

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

In the Matter of the Accusation Against:

**SAFeway PHARMACY INC.¹
d.b.a Safeway Pharmacy #4905
6100 Hellyer Avenue, Suite 100
San Jose, California 95138**

Original Permit No. PHY 53416,

Respondent.

Case No. 5605
OAH No. 2016050394

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 The accusation is against "Safeway Pharmacy Inc."; however, the incorporated entity is "Safeway Inc."

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

11 In the Matter of the Accusation Against:

12 **SAFeway PHARMACY INC.¹**
13 **d.b.a. Safeway Pharmacy #4905**
14 **6100 Hellyer Avenue, Suite 100**
15 **San Jose, California 95138**

16 **Original Permit No. PHY 53416,**

17 **Respondent.**

Case No. 5605
OAH No. 2016050394

18 **STIPULATED SETTLEMENT AND**
19 **DISCIPLINARY ORDER**

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

22 **PARTIES**

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

27 2. Respondent Safeway Inc., d.b.a. Safeway Pharmacy #4905, is represented in this
28 proceeding by attorney Craig O'Loughlin and Alissa Brice Castaneda, whose address is Two

¹ The accusation is against "Safeway Pharmacy Inc."; however, the incorporated entity is "Safeway Inc." This Stipulated Settlement will use the correct name "Safeway Inc."

1 North Central Avenue, Phoenix, AZ 95004.

2 3. On February 27, 2015, the board issued Original Permit No. PHY 53416 to
3 respondent Safeway Inc., d.b.a. Safeway Pharmacy #4905. This original permit will expire on
4 January 1, 2017, unless renewed.

5 JURISDICTION

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

10 5. A copy of Accusation No. 5605 is attached as exhibit I and incorporated by
11 reference.

12 ADVISEMENT AND WAIVERS

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

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

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

25 CULPABILITY

26 9. Respondent understands and agrees that the charges and allegations in Accusation
27 No. 5605, if proven at a hearing, constitute cause for imposing discipline upon its Original Permit
28 No. PHY 53416.

1 10. For the purpose of resolving the accusation without the expense and uncertainty of
2 further proceedings, respondent agrees that, at a hearing, complainant could establish a factual
3 basis for the charges in the accusation, and that respondent gives up its right to contest those
4 charges.

5 11. Respondent agrees that its Original Permit No. PHY 53416 is subject to discipline
6 and it agrees to be bound by the board's probationary terms as set forth in the Disciplinary Order
7 below.

8 **RESERVATION**

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

13 **CONTINGENCY**

14 13. This stipulation shall be subject to approval by the board. Respondent understands
15 and agrees that counsel for complainant and the staff of the board may communicate directly with
16 the board regarding this stipulation and settlement, without notice to or participation by
17 respondent or its counsel. By signing the stipulation, respondent understands and agrees that it
18 may not withdraw its agreement or seek to rescind the stipulation prior to the time the board
19 considers and acts upon it. If the board fails to adopt this stipulation as its Decision and Order,
20 the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this
21 paragraph; it shall be inadmissible in any legal action between the parties; and the board shall not
22 be disqualified from further action by having considered this matter.

23 14. The parties understand and agree that portable document format (PDF) and facsimile
24 copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile
25 signatures, shall have the same force and effect as the originals.

26 15. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an
27 integrated writing representing the complete, final, and exclusive embodiment of their agreement.
28 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,

1 negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary
2 Order may not be altered, amended, modified, supplemented, or otherwise changed except by a
3 writing executed by an authorized representative of each of the parties.

4 16. In consideration of the foregoing admissions and stipulations, the parties agree that
5 the board may, without further notice or formal proceeding, issue and enter the following
6 Disciplinary Order:

7 **DISCIPLINARY ORDER**

8 IT IS ORDERED that Original Permit No. PHY 53416 issued to respondent Safeway Inc.,
9 d.b.a. Safeway Pharmacy #4905, is revoked. However, the revocation is stayed and respondent is
10 placed on probation for two (2) years on the following terms and conditions.

11 **1. Obey All Laws**

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

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

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

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

25 **2. Report to the Board**

26 Respondent shall report to the board quarterly, on a schedule as directed by the board or its
27 designee. The report shall be made either in person or in writing, as directed. Among other
28 requirements, respondent shall state in each report under penalty of perjury whether there has

1 been compliance with all the terms and conditions of probation. Failure to submit timely reports
2 in a form as directed shall be considered a violation of probation. Any period(s) of delinquency
3 in submission of reports as directed may be added to the total period of probation. Moreover, if
4 the final probation report is not made as directed, probation shall be automatically extended until
5 such time as the final report is made and accepted by the board.

6 **3. Interview with the Board**

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

12 **4. Cooperate with Board Staff**

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

16 **5. Reimbursement of Board Costs**

17 As a condition precedent to successful completion of probation, respondent shall pay to the
18 board its costs of investigation and prosecution in the amount of \$10,766.75. Respondent is
19 responsible for these costs jointly and severally with respondents John Vincent Castaldo, Karen
20 Lyn Muir, and Christine Moheb Stephanos, who are also named in Accusation No. 5605, to the
21 extent that each respondent is held responsible for those costs by a settlement agreement or final
22 adjudication of the accusation. Respondent shall be permitted to pay these costs in a payment
23 plan approved by the board or its designee, with payments to be completed no later than one
24 month prior to the end of the probation term.

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

28 The filing of bankruptcy by respondent shall not relieve respondent of its responsibility to

1 reimburse the board its costs of investigation and prosecution.

2 **6. Probation Monitoring Costs**

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

7 **7. Status of License**

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

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

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

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

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

27 Respondent shall also, by the effective date of this decision, arrange for the continuation of
28 care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing

1 patients that specifies the anticipated closing date of the pharmacy and that identifies one or more
2 area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary
3 in the transfer of records or prescriptions for ongoing patients. Within five days of its provision
4 to the pharmacy's ongoing patients, respondent shall provide a copy of the written notice to the
5 board. For the purposes of this provision, "ongoing patients" means those patients for whom the
6 pharmacy has on file a prescription with one or more refills outstanding, or for whom the
7 pharmacy has filled a prescription within the preceding sixty (60) days.

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

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

13 **9. Notice to Employees**

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

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

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

28 Respondent shall provide, within thirty (30) days after the effective date of this decision,

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

6 **11. Posted Notice of Probation**

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

10 Respondent shall not, directly or indirectly, engage in any conduct or make any statement
11 which is intended to mislead or is likely to have the effect of misleading any patient, customer,
12 member of the public, or other person(s) as to the nature of and reason for the probation of the
13 licensed entity.

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

15 **12. Violation of Probation**

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

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

28 ///

1 **13. Community Services Program**

2 Within sixty (60) days of the effective date of this decision, respondent shall submit to the
3 board or its designee, for prior approval, a community service program in which respondent shall
4 provide free health-care related services on a regular basis to a community or charitable facility or
5 agency for at least 100 hours per year during the period of probation. Within thirty (30) days of
6 board approval of these services, respondent shall submit documentation to the board
7 demonstrating commencement of the community service program. A record of this notification
8 must be provided to the board upon request. Respondent shall report on progress with the
9 community service program in the quarterly reports. Failure to timely submit, commence, or
10 comply with the program shall be considered a violation of probation.

11 **14. Separate File of Records**

12 Respondent shall maintain and make available for inspection a separate file of all records
13 pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such
14 file or make it available for inspection shall be considered a violation of probation.

15 **15. Consultant**

16 During the period of probation, respondent shall retain at its own expense an independent
17 consultant who specializes in compounding, and who shall be responsible for reviewing
18 pharmacy operations on a monthly basis for compliance by respondent with state and federal laws
19 and regulations governing the practice of a compounding pharmacy and for compliance by
20 respondent with the obligations of a pharmacist-in-charge. This consultant shall be a pharmacist
21 licensed by and not on probation with the board, and whose name shall be submitted to the board
22 or its designee for prior approval within thirty (30) days of the effective date of this decision.

23 During the period of probation, the board or its designee retains the discretion to reduce the
24 frequency of the pharmacist consultant's review of respondent's operations. Failure to timely
25 retain, seek approval of, or ensure timely reporting by the consultant shall be considered a
26 violation of probation.

27 **16. Completion of Probation**

28 Upon written notice by the board or its designee indicating successful completion of

1 probation, respondent license will be fully restored.

2 **ACCEPTANCE**

3 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
4 discussed it with my attorneys, Craig O'Loughlin and Alissa Brice Castaneda. I understand the
5 stipulation and the effect it will have on Original Permit No. PHY 53416. I enter into this
6 Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree
7 to be bound by the Decision and Order of the Board of Pharmacy.

8 DATED: _____
9 **SAFeway INC.**
Respondent

10 I have read and fully discussed with respondent Safeway Inc., d.b.a. Safeway Pharmacy
11 #4905, the terms and conditions and other matters contained in the above Stipulated Settlement
12 and Disciplinary Order. I approve its form and content.

13 DATED: _____
14 **CRAIG O'LOUGHLIN**
ALISSA BRICE CASTANEDA
Attorneys for Respondent

16 **ENDORSEMENT**

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

19
20 Dated: Respectfully submitted,
21 **KAMALA D. HARRIS**
22 **Attorney General of California**
DIANN SOKOLOFF
23 **Supervising Deputy Attorney General**

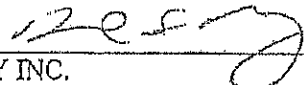
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25 **GREGORY TUSS**
Deputy Attorney General
Attorneys for Complainant

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8 DATED: 10/17/16 
9 SAFEWAY INC.
Respondent

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11 #4905, the terms and conditions and other matters contained in the above Stipulated Settlement
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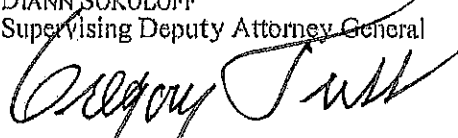
13 DATED: 10/17/16 
14 CRAIG O'LOUGHLIN
15 ALISSA BRICE CASTANEDA
16 Attorneys for Respondent

17 **ENDORSEMENT**

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20 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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28 Safeway Settlement.doc

Exhibit 1

Accusation No. 5605

1 KAMALA D. HARRIS
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2 DIANN SOKOLOFF
Supervising Deputy Attorney General
3 GREGORY TUSS
Deputy Attorney General
4 State Bar No. 200659
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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 **Respondents.**

6 Complainant Virginia Herold alleges:

7 **I. PARTIES**

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

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

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

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

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

26 6. On November 20, 2008, the Board issued Original Pharmacist License No. RPH
27 61981 to respondent Christine Moheb Stephanos. This original pharmacist license was in full
28 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:

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

12. Section 4301 states in part:

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

...

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

13. Section 4306.5 states in part:

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

...

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

14. Health and Safety Code section 111335 states:

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

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

“Any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United 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**
9 **Business and Professions Code sections 4301, 4306.5, subdivision (b)**

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

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

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

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

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

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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

1 respondent Christine Moheb Stephanos;

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

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

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

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

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

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

18 DATED: 12/22/15

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

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