
25 effect at all times relevant to the charges brought in this accusation and will expire on April 30,
26 2016, unless renewed.

27 6. On November 20, 2008, the Board issued Original Pharmacist License No. RPH
28 61981 to respondent Christine Moheb Stephanos. This original pharmacist license was in full
force and effect at all times relevant to the charges brought in this accusation and will expire on

1 January 31, 2016, unless renewed.

2 II. JURISDICTION

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

5 8. Section 4300 states in part:

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

7 "(b) The board shall discipline the holder of any license issued by the board, whose
8 default has been entered or whose case has been heard by the board and found guilty, by any of
9 the following methods:

10 "(1) Suspending judgment.

11 "(2) Placing him or her upon probation.

12 "(3) Suspending his or her right to practice for a period not exceeding one year.

13 "(4) Revoking his or her license.

14 "(5) Taking any other action in relation to disciplining him or her as the board in its
15 discretion may deem proper."

16 9. Section 4300.1 states:

17 "The expiration, cancellation, forfeiture, or suspension of a board-issued license by
18 operation of law or by order or decision of the board or a court of law, the placement of a license
19 on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board
20 of jurisdiction to commence or proceed with any investigation of, or action or disciplinary
21 proceeding against, the licensee or to render a decision suspending or revoking the license."

22 10. Section 4304 states:

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

26 III. STATUTORY AND REGULATORY PROVISIONS

27 11. Section 4169, subdivision (a), states in part:

28 "A person or entity shall not do any of the following:

1 ...
2 "(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably
3 should have known were misbranded, as defined in Section 111335 of the Health and Safety
4 Code."

5 12. Section 4301 states in part:

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

10 ...
11 "(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the
12 violation of or conspiring to violate any provision or term of this chapter or of the applicable
13 federal and state laws and regulations governing pharmacy, including regulations established by
14 the board or by any other state or federal regulatory agency."

15 13. Section 4306.5 states in part:

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

17 ...
18 "(b) Acts or omissions that involve, in whole or in part, the failure to exercise or
19 implement his or her best professional judgment or corresponding responsibility with regard to
20 the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or
21 with regard to the provision of services."

22 14. Health and Safety Code section 111335 states:

23 "Any drug or device is misbranded if its labeling or packaging does not conform to the
24 requirements of Chapter 4 (commencing with Section 110290)."

25 15. Health and Safety Code section 111397 subdivision (a), states:

26 "Any foreign dangerous drug that is not approved by the United States Food and Drug
27 Administration or that is obtained outside of the licensed supply chain regulated by the United
28 States Food and Drug Administration, California State Board of Pharmacy, or State Department

1 of Public Health is misbranded."

2 16. Health and Safety Code section 111400 states:

3 "Any drug or device is misbranded if it is dangerous to health when used in the dosage, or
4 with the frequency or duration prescribed, recommended, or suggested in its labeling."

5 17. Health and Safety Code section 111440 states:

6 "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug
7 or device that is misbranded."

8 18. California Code of Regulations, title 16, section 1735.3, subdivision (a), states in
9 part:

10 "For each compounded drug product, the pharmacy records shall include:

11 ...

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

13 IV. COST RECOVERY

14 19. Section 125.3, subdivision (a), states:

15 "Except as otherwise provided by law, in any order issued in resolution of a disciplinary
16 proceeding before any board within the department or before the Osteopathic Medical Board,
17 upon request of the entity bringing the proceedings, the administrative law judge may direct a
18 licensee found to have committed a violation or violations of the licensing act to pay a sum not
19 to exceed the reasonable costs of the investigation and enforcement of the case."

20 V. DRUGS

21 20. Domperidone is an anti-dopaminergic drug which acts as an antiemetic and
22 prokinetic agent. It is used relieve nausea and vomiting, and to increase lactation. It is a
23 dangerous drug under Business and Professions Code section 4022. Although the United States
24 Food and Drug Administration (FDA) may approve an application to use domperidone as an
25 investigational new drug in treating various gastrointestinal conditions, the use of domperidone is
26 not approved in the United States for any indication. The FDA has determined that any products
27 containing domperidone are unapproved new drugs and misbranded. Consequently, any product
28 containing domperidone violates the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et

1 seq.).

2 VI. FACTUAL BACKGROUND

3 21. On April 8, 2015, the Board inspected respondent Safeway at its present address of
4 record. The inspectors found a 500 gram bulk powder container of domperidone with an
5 expiration date of January 30, 2018. The container stated "NOT FOR HUMAN USE NOT FOR
6 US[E] IN FOOD[-]PRODUCING ANIMALS." Respondent Castaldo, the pharmacist-in-charge
7 at respondent Safeway, said that Safeway had been compounding domperidone. He said that the
8 domperidone manufacturer told him that the FDA told the manufacturer to put the warning on the
9 label but it is safe to use on humans. Respondent Castaldo told the inspectors that the
10 Professional Compounding Centers of America said to keep compounding with domperidone
11 until "somebody shuts you down." He said that nevertheless respondent Safeway had stopped
12 compounding domperidone about a month before the inspection. The inspectors embargoed the
13 domperidone.

14 22. Worksheets show the following instances of domperidone compounding at
15 respondent Safeway. All worksheets list respondent Castaldo as the pharmacist.

- | | | | |
|----|-------------|-------------------|---------------------------------|
| 16 | a) 7/21/14 | 600 10mg capsules | Checked by Muir |
| 17 | b) 10/8/14 | 300 30mg capsules | Checked by Muir |
| 18 | c) 10/27/14 | 300 10mg capsules | Checked by Castaldo |
| 19 | d) 11/13/14 | 300 10mg capsules | Checked by Muir |
| 20 | e) 12/11/14 | 300 10mg capsules | Checked by [unknown] |
| 21 | f) 1/12/15 | 300 10mg capsules | Checked by [blank] |
| 22 | g) 2/6/15 | 300 20mg capsules | Checked by [blank] |
| 23 | h) 2/18/15 | 300 10mg capsules | Checked by [blank] |
| 24 | i) 3/4/15 | 300 20mg capsules | Checked by [blank] ¹ |

25 23. Pharmacy records show respondent Safeway dispensed approximately 423
26 prescriptions for domperidone totaling approximately 45,898 capsules ranging from 5mg to

27 ¹ Instances a) through e) are attributable to respondent Safeway PHY 51192, f)
28 through h) to respondent Safeway PHY 52537, and i) to respondent Safeway PHY 53416.

1 40mg. Approximately 374 of these prescriptions totaling approximately 28,693 capsules were
2 dispensed by respondent Safeway PHY 51192, approximately 39 prescriptions totaling
3 approximately 16,263 capsules by respondent Safeway PHY 52537, and approximately 10
4 prescriptions totaling approximately 942 capsules by respondent Safeway PHY 53416.

5 24. Respondent Castaldo dispensed and verified approximately 190 prescriptions for
6 domperidone totaling approximately 21,360 capsules. Respondent Muir dispensed and verified
7 approximately 161 prescriptions totaling approximately 16,813 capsules. Respondent Stephanos
8 dispensed and verified 72 prescriptions totaling approximately 7,725 capsules.

9 **VII. CAUSES FOR DISCIPLINE**

10 **A. Safeway PHY 51192**

11 **First Cause for Discipline**
12 **Unprofessional Conduct – Manufacturing Misbranded Drugs**
13 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
14 **Health and Safety Code section 111440**

15 25. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
16 if fully set forth.

17 26. Respondent Safeway has subjected its Original Permit No. PHY 51192 to
18 discipline for the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code,
19 §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Approximately 28,693
20 domperidone capsules were compounded at respondent Safeway PHY 51192.

21 **Second Cause for Discipline**
22 **Unprofessional Conduct – Selling, Transferring, and Delivering Misbranded Drugs**
23 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
24 **Health and Safety Code section 111440**

25 27. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
26 if fully set forth.

27 28. Respondent Safeway has subjected its Original Permit No. PHY 51192 to
28 discipline for the unprofessional conduct of selling, transferring, and delivering misbranded drugs
(Bus. & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440).
Respondent Safeway PHY 51192 dispensed approximately 374 prescriptions for domperidone

1 totaling approximately 28,693 capsules.

2 **B. Safeway PHY 52537**

3 **Third Cause for Discipline**
4 **Unprofessional Conduct – Manufacturing Misbranded Drugs**
5 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
6 **Health and Safety Code section 111440**

7 29. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
8 if fully set forth.

9 30. Respondent Safeway has subjected its Original Permit No. PHY 52537 to
10 discipline for the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code,
11 §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Approximately 16,263
12 domperidone capsules were compounded at respondent Safeway PHY 52537.

13 **Fourth Cause for Discipline**
14 **Unprofessional Conduct – Selling, Transferring, and Delivering Misbranded Drugs**
15 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
16 **Health and Safety Code section 111440**

17 31. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
18 if fully set forth.

19 32. Respondent Safeway has subjected its Original Permit No. PHY 52537 to
20 discipline for the unprofessional conduct of selling, transferring, and delivering misbranded drugs
21 (Bus. & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440).
22 Respondent Safeway PHY 52537 dispensed approximately 39 prescriptions for domperidone
23 totaling approximately 16,263 capsules.

24 **C. Safeway PHY 53416**

25 **Fifth Cause for Discipline**
26 **Unprofessional Conduct – Manufacturing Misbranded Drugs**
27 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
28 **Health and Safety Code section 111440**

33. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
if fully set forth.

34. Respondent Safeway has subjected its Original Permit No. PHY 53416 to

1 discipline for the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code,
2 §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Approximately 942
3 domperidone capsules were compounded at respondent Safeway PHY 53416.

4 **Sixth Cause for Discipline**
5 **Unprofessional Conduct – Selling, Transferring, and Delivering Misbranded Drugs**
6 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
7 **Health and Safety Code section 111440**

8 35. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
9 if fully set forth.

10 36. Respondent Safeway has subjected its Original Permit No. PHY 53416 to
11 discipline for the unprofessional conduct of selling, transferring, and delivering misbranded drugs
12 (Bus. & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440).
13 Respondent Safeway PHY 53416 dispensed approximately 10 prescriptions for domperidone
14 totaling approximately 942 capsules.

15 **D. Castaldo**

16 **Seventh Cause for Discipline**
17 **Unprofessional Conduct – Manufacturing Misbranded Drugs**
18 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
19 **Health and Safety Code section 111440**

20 37. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
21 if fully set forth.

22 38. Respondent Castaldo has subjected his original pharmacist license to discipline for
23 the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code, §§ 4301,
24 subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Respondent compounded
25 domperidone.

26 **Eighth Cause for Discipline**
27 **Unprofessional Conduct – Selling, Transferring, and Delivering Misbranded Drugs**
28 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
29 **Health and Safety Code section 111440**

30 39. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
31 if fully set forth.

1 40. Respondent Castaldo has subjected his original pharmacist license to discipline for
2 the unprofessional conduct of selling, transferring, and delivering misbranded drugs (Bus. & Prof.
3 Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Respondent
4 Castaldo dispensed and verified approximately 190 prescriptions for domperidone totaling
5 approximately 21,360 capsules.

6 **Ninth Cause for Discipline**
7 **Unprofessional Conduct – Failure to Exercise or Implement Best Professional Judgment or**
8 **Corresponding Responsibility**
 Business and Professions Code sections 4301, 4306.5, subdivision (b)

9 41. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
10 if fully set forth.

11 42. Respondent Castaldo has subjected his original pharmacist license to discipline for
12 the unprofessional conduct of failing to exercise or implement his best professional judgment or
13 corresponding responsibility with regard to the dispensing or furnishing of dangerous drugs (Bus.
14 & Prof. Code, §§ 4301, 4306.5, subd. (b)). Respondent compounded, dispensed, and verified
15 prescriptions for domperidone.

16 **Tenth Cause for Discipline**
17 **Unprofessional Conduct – Failure to Identify Identity of Reviewing Pharmacist**
18 **Business and Professions Code section 4301, subdivision (o),**
 California Code of Regulations, title 16, section 1735.3, subdivision (a)

19 43. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
20 if fully set forth.

21 44. Respondent Castaldo has subjected his original pharmacist license to discipline for
22 the unprofessional conduct of failing to identify the pharmacist reviewing the final drug product
23 (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.3, subd. (a)). Respondent
24 Castaldo was the pharmacist-in-charge at respondent Safeway. Four compounding worksheets
25 for domperidone did not include the identity of the pharmacist who reviewed the final drug
26 product.

27 ///

E. Muir

**Eleventh Cause for Discipline
Unprofessional Conduct – Manufacturing Misbranded Drugs
Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),
Health and Safety Code section 111440**

45. The allegations of paragraphs 20-24 are realleged and incorporated by reference as if fully set forth.

46. Respondent Muir has subjected her original pharmacist license to discipline for the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Respondent compounded domperidone.

**Twelfth Cause for Discipline
Unprofessional Conduct – Selling, Transferring, and Delivering Misbranded Drugs
Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),
Health and Safety Code section 111440**

47. The allegations of paragraphs 20-24 are realleged and incorporated by reference as if fully set forth.

48. Respondent Muir has subjected her original pharmacist license to discipline for the unprofessional conduct of selling, transferring, and delivering misbranded drugs (Bus. & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Respondent Muir dispensed and verified approximately 161 prescriptions for domperidone totaling approximately 16,813 capsules.

**Thirteenth Cause for Discipline
Unprofessional Conduct – Failure to Exercise or Implement Best Professional Judgment or
Corresponding Responsibility
Business and Professions Code sections 4301, 4306.5, subdivision (b)**

49. The allegations of paragraphs 20-24 are realleged and incorporated by reference as if fully set forth.

50. Respondent Muir has subjected her original pharmacist license to discipline for the unprofessional conduct of failing to exercise or implement her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of dangerous drugs (Bus. & Prof. Code, §§ 4301, 4306.5, subd. (b)). Respondent compounded, dispensed, and verified

1 prescriptions for domperidone.

2 **F. Stephanos**

3 **Fourteenth Cause for Discipline**
4 **Unprofessional Conduct – Selling, Transferring, and Delivering Misbranded Drugs**
5 **Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),**
6 **Health and Safety Code section 111440**

7 51. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
8 if fully set forth.

9 52. Respondent Stephanos has subjected her original pharmacist license to discipline
10 for the unprofessional conduct of selling, transferring, and delivering misbranded drugs (Bus. &
11 Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Respondent
12 Stephanos dispensed and verified 72 prescriptions for domperidone totaling approximately 7,725
13 capsules.

14 **Thirteenth Cause for Discipline**
15 **Unprofessional Conduct – Failure to Exercise or Implement Best Professional Judgment or**
16 **Corresponding Responsibility**
17 **Business and Professions Code sections 4301, 4306.5, subdivision (b)**

18 53. The allegations of paragraphs 20-24 are realleged and incorporated by reference as
19 if fully set forth.

20 54. Respondent Stephanos has subjected her original pharmacist license to discipline
21 for the unprofessional conduct of failing to exercise or implement her best professional judgment
22 or corresponding responsibility with regard to the dispensing or furnishing of dangerous drugs
23 (Bus. & Prof. Code, §§ 4301, 4306.5, subd. (b)). Respondent dispensed and verified prescriptions
24 for domperidone.

25 **VIII. OTHER DISCIPLINARY CONSIDERATIONS**

26 55. To determine the degree of discipline, if any, to be imposed on Original Permit
27 No. PHY 51192 issued to respondent Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4626,
28 complainant alleges that on February 18, 2014, the Board issued Citation No. CI 2013 60059
against Original Permit No. PHY 51192 issued to respondent Safeway Pharmacy Inc., d.b.a.
Safeway Pharmacy #4626. The citation assessed a civil penalty of \$1,000 against respondent

1 Safeway for not maintaining its location so that drugs are properly maintained, secured, and
2 distributed (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1714, subd. (b)). An
3 audit revealed losses of over 5,000 tablets of oxycodone. On March 3, 2014, respondent Safeway
4 appealed the citation. Respondent Safeway withdrew its request for appeal on August 19, 2015,
5 and paid the citation.

6 56. To determine the degree of discipline, if any, to be imposed on Original
7 Pharmacist License No. RPH 31324 issued to respondent John Vincent Castaldo, complainant
8 alleges that on February 18, 2014, the Board issued Citation No. CI 2013 60060 against
9 respondent Castaldo's original pharmacist license. The citation assessed a civil penalty of \$1,000
10 for not effectively controlling against theft or diversion of dangerous drugs, and the records for
11 those drugs, as the pharmacist-in-charge (Cal. Code Regs., tit. 16, § 1714, subd. (d)). An audit
12 revealed losses of over 5,000 tablets of oxycodone. On March 3, 2014, respondent Castaldo
13 appealed the citation. Respondent Castaldo withdrew his request for appeal on August 14, 2015,
14 and paid the citation.

15 IX. PRAYER

16 WHEREFORE, complainant requests that a hearing be held on the matters alleged in this
17 accusation, and that following the hearing, the Board of Pharmacy issues a decision:

18 1. Revoking or suspending Original Permit No. PHY 52537 issued to respondent
19 Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4905;

20 2. Revoking or suspending Original Permit No. PHY 53416 issued to respondent
21 Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4905;

22 3. Revoking or suspending Original Permit No. PHY 51192 issued to respondent
23 Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4626;

24 4. Revoking or suspending Original Pharmacist License No. RPH 31324 issued to
25 respondent John Vincent Castaldo;

26 5. Revoking or suspending Original Pharmacist License No. RPH 39228 issued to
27 respondent Karen Lyn Muir;

28 6. Revoking or suspending Original Pharmacist License No. RPH 61981 issued to

respondent Christine Moheb Stephanos;

7. Ordering respondent Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4905, under Business and Professions Code section 125.3 to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case;

8. Ordering respondent Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4626, under Business and Professions Code section 125.3 to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case;

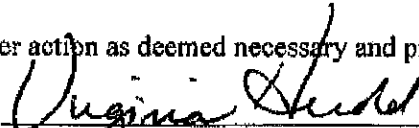
9. Ordering respondent John Vincent Castaldo under Business and Professions Code section 125.3 to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case;

10. Ordering respondent Karen Lyn Muir under Business and Professions Code section 125.3 to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case;

11. Ordering respondent Christine Moheb Stephanos under Business and Professions Code section 125.3 to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case; and

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

DATED: 12/22/15


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

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