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

In the Matter of the Accusation Against:

SAFEWAY PHARMACY INC.
d.b.a. Safeway Pharmacy #4905,
6100 Hellyer Avenue, Suite 100
San Jose, California 95138
License Nos. PHY 52537 and PHY 53416;

SAFEWAY PHARMACY INC.
d.b.a. Safeway Pharmacy #4526
255 Second Street
Los Altos, California 94022
License No. PHY 51192;

JOHN VINCENT CASTALDO
23750 Hutchinson Road
Los Gatos, California 95033
Pharmacist License No. RPH 31324;

KAREN LYN MUIR
156 Dunsmuir Way
Menlo Park, California 94025
Pharmacist License No. RPH 39228; and

CHRISTINE MOHEB STEPHANOS
1845 Orangetree Lane
Mountain View, California 94040
Pharmacist License No. RPH 61981,

Respondents.

Case No. 5605

OAH No. 2016050394

DECISION AND ORDER
(As to Respondents KAREN LYN MUIR and CHRISTINE MOHEB STEPHANOS, Only)

The attached Proposed Decision of the administrative law judge is hereby adopted as the decision of the California State Board of Pharmacy in the above-entitled matter, except that, pursuant to the provisions of Business and Professions Code section 495 and Government Code section 11517, subdivision (c)(2)(B), the penalties against the pharmacist licenses of Karen Lynn Muir (RPH 39228) and Christine Moheb Stephanos (RPH 61981) are modified as follows:

ORDER

1. Respondent Karen Lynn Muir, Pharmacist License Number RPH 39228, is hereby publicly reproved. Respondent is required to report this reproval as a disciplinary action. Notwithstanding Legal Conclusion 23, Respondent is not ordered to pay cost recovery.

2. Respondent Christine Moheb Stephanos, Pharmacist License Number RPH 61981, is hereby publicly reproved. Respondent is required to report this reproval as a disciplinary action. Notwithstanding Legal Conclusion 23, Respondent is not ordered to pay cost recovery.

This Decision shall become effective at 5:00 p.m. on January 23, 2017.

IT IS SO ORDERED on this 22nd day of December, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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

In the Matter of Accusation Against: SAFEWAY PHARMACY INC. d.b.a. Safeway Pharmacy #4905 Original Permit No. PHY 52537 Original Permit No. PHY 53416 SAFEWAY PHARMACY INC. d.b.a. Safeway Pharmacy #4526 Original Permit No. PHY 51192 JOHN VINCENT CASTALDO Original Pharmacist Lic. No. RPH 31324, KAREN LYN MUIR Original Pharmacist Lic. No. RPH 39228, and CHRISTINE MOHEB STEPHANOS Original Pharmacist Lic. No. RPH 61981, Respondents.	Case No. 5605 OAH No. 2016050394

PROPOSED DECISION

Administrative Law Judge Michael A. Scarlett, State of California, Office of Administrative Hearings, heard this matter on September 8, 2016, in Oakland, California.

Gregory Tuss, Deputy Attorney General, represented Virgina Herold (complainant), Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

Alissa Brice-Castañeda and Amy R. Cotton, Attorneys at Law, Quarles & Brady LLP, represented Safeway Pharmacy Inc. (respondent Safeway), John Vincent Castaldo (respondent Castaldo), Karen Lyn Muir (respondent Muir), and Christine Moheb Stephanos (respondent Stephanos). Respondents Muir and Stephanos were present at hearing. Respondents Safeway and Castaldo entered into a Stipulation and Settlement Agreement prior to hearing and did not appear.

Oral and documentary evidence was received and the matter was submitted for decision on September 8, 2016. However, the record was reopened to allow the parties to finalize the Stipulation and Settlement Agreement between respondents Safeway and Castaldo and the Board, which was not signed until October 17, 2016. The matter was submitted for decision on October 17, 2016.

FACTUAL FINDINGS

1. Complainant filed the Accusation solely in her official capacity as the Executive Officer of the Board.

2. Respondents Safeway and Castaldo entered into a settlement agreement prior to commencement of this hearing, and thus, did not participate in this proceeding. On September 8, 2016, complainant and respondents Muir and Stephanos entered into a stipulation regarding the facts, charges and allegations in the Accusation. Pursuant to the stipulation, the parties agreed that the facts, charges, and allegations contained in paragraphs 1-24 and 45-54 of the Accusation are true. Respondents Muir and Stephanos do not contest the facts, charges, and allegations in the Accusation in this proceeding. Consequently, these respondents offered evidence in mitigation only for purposes of establishing the level of discipline, if any, to be imposed by the Board. Factual Findings 3 through 9, and Legal Conclusions 9 through 14 are based on the September 8, 2016 Stipulation.

License History

3. On March 14, 1985, the Board issued Original Pharmacist License No. RPH 39228 to respondent Muir. The pharmacist license was in full force and effect at all times relevant to the charges in the Accusation and will expire on April 30, 2018, unless it is renewed.

4. On November 20, 2008, the Board issued Original Pharmacist License No. RPH 61981 to respondent Stephanos. The pharmacist license was in full force and effect at all times relevant to the charges in the Accusation and expired on January 31, 2018, unless it is renewed.

Relevant Drug

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

Factual Background

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

7. Worksheets show the following instances of domperidone compounding at respondent Safeway. All worksheets list respondent Castaldo as the PIC.

a) 7/21/14	600 10mg capsules	Checked by Muir
b) 10/8/14	300 30mg capsules	Checked by Muir
c) 10/27/14	300 10mg capsules	Checked by Castaldo
d) 11/13/14	300 10mg capsules	Checked by Muir
e) 12/11/14	300 10mg capsules	Checked by [unknown]
f) 1/12/15	300 10mg capsules	Checked by [blank]
g) 2/6/15	300 20mg capsules	Checked by [blank]

h)	2/18/15	300 10mg capsules	Checked by [blank]
i)	3/4/15	300 20mg capsules	Checked by [blank][1]

8. Pharmacy records show that respondent Safeway dispensed approximately 423 prescriptions for domperidone totaling approximately 45,898 capsules ranging from 5mg to 40mg. Approximately 374 of these prescriptions totaling 28,693 capsules were dispensed by respondent Safeway PHY 51192, approximately 39 prescriptions totaling 16,263 capsules by respondent Safeway 52537, and approximately 10 prescriptions totaling 942 capsules by respondent Safeway PHY 53416.

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

Other Relevant Facts

10. On June 7, 2004, in response to reports that women may have been using domperidone to increase milk production (lactation), the FDA issued a warning to breastfeeding women not to use the "unapproved" drug because of safety concerns. The warning was issued on the FDA internet website, "Drug Safety and Availability Information by Drug Class." The FDA's warning stated that "although domperidone is approved in several countries outside of the U.S. to treat certain gastric disorders, it is not approved in any country, including the U.S., for enhancing breast milk production in lactating women and is also not approved in the U.S. for any indication." On the same day, the FDA issued six warning letters to pharmacies that compounded products containing domperidone, and firms that supplied domperidone for use in compounding. The FDA warning letters stated that all drug products containing domperidone (whether compounded or not) violated the Federal Food, Drug, and Cosmetic Act (Act) because they were unapproved new drugs and misbranded. The warning letters notified recipients that distribution of domperidone in the U.S., or importation of domperidone-containing products, violated the law.

11. In December 2013, respondent Safeway purchased the Los Altos Pharmacy. Respondent Castaldo was the Pharmacist-In-Charge (PIC) at the respondent Safeway pharmacy in Los Altos. Respondent Castaldo was responsible for ordering, receiving, and inventorying all of the drugs used in respondent Safeway from December 2013, through January 2015.

12. In January 2015, respondent Safeway moved from Los Altos to a new location in San Jose. New operation procedures were implemented to order, receive, inventory, and

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

compound drugs at the new facility. Respondent Castaldo was no longer the sole person authorized to order, receive and inventory drugs. Instead shipping persons, pharmacy technicians, and pharmacists were all involved in processing new drug inventory. A computerized inventory system was implemented to efficiently track the drugs used in the pharmacy. Respondent Safeway did not order or receive any new shipments of domperidone after moving to the new facility in January 2015. However, one 500 gram bulk powder container of domperidone was brought over from the Los Altos location.

13. In approximately March 2015, respondent Safeway notified physicians that "due to new FDA regulations," respondent Safeway would no longer be able to compound domperidone. Respondent Safeway compounded domperidone from at least July 2014, through March 2015.

14. The Code of Federal Regulations, title 21, section 216.24, relating to "Pharmacy Compounding" and "Compounded Drug Products," provides a list of drug products that were withdrawn or removed from the market because such drugs or components of such drugs were found to be unsafe or not effective. Listed drugs are prohibited from being compounded by the FDA. As of April 1, 2015, the FDA "Do Not Compound List," did not list "domperidone" as one of the drugs that was "withdrawn or removed" from the market and prohibited from being compounded. The FDA "Do Not Compound List" is not an exhaustive list of the drugs that are prohibited by the FDA from compounding. The list specifically refers to drugs that have been "withdrawn or removed from the market," suggesting that a drug on the list had to be initially approved by the FDA for use in the United States. Domperidone was not approved for use in the United States for any indication by the FDA, which suggests that the drug would not have been included on the FDA "Do Not compound List."

15. On April 14, 2015, the Board issued a notice that stated: "[d]omperidone is not FDA-approved for any use in humans in the United States. Drug products compounded using domperidone are subject to the approval requirements of the Federal Food, Drug, and Cosmetic Act." The Board's notice included reference to the June 7, 2004 FDA warning. The Board's notice further warned that an intravenous form of domperidone had been withdrawn from the market in a number of countries, and where oral forms of the drug continued to be used, labels on the product specifically warned against use of domperidone by breastfeeding women.

16. On October 27, 2015, the FDA added domperidone to its "Do Not Compound List" with a notification that "domperidone is associated with a serious risk of life-threatening cardiac arrhythmias and sudden cardiac death in all populations, including healthy lactating women. Domperidone is transferred into human breast milk, but it is unknown to what extent domperidone in breast milk is absorbed by the breastfed infant and what the resulting drug levels and drug side effects in the exposed infant would be."

Respondent Stephanos's Mitigation Facts

17. Respondent Stephanos has been practicing as a pharmacist in California since 2008. In 2001 she received her Bachelor of Pharmacy degree in Alexandra, Egypt and passed the Foreign Equivalency Examination in 2005. From 2008 to 2011, respondent Stephanos was a pharmacy manager at "Pharmica," a small pharmacy in Mill Valley. In 2011, she began working as a pharmacist at Los Altos Pharmacy, which was purchased by respondent Safeway in December 2013. Respondent Stephanos is certified in sterile drug compounding, and received sterile drug compound training in 2013 and 2015. Since August 2016, she has been employed at San Mateo Neighborhood Pharmacy.

18. Starting in December 2013, respondent Stephanos exclusively compounded sterile drugs at respondent Safeway, and domperidone is a non-sterile drug. On occasion she compounded non-sterile drug prescriptions, but this occurred only when the pharmacy was short-staffed and needed assistance. Respondent Stephanos never compounded domperidone at respondent Safeway. However, she admitted that she verified and dispensed domperidone prescriptions at respondent Safeway. Respondent Stephanos was unaware that the domperidone bulk container label indicated that the drug was not for human use. She did not inspect the domperidone bulk container prior to verifying and dispensing domperidone prescriptions.

19. When respondent Safeway moved to its new location in San Jose in January 2015, respondent Stephanos was instrumental in implementing the new operation procedures at the new location. Respondent Stephanos testified that under the new procedures, new drugs were received and placed in an inventory log, bar-coded, and electronically entered into the pharmacy's computerized inventory system. The pharmacy had a compound log which included master formulas that pharmacy technicians used in compounding drugs and filling prescriptions. As technicians compounded drugs, computer entries were generated to reflect the quantity of drugs used and the drugs that remained in stock. The pharmacist verified that the drugs were compounded properly and dispensed the prescription to the patient. The new operation procedures were more efficient and accurate than the procedures utilized at the old location in Los Altos.

20. Respondent Stephanos tried to stay informed regarding all state and federal regulations pertaining to compounding drugs. She reviewed all of the Board's e-mails and "script" related to drug compounding, and received the International Journal for Pharmaceutical Compounding and Compounding Today, both informative journals for pharmaceutical compounding. Respondent Stephanos also relied on the US Pharmacopeial, a nonprofit organization that sets drug standards that are relied on by the FDA in the United States. She also used an extensive reference library at respondent Safeway frequently on a daily basis when compounding drugs at the pharmacy.

21. Prior to January 2015, respondent Stephanos believed that it was permissible to compound domperidone because the drug was not on the FDA "Do Not Compound List." She had previously checked the FDA list for the drug because domiperidone was not

frequently compounded at the pharmacy and she was unfamiliar with the drug. Respondent Stephanos admitted that her research revealed that domperidone could not be sold as a manufactured drug in the United States. However, she relied on European reference materials which indicated domperidone was safe in small doses to increase lactation for breastfeeding women. Respondent Stephanos believed further research on domperidone was unnecessary because the drug was already being compounded by respondent Safeway, was in the pharmacy's master formula compound log, and was not included on the FDA "Do Not Compound List." She was further convinced that the drug was approved for compounding because other pharmacies and physicians requested and wrote domperidone prescriptions. Respondent Stephanos was also not concerned about domperidone prescriptions because the Board had inspected respondent Safeway annually prior to April 2015, and never raised an issue regarding respondent Safeway's use of domperidone.

22. Respondent Stephanos did not discover the June 7, 2004 FDA warning during the course of her research. However, it does not appear that she contacted the FDA or accessed the FDA internet website to clarify whether domperidone was approved for use in humans in the United States. Respondent Stephanos concluded that the drug was approved in the United States based primarily on its exclusion from the FDA "Do Not Compound Lists." She stated that had she known about the June 7, 2004 FDA warning, she would not have verified or dispensed domperidone prescriptions. Respondent Stephanos testified that respondent Castaldo intentionally concealed the domperidone bulk container from the pharmacists, and that had she known the label indicated the drug was not for human use, she would not have verified or dispensed domperidone prescriptions. Respondent Stephanos, however, admitted that it was ultimately her responsibility to ensure that domperidone was an approved drug regardless of respondent Castaldo's conduct. In verifying a prescription, she admitted that she should have inspected the domperidone bulk container.

23. In January 2015, respondent Muir told respondent Stephanos about a journal article that stated domperidone was not approved for compounding in the United States. Both respondents Stephanos and Muir became concerned about respondent Safeway's use of domperidone, and respondent Muir urged respondent Castaldo to discontinue compounding domperidone. Respondent Castaldo stopped compounding domperidone in March 2015, and notified pharmacists, physicians and patients that the pharmacy would no longer compound the drug. Respondent Stephanos asserted that the new operation procedures eliminated the possibility that an unapproved drug like domperidone could be dispensed today. She stated that she no longer dispenses prescriptions without verifying every step of the compound formula, and if she is not familiar with the drug, she performs additional research to ensure that the drug is approved by the FDA.

24. In May 2015, Respondent Stephanos was instrumental helping respondent Safeway receive a PACB Certificate of Accreditation from the Accreditation Commission for Health Care for prescription compounding.

25. Respondent Stephanos has no prior discipline by the Board.

Respondent Muir's Mitigation Facts

26. Respondent Muir has been a pharmacist in California since 1985. She worked for Long's Pharmacy from 1985 to 2000, becoming a pharmacy manager in approximately 1989. In 2000, respondent Muir started her own pharmacist staffing company, placing temporary pharmacists at pharmacies to fill in for pharmacists on leave. In June 2013, she began working part-time for respondent Safeway as a compounding pharmacist and bioidentical hormone consultant for patients undergoing natural hormone replacement therapy.

27. Respondent Muir agreed that the new operation procedures at respondent Safeway improved the pharmacy's operation and efficiency. Since January 2015, the pharmacy regularly tests its non-sterile drugs and frequently reviews its compounding formulas. Respondent Safeway's pharmacists are regularly tested for drug compounding proficiency and participate in regular meetings to discuss new developments in drug compounding. According to respondent Muir, the new procedures allow the pharmacists to effectively verify drug compounding performed by pharmacy technicians prior to dispensing a prescription.

28. Respondent Muir testified that she was unaware that domperidone was not approved for compounding in the United States until January 2015. She was unfamiliar with domperidone in 2013 and 2014. Respondent Castaldo told respondent Muir that domperidone was used for gastrointestinal conditions and lactation, and that although the drug was commercially unavailable in the United States, domperidone had been used for years and was sold over-the-counter in Canada. Respondent Muir did not conduct independent research to verify respondent Castaldo's opinion about the drug. She also relied on the FDA "Do Not Compound List" in concluding that domperidone was approved for use in the United States. Respondent Muir testified that she never physically compounded domperidone, but admitted that she supervised pharmacy technicians compounding the drug. She also admitted that she verified and dispensed domperidone prescriptions. Respondent Muir was also led to believe domperidone was approved by the FDA because other pharmacies were filling and requesting domperiodone presriptions, and Compounding Today, a pharmacy website, published a domperidone compound formula.

29. In January 2015, respondent Muir discovered a journal article discussing domperidone which indicated that the drug was unapproved for use in the United States. She asked respondent Castaldo about compounding domperidone. Respondent Castaldo informed her that he was aware of the June 7, 2004 FDA warning, and that domperidone had been controversial since 2004. Respondent Muir researched domperidone and discovered the June 7, 2004 FDA warning. She believed that the studies on domperidone, including the studies relied on by the FDA in 2004, were not conclusive and that oral use of the drug was not unsafe. However, because the FDA did not approve domperridone's use, she decided that respondent Safeway should not compound the drug. Respondent Muir urged respondent Castaldo to discontinue compounding domperidone at the pharmacy. Through her persistence, respondent Muir convinced respondent Castaldo to discontinue compounding

domperidone at respondent Safeway in March 2015. All compounded domperidone pills were destroyed prior to the Board's inspection on April 8, 2015, but the bulk container of the drug was not destroyed unbeknownst to respondent Muir. She was not aware that the Board had an issue with domperidone until the Board's inspection in April 2015.

30. Respondent Muir did not become aware of the domperidone bulk container label until March 2015 when a pharmacy technician told her about the label. She stated she was shocked and that she would not have dispensed domperidone prescriptions had she known of the label. Respondent Muir corroborated respondent Stephanos's testimony that respondent Castaldo was responsible for ordering and inventorying drugs prior to the move to the new location in January 2015, and that the pharmacists were not aware of the domperidone bulk container label.

31. Respondent Muir has changed her approach to verifying and dispensing prescriptions. She currently researches and verifies all compounding formulas and drugs that are used for the prescriptions she dispenses. She no longer relies on the opinion of a pharmacy manager or PIC in dispensing prescriptions. Respondent Muir independently verifies that all drugs are approved for use by the FDA prior to dispensing the prescription, and new drugs used by the pharmacy are researched and verified by at least two pharmacists.

32. Respondent Muir is in compliance with her continuing education requirements and stays informed regarding drug compounding regulations and requirements. She is active in the California Pharmacist Association and the San Mateo County Pharmacist Association, serving as a past president of the latter. Respondent Muir was also involved in securing the PCAB Certificate of Accreditation for respondent Safeway in May 2015.

33. Respondent Muir has had no prior disciplinary action by the Board.

Costs of Investigation and Prosecution

34. The Board certified that its total costs for investigating and prosecuting this case were $10,766.75. These costs are reasonable and justified given the nature and scope of the allegations in the Accusation.

LEGAL CONCLUSIONS

Standard of Proof

1. The standard of proof applicable to this case is clear and convincing evidence to a reasonable certainty. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) This means the burden rests on complainant to establish the charging allegations by proof that is clear, explicit and unequivocal--so clear as to leave no substantial doubt, and sufficiently strong to command the unhesitating assent of every reasonable mind. (*In re Marriage of Weaver* (1990) 224 Cal.App.3d 478.) "Evidence of a charge is clear and

convincing so long as there is a 'high probability' that the charge is true. [Citations.] The evidence need not establish the fact beyond a reasonable doubt." (*Broadman v. Comm'n on Judicial Performance* (1998) 18 Cal.4th 1079, 1090.)

Applicable Law

2. Business and Professions Code section 4169, subdivision (a), provides in pertinent part:[2]

> A person or entity shall not do any of the following:
>
> [¶] . . . .[¶]
>
> (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.

3. Section 4301 states in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or 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.

4. Section 4306.5 states in pertinent part:

> Unprofessional conduct for a pharmacist may include any of the following:
>
> [¶] . . . [¶]

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[2] All further statutory references shall be to the Business and Professions unless otherwise specified.

(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 dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

5. 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)." 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 of Public Health is misbranded." Health and Safety Code section 111400 provides: "any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling." Health and Safety Code section 111440 provides: "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

6. California Code of Regulations, title 16, section 1735.3, subdivision (a), states in pertinent part that: "For each compounded drug product, the pharmacy records shall include: . . . (4) The identity of the pharmacist reviewing the final drug product."

7. California Code of Regulations, title 16, section 1760 provides that in reaching a decision on a disciplinary action the Board shall consider the "Disciplinary Guidelines" (Rev. 10/2007), which are incorporated by reference. Deviation from the guidelines is appropriate where the Board, in its discretion, determines that the facts of the particular case, including the presence of mitigating factors, the age of the case, evidentiary problems, etc., warrant such a deviation. (Cal. Code Regs., tit. 16, § 1760.)

8. Section 125.3. subdivision (a), provides that: "[e]xcept as otherwise provided by law, in any order issued in resolution of a disciplinary proceeding before any board . . . , the administrative law judge may direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case."

Causes for Discipline

RESPONDENT STEPHANOS

9. Cause exists to discipline respondent Stephanos's pharmacist license for unprofessional conduct pursuant to sections 4301, subdivision (o), 4169, subdivision (a)(3), and Health and Safety Code section 111440, in that respondent Stephanos verified and dispensed approximately 72 prescriptions for domperidone totaling approximately 7,725 capsules, by reason of Factual Findings 2, and 5 through 9.

10. Cause exists to discipline respondent Stephanos's pharmacist license for unprofessional conduct pursuant to sections 4301 and 4306.5, subdivision (b), in that respondent Stephanos failed to exercise or implement her best professional judgment or corresponding responsibility with regards to dispensing domperidone, a dangerous drug, by reason of Factual Findings 2 and 5 through 9.

RESPONDENT MUIR

11. Cause exists to discipline respondent Muir's pharmacist license for unprofessional conduct pursuant to sections 4301, subdivision (o), 4169, subdivision (a)(3), and Health and Safety Code section 111440, in that respondent Muir compounded domperidone, by reason of Factual Findings 2 and 5 through 9.

12. Cause exists to discipline respondent Muir's pharmacist license for unprofessional conduct pursuant to sections 4301, subdivision (o), 4169, subdivision (a)(3), and Health and Safety Code section 111440, in that respondent Muir verified and dispensed approximately 161 prescriptions for domperidone totaling approximately16,813 capsules, by reason of Factual Findings 2 and 5 through 9.

13. Cause exists to discipline respondent Muir's pharmacist license for unprofessional conduct pursuant to sections 4301 and 4306.5, subdivision (b), in that respondent Muir failed to exercise or implement her best professional judgment or corresponding responsibility with regards to dispensing domperidone, a dangerous drug, by reason of Factual Findings 2 and 5 through 9.

14. Pursuant to the September 8, 2016 Stipulation, respondents Stephanos and Muir do not dispute the factual allegations or that cause exist to discipline their pharmacist licenses. They ask that the Board consider the factors in mitigation in ordering discipline in the case.

Mitigation Considerations

15. Respondents Stephanos and Muir believed that domperidone was approved for use in the United States because the drug did not appear on the FDA "Do Not Compound List" (21 CFR 216.24), and was widely used by other pharmacies and physicians in California. They also relied on respondent Castaldo's opinion that it was appropriate to compound the drug and were unaware that the domperidone bulk container label indicated the drug was not for human use. Consequently, respondents Stephanos and Muir did not intentionally violate pharmacy laws and regulations when they verified and dispensed domperidone prescriptions.

16. However, respondents Stephanos and Muir should have known domperidone was not approved for use in the United States. Both respondents admitted that they were initially unfamiliar with domperidone and that their initial research revealed that the manufactured drug was unavailable in the United States. These factors alone required

respondents to exercise their best professional judgment and thoroughly research domperidone prior to dispensing prescriptions containing the drug. Thorough research would have revealed the FDA's June 7, 2004 warning, and that the drug was not approved for use in the United States by the FDA. It does not appear that respondents Stephanos and Muir contacted the FDA or accessed the FDA internet website prior to January 2015, to confirm that domperidone was approved for human use by the FDA. Reliance on the FDA "Do Not Compound List" was misplaced because the list is not an exhaustive of list of drugs prohibited by the FDA. Respondents Stephanos and Muir also should not have simply relied on respondent Castaldo's expertise and opinion in deciding to dispense domperidone at respondent Safeway. Best practice and judgment required that they exercise independent judgment when verifying and dispensing a dangerous drug, particularly when they both were unfamiliar with domperidone, and knew the manufactured drug was unavailable in the United States. They should have diligently researched the use of domperidone and inspected the bulk container for the drug prior to verifying and dispensing domperidone prescriptions.

17. Respondents Stephanos and Muir, however, were not the pharmacy managers or PIC's at respondent Safeway. Respondent Castaldo made the ultimate decision to compound domperidone and he was solely responsible for ordering and inventorying the drug at respondent Safeway. Respondent Muir was also instrumental in convincing respondent Castaldo to discontinue compounding domperidone in March 2015.

18. It is also significant that the Board did not notify respondent Safeway until April 14, 2015, that domperidone was not approved for use in humans. This notification occurred after the Board's April 8, 2015, inspection at respondent Safeway. Respondent Safeway had already stopped compounding domperidone when the Board's inspection occurred. The FDA also did not place domperidone on its "Do Not Compound List" until October 27, 2015.

19. Finally, respondents Stephanos and Muir have been otherwise good pharmacists with no history of disciplinary actions on their licenses prior to the April 2015 Board inspection. They have complied with continuing education requirements, trying to stay abreast of the compounding rules and regulations, and have been actively involved in professional pharmacy organizations. Both respondents credibly testified that they have learned from this experience and currently conduct extensive research for any unfamiliar drug that is used in a prescription. Respondents Stephanos and Muir now understand that they must exercise independent judgment prior to verifying and dispensing all prescriptions, and must not rely on a pharmacy manager or PIC for authority to dispense drug prescriptions.

20. Accordingly, after consideration of the factors in mitigation (Factual Findings 17 through 33), it would not pose a significant risk to the public's health, safety and welfare if respondents Stephanos and Muir were allowed to retain a three-year probationary license with appropriate terms and conditions.

21. Under the Board's Disciplinary Guidelines, incorporated at California Code of Regulations, title 16, section 1760, violations of sections 4169, subdivision (a), and 4306.5,

subdivision (b), warrant Category II discipline which recommends a minimum three-year probation. Category II discipline is recommended for violations involving a serious potential for harm to a patient or the public. Dispensing domperidone prescriptions posed a serious potential for harm to respondent Safeway's patients. A violation of section 4301, subdivision (o), warrants Category III discipline which recommends a minimum three to five-year probation, and a 90-day suspension. However, Category III discipline is typically imposed when a licensee knowingly and willfully violates the pharmacy laws and regulations pertaining to dispensing a dangerous drug or controlled substance. This did not occur in this case. Consequently, respondents Stephanos's and Muir's violations warrant Category II discipline under the guidelines.

Cost Recovery

22. *Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32 held that the imposition of costs for investigation and did not violate due process in a case involving the discipline of a licensee. The Supreme Court set forth four factors that the licensing agency was required to consider in deciding whether to reduce or eliminate costs: (1) whether the licensee used the hearing process to obtain dismissal of other charges or a reduction in the severity of the discipline imposed; (2) whether the licensee had a "subjective" good faith belief in the merits of his position; (3) whether the licensee raised a "colorable challenge" to the proposed discipline; and (4) whether the licensee had the financial ability to make payments.

23. Cause exists to award the Board's cost of investigation and prosecution pursuant to Business and Professions Code section 125.3, in that the Board's costs are determined to be reasonable, by reason of Factual Finding 34. Respondents Stephanos and Muir admitted that the facts, charges, and allegations in the Accusation pertinent to their conduct are true. Consequently, respondents Stephanos and Muir shall reimburse the Board's costs. The actual amount of cost reimbursement for each respondent shall be determined by the Board.

ORDER

Respondent Christine Moheb Stephanos Disciplinary Order

Original Pharmacist License No. RPH 61981, issued to respondent Christine Moheb Stephanos is revoked; however, the revocation is stayed and respondent is placed on probation for three years upon the following terms and conditions of probation:

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

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 contendre 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 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 her 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 Case Number 5605, OAH Case Number 2016050394, 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 her 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 Case Number 5605, OAH Case Number 2016050394, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that her 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 her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in Case Number 5605, OAH Case Number 2016050394, 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 her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that she has read the decision in Case Number 5605, OAH Case Number 2016050394, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

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

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

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

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

8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $10,766.55. Respondent's individual share of the costs amount shall be determined by the board, and respondent shall make payments as determined by the board.

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

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

9. Probation Monitoring Costs

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

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 her 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 her 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. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.
Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. Tolling of Probation

Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the board or its designee may consider a modification of this requirement. If respondent fails to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.

14. Violation of Probation

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

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

15. Completion of Probation

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

Respondent Karen Lyn Muir Disciplinary Order

Original Pharmacist License number RPH 39228, issued to respondent Karen Lyn Muir is revoked; however the revocation is stayed and respondent is placed on probation for three years upon the following terms and conditions:

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

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 contendre 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 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 her 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 Case Number 5605, OAH Case Number 2016050394, 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 her 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 Case Number 5605, OAH Case Number 2016050394, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that her 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 her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in Case Number 5605, OAH Case Number 2016050394, 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 her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that she has read the decision in Case Number 5605, OAH Case Number 2016050394, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

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

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

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

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

8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $10,766.55. Respondent's individual share of the costs amount shall be determined by the board, and respondent shall make payments as determined by the board.

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

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

9. Probation Monitoring Costs

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

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 her 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 her 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. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.
Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. Tolling of Probation

Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the board or its designee may consider a modification of this requirement. If respondent fails

to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.

14. Violation of Probation

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

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

15. Completion of Probation

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

DATED: November 16, 2016

DocuSigned by:
Michael A. Scarlett
834BAC07732D402...

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

In the Matter of the Accusation Against:	Case No. 5605
SAFEWAY PHARMACY INC. **d.b.a. Safeway Pharmacy #4905** **6100 Hellyer Avenue, Suite 100** **San Jose, California 95138** **Original Permit No. PHY 52537** **Original Permit No. PHY 53416,** **SAFEWAY PHARMACY INC.** **d.b.a. Safeway Pharmacy #4526** **255 Second Street** **Los Altos, California 94022** **Original Permit No. PHY 51192,** **JOHN VINCENT CASTALDO** **23750 Hutchinson Road** **Los Gatos, California 95033** **Original Pharmacist License No. RPH 31324,** **KAREN LYN MUIR** **156 Dunsmuir Way** **Menlo Park, California 94025** **Original Pharmacist License No. RPH 39228,** **and**	**ACCUSATION**

CHRISTINE MOHEB STEPHANOS
1845 Orangetree Lane
Mountain View, California 94040

Original Pharmacist License No. RPH 61981,

Respondents.

Complainant Virginia Herold alleges:

I. PARTIES

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

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

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

4. On August 8, 1977, the Board issued Original Pharmacist License No. RPH 31324 to respondent John Vincent Castaldo. 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 December 31, 2016, unless renewed.

5. On March 14, 1985, the Board issued Original Pharmacist License No. RPH 39228 to respondent Karen Lyn Muir. 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 April 30, 2016, unless renewed.

6. On November 20, 2008, the Board issued Original Pharmacist License No. RPH 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

January 31, 2016, unless renewed.

II. JURISDICTION

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

8. Section 4300 states in part:

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

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

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

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

"(4) Revoking his or her license.

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

9. Section 4300.1 states:

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

10. Section 4304 states:

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

III. STATUTORY AND REGULATORY PROVISIONS

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

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

. . .

"(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

of Public Health is misbranded."

16. Health and Safety Code section 111400 states:

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

17. Health and Safety Code section 111440 states:

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

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

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

. . .

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

IV. COST RECOVERY

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

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

V. DRUGS

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

seq.).

VI. FACTUAL BACKGROUND

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

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

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

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

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

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

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

VII. CAUSES FOR DISCIPLINE

A. Safeway PHY 51192

First 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

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

26. Respondent Safeway has subjected its Original Permit No. PHY 51192 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). Approximately 28,693 domperidone capsules were compounded at respondent Safeway PHY 51192.

Second 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

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

28. Respondent Safeway has subjected its Original Permit No. PHY 51192 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 Safeway PHY 51192 dispensed approximately 374 prescriptions for domperidone

totaling approximately 28,693 capsules.

B. Safeway PHY 52537

Third 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

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

30. Respondent Safeway has subjected its Original Permit No. PHY 52537 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). Approximately 16,263 domperidone capsules were compounded at respondent Safeway PHY 52537.

Fourth 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

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

32. Respondent Safeway has subjected its Original Permit No. PHY 52537 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 Safeway PHY 52537 dispensed approximately 39 prescriptions for domperidone totaling approximately 16,263 capsules.

C. Safeway PHY 53416

Fifth 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

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

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

Sixth 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

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

36. Respondent Safeway has subjected its Original Permit No. PHY 53416 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 Safeway PHY 53416 dispensed approximately 10 prescriptions for domperidone totaling approximately 942 capsules.

D. Castaldo

Seventh 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

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

38. Respondent Castaldo has subjected his 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.

Eighth 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

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

40. Respondent Castaldo has subjected his 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 Castaldo dispensed and verified approximately 190 prescriptions for domperidone totaling approximately 21,360 capsules.

Ninth 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)

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

42. Respondent Castaldo has subjected his original pharmacist license to discipline for the unprofessional conduct of failing to exercise or implement his 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 prescriptions for domperidone.

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

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

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

prescriptions for domperidone.

F. Stephanos

Fourteenth 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

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

52. Respondent Stephanos 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 Stephanos dispensed and verified 72 prescriptions for domperidone totaling approximately 7,725 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)

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

54. Respondent Stephanos 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 dispensed and verified prescriptions for domperidone.

VIII. OTHER DISCIPLINARY CONSIDERATIONS

55. To determine the degree of discipline, if any, to be imposed on Original Permit No. PHY 51192 issued to respondent Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4626, 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

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

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

IX. PRAYER

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

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

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

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

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

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

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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