

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

In the Matter of the Accusation Against:

Case No. 5667

**SILICON VALLEY PHARMACY  
14107 S. Winchester Boulevard  
Los Gatos, CA 95032**

OAH No. 2016100169

**Original Permit License No. PHY 44228,**

**STIPULATED SETTLEMENT AND  
DISCIPLINARY ORDER FOR PUBLIC  
REPROVAL AS TO SILICON VALLEY  
PHARMACY, VIVIAN CHOI MATSUO  
AND DAVID S. MATSUO**

**VIVIAN CHOI MATSUO  
14107 S. Winchester Boulevard  
Los Gatos, CA 95032**

**Pharmacist License No. RPH 36646**

**DAVID S. MATSUO  
14107 S. Winchester Boulevard  
Los Gatos, CA 95032**

**Pharmacist License No. RPH 36383**

Respondents.

**DECISION AND ORDER**

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

This Decision shall become effective at 5:00 p.m. on April 20, 2017.

It is so ORDERED on March 21, 2017.

BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA



By \_\_\_\_\_

Amy Gutierrez, Pharm.D.  
Board President

1 XAVIER BECERRA  
Attorney General of California  
2 DIANN SOKOLOFF  
Supervising Deputy Attorney General  
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Deputy Attorney General  
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9 **BEFORE THE**  
**BOARD OF PHARMACY**  
**DEPARTMENT OF CONSUMER AFFAIRS**  
10 **STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 5667

12 **SILICON VALLEY PHARMACY**  
13 **14107 S. Winchester Boulevard**  
**Los Gatos, CA 95032**

OAH No. 2016100169

14 **Pharmacy Permit No. PHY 44228;**

**STIPULATED SETTLEMENT AND**  
**DISCIPLINARY ORDER FOR PUBLIC**  
**REPROVAL AS TO SILICON VALLEY**  
**PHARMACY, VIVIAN CHOI MATSUO,**  
**AND DAVID S. MATSUO**

15 **VIVIAN CHOI MATSUO**  
16 **14107 S. Winchester Boulevard**  
**Los Gatos, CA 95032**

[Bus. & Prof. Code § 495]

17 **Pharmacist License No. RPH 36646;**

18 **DAVID S. MATSUO**  
19 **14107 S. Winchester Boulevard**  
**Los Gatos, CA 95032**

20 **Pharmacist License No. RPH 36383;**

21 **ANABELLA SAI-YAN FOO**  
22 **931 Amarillo Avenue**  
**Palo Alto, CA 94303**

23 **Pharmacist License No. RPH 35288; and**

24 **JENNIFER HWA-YOUNG LEE**  
25 **761 N. 11<sup>th</sup> Street**  
**San Jose, CA 95112**

26 **Pharmacist License No. RPH 39041**

27 Respondents.  
28

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

3 PARTIES

4 1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy  
5 ("Board"). She brought this action solely in her official capacity and is represented in this matter  
6 by Kathleen A. Kenealy, Acting Attorney General of the State of California, by Carter Ott,  
7 Deputy Attorney General.

8 2. Respondents Silicon Valley Pharmacy, Vivian Choi Matsuo, and David S. Matsuo are  
9 represented in this proceeding by Ivan Petrzelka, California Pharmacy Lawyers, 2855 Michelle  
10 Drive, Suite 180, Irvine, CA 92606-1027.

11 JURISDICTION

12 3. On or about June 8, 1999, the Board of Pharmacy ("Board") issued Pharmacy Permit  
13 Number PHY 44228 to Respondent Silicon Valley Pharmacy. The Pharmacy Permit was in full  
14 force and effect at all times relevant to the charges brought in Accusation No. 5667 and will  
15 expire on June 1, 2017, unless renewed.

16 4. On or about August 13, 1981, the Board issued Pharmacist License Number RPH  
17 36383 to Respondent David S. Matsuo. The Pharmacist License was in full force and effect at all  
18 times relevant to the charges brought in Accusation No. 5667 and will expire on January 31,  
19 2019, unless renewed. Respondent David Matsuo has been the President and a 50% shareholder  
20 of Respondent Silicon Valley Pharmacy since June 8, 1999. At all times relevant to the charges  
21 brought in Accusation No. 5667, Respondent David Matsuo functioned as a compounding  
22 pharmacist at Respondent Silicon Valley Pharmacy.

23 5. On or about August 20, 1981, the Board issued Pharmacist License Number RPH  
24 36646 to Respondent Vivian Choi Matsuo. The Pharmacist License was in full force and effect at  
25 all times relevant to the charges brought in Accusation No. 5667 and will expire on September  
26 30, 2017, unless renewed. Respondent Vivian Matsuo has been the Treasurer/Chief Financial  
27 Officer and a 50% shareholder of Respondent Silicon Valley Pharmacy since June 8, 1999. At all  
28

1 times relevant to the charges brought in Accusation No. 5667, Respondent Vivian Matsuo served  
2 as Respondent Silicon Valley Pharmacy's Pharmacist-in-Charge.

3 6. Accusation No. 5667 was filed before the Board of Pharmacy ("Board"), Department  
4 of Consumer Affairs and is currently pending against Respondent. The Accusation and all other  
5 statutorily required documents were properly served on Respondent on June 27, 2016.  
6 Respondent timely filed her Notice of Defense contesting the Accusation. A copy of Accusation  
7 No. 5667 is attached as Exhibit A and incorporated herein by reference.

#### 8 ADVISEMENT AND WAIVERS

9 7. Respondents have carefully read, fully discussed with counsel, and understand the  
10 charges and allegations in Accusation No. 5667. Respondents have also carefully read, fully  
11 discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary  
12 Order for Public Repeval.

13 8. Respondents are fully aware of their legal rights in this matter, including the right to a  
14 hearing on the charges and allegations in the Accusation; the right to be represented by counsel at  
15 their own expense; the right to confront and cross-examine the witnesses against them; the right  
16 to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to  
17 compel the attendance of witnesses and the production of documents; the right to reconsideration  
18 and court review of an adverse decision; and all other rights accorded by the California  
19 Administrative Procedure Act and other applicable laws.

20 9. Respondents voluntarily, knowingly, and intelligently waive and give up each and  
21 every right set forth above.

#### 22 CULPABILITY

23 10. Respondents understand and agree that the charges and allegations in Accusation No.  
24 5667, if proven at a hearing, constitute cause for imposing discipline upon their Pharmacy Permit  
25 and Pharmacist Licenses.

26 11. For the purpose of resolving the Accusation without the expense and uncertainty of  
27 further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual  
28

1 basis for the charges in the Accusation, and that Respondents hereby give up their right to contest  
2 those charges.

3 12. Respondents agree that their Pharmacy Permit and Pharmacist Licenses are subject to  
4 discipline and they agree to be bound by the Disciplinary Order below.

5 RESERVATION

6 13. The admissions made by Respondents herein are only for the purposes of this  
7 proceeding, or any other proceedings in which the Board or other professional licensing agency is  
8 involved, and shall not be admissible in any other criminal or civil proceeding.

9 CONTINGENCY

10 14. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents  
11 understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may  
12 communicate directly with the Board regarding this stipulation and settlement, without notice to  
13 or participation by Respondents or their counsel. By signing the stipulation, Respondents  
14 understand and agree that they may not withdraw their agreement or seek to rescind the  
15 stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this  
16 stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public  
17 Repeval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any  
18 legal action between the parties, and the Board shall not be disqualified from further action by  
19 having considered this matter.

20 15. The parties understand and agree that Portable Document Format ("PDF") and  
21 facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Repeval,  
22 including Portable Document Format ("PDF") and facsimile signatures thereto, shall have the  
23 same force and effect as the originals.

24 16. This Stipulated Settlement and Disciplinary Order for Public Repeval is intended by  
25 the parties to be an integrated writing representing the complete, final, and exclusive embodiment  
26 of their agreement. It supersedes any and all prior or contemporaneous agreements,  
27 understandings, discussions, negotiations, and commitments (written or oral). This Stipulated  
28 Settlement and Disciplinary Order for Public Repeval may not be altered, amended, modified,

1 supplemented, or otherwise changed except by a writing executed by an authorized representative  
2 of each of the parties.

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

6 **DISCIPLINARY ORDER**

7 IT IS HEREBY ORDERED Pharmacy Permit Number PHY 44228, issued to Respondent  
8 Silicon Valley Pharmacy; Pharmacist License Number RPH 36383, issued to Respondent David  
9 S. Matsuo; and Pharmacist License Number RPH 36646, issued to Respondent Vivian Choi  
10 Matsuo, shall be publicly reprovved by the Board of Pharmacy under Business and Professions  
11 Code section 495 in resolution of Accusation No. 5667, attached as Exhibit A.

12 **Cost Recovery.** Respondents shall jointly or severally pay \$12,500.00 to the Board for its  
13 costs associated with the investigation and enforcement of this matter. Respondents shall be  
14 permitted to pay these costs in a payment plan approved by the Board. If Respondent fails to pay  
15 the Board costs as ordered, Respondents shall not be allowed to renew their Pharmacy Permit and  
16 Pharmacist License until the costs are paid in full.

17 **ACCEPTANCE**

18 I have carefully read the above Stipulated Settlement and Disciplinary Order for Public  
19 Reapproval and have fully discussed it with my attorney, Ivan Petrzelka. I understand the  
20 stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated  
21 Settlement and Disciplinary Order for Public Reapproval voluntarily, knowingly, and intelligently,  
22 and agree to be bound by the Decision and Order of the Board of Pharmacy.

23  
24 DATED: 2/15/17 [Signature]  
25 SILICON VALLEY PHARMACY  
26 Respondent

26 /////  
27 /////  
28 //

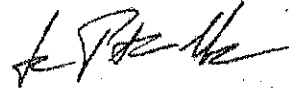
1 I have carefully read the above Stipulated Settlement and Disciplinary Order for Public  
2 Reapproval and have fully discussed it with my attorney, Ivan Petrzelka. I understand the  
3 stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated  
4 Settlement and Disciplinary Order for Public Reapproval voluntarily, knowingly, and intelligently,  
5 and agree to be bound by the Decision and Order of the Board of Pharmacy.

6  
7 DATED: 2/15/17   
8 VIVIAN CHOI MATSUO  
9 Respondent

10 I have carefully read the above Stipulated Settlement and Disciplinary Order for Public  
11 Reapproval and have fully discussed it with my attorney, Ivan Petrzelka. I understand the  
12 stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated  
13 Settlement and Disciplinary Order for Public Reapproval voluntarily, knowingly, and intelligently,  
14 and agree to be bound by the Decision and Order of the Board of Pharmacy.

15 DATED: 2/15/17   
16 DAVID S. MATSUO  
17 Respondent

18 I have read and fully discussed with Respondents Silicon Valley Pharmacy, Vivian Choi  
19 Matsuo, and David S. Matsuo the terms and conditions and other matters contained in the above  
20 Stipulated Settlement and Disciplinary Order for Public Reapproval. I approve its form and content.

21 DATED: 2/15/2017   
22 IVAN PETRZELKA  
23 Attorney for Respondents

24 /////  
25 /////  
26 /////  
27 /////  
28 //

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ENDORSEMENT

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

Dated: 2/16/17

Respectfully submitted,

XAVIER BECERRA  
Attorney General of California  
DIANN SOKOLOFF  
Supervising Deputy Attorney General



CARTER OTT  
Deputy Attorney General  
*Attorneys for Complainant*

SF2015900835



**Exhibit A**

**Accusation No. 5667**

1 KAMALA D. HARRIS  
Attorney General of California  
2 DIANN SOKOLOFF  
Supervising Deputy Attorney General  
3 CARTER OTT  
Deputy Attorney General  
4 State Bar No. 221660  
1515 Clay Street, 20th Floor  
5 P.O. Box 70550  
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6 Telephone: (510) 622-2219  
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7 E-mail: Carter.Ott@doj.ca.gov  
*Attorneys for Complainant*

8  
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13 **14107 S. Winchester Boulevard**  
**Los Gatos, CA 95032**

**ACCUSATION**

14 **Pharmacy Permit No. PHY 44228;**

15 **VIVIAN CHOI MATSUO**  
16 **14107 S. Winchester Boulevard**  
**Los Gatos, CA 95032**

17 **Pharmacist License No. RPH 36646;**

18 **DAVID S. MATSUO**  
19 **14107 S. Winchester Boulevard**  
**Los Gatos, CA 95032**

20 **Pharmacist License No. RPH 36383;**

21 **ANABELLA SAI-YAN FOO**  
22 **931 Amarillo Avenue**  
**Palo Alto, CA 94303**

23 **Pharmacist License No. RPH 35288; and**

24 **JENNIFER HWA-YOUNG LEE**  
25 **761 N. 11<sup>th</sup> Street**  
**San Jose, CA 95112**

26 **Pharmacist License No. RPH 39041**

27 Respondents.  
28

1 Complainant alleges:

2 PARTIES

3 1. Virginia Herold (“Complainant”) brings this Accusation solely in her official capacity  
4 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

5 2. On or about June 8, 1999, the Board of Pharmacy issued Pharmacy Permit Number  
6 PHY 44228 to Silicon Valley Pharmacy (“Respondent SV Pharmacy”). The Pharmacy Permit  
7 was in full force and effect at all times relevant to the charges brought in this Accusation and will  
8 expire on June 1, 2016, unless renewed.

9 3. On or about August 13, 1981, the Board of Pharmacy issued Pharmacist License  
10 Number RPH 36383 to David S. Matsuo (“Respondent David Matsuo”). The Pharmacist License  
11 was in full force and effect at all times relevant to the charges brought in this Accusation and will  
12 expire on January 31, 2017, unless renewed. Respondent David Matsuo has been the President  
13 and a 50% shareholder of Respondent SV Pharmacy since June 8, 1999. At all times relevant to  
14 the charges brought in this Accusation against him, Respondent David Matsuo functioned as a  
15 compounding pharmacist at Respondent SV Pharmacy.

16 4. On or about August 20, 1981, the Board of Pharmacy issued Pharmacist License  
17 Number RPH 36646 to Vivian Choi Matsuo (“Respondent Vivian Matsuo”). The Pharmacist  
18 License was in full force and effect at all times relevant to the charges brought in this Accusation  
19 and will expire on September 30, 2017, unless renewed. Respondent Vivian Matsuo has been the  
20 Treasurer/Chief Financial Officer and a 50% shareholder of Respondent SV Pharmacy since June  
21 8, 1999. At all times relevant to the charges brought in this Accusation against her, Respondent  
22 Vivian Matsuo served as Respondent SV Pharmacy’s Pharmacist-in-Charge (“PIC”).

23 5. On or about February 21, 1980, the Board of Pharmacy issued Pharmacist License  
24 Number RPH 35288 to Anabella Sai-Yan Foo (“Respondent Foo”). The Pharmacist License was  
25 in full force and effect at all times relevant to the charges brought in this Accusation and will  
26 expire on March 31, 2016, unless renewed. At all times relevant to the charges brought in this  
27 Accusation against her, Respondent Foo was employed as a pharmacist at Respondent SV  
28 Pharmacy.



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

3           ... .

4           “(e) The proceedings under this article shall be conducted in accordance with Chapter 5  
5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board  
6 shall have all the powers granted therein. The action shall be final, except that the propriety of  
7 the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of  
8 Civil Procedure.”

9                                   RELEVANT STATUTES AND REGULATIONS

10          10. Health and Safety Code section 111335 states:

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

13          11. Health and Safety Code section 111375 states, in part:

14           “Any drug or device is misbranded unless its labeling bears all of the following  
15 information:

16           ... .

17           “(c) Adequate warning against unsafe dosage or methods or duration of administration or  
18 application.

19           “Warnings shall be in a manner and form as are necessary for the protection of users.

20           “If the department determines that any requirement of subdivision (a), as applied to any  
21 drug or device, is not necessary for the protection of the public health, the department may adopt  
22 regulations exempting the drug or device from these requirements.

23           Any drug or device exempted under Section 502(f) of the federal act (21 U.S.C. Sec. 352(f)) is  
24 exempt from the requirement of this section. The department, however, may adopt any regulation  
25 including a drug or device within, or excluding a drug or device from the requirements of this  
26 section, whether or not the inclusion or exclusion of the drug or device is in accord with the  
27 federal act.”

28        ////

1 12. Health and Safety Code section 111400 states:

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

4 13. Section 4169 states, in part:

5 "(a) A person or entity shall not do any of the following:

6 ...

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

10 ...."

11 14. Section 4301 states, in part:

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

14 Unprofessional conduct shall include, but is not limited to, any of the following:

15 ...

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

20 ...."

21 15. Section 4306.5 states, in part:

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

23 ...

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

28 ...."

1 16. California Code of Regulations, title 16, section 1707.5 states, in part:

2 “(a) Labels on drug containers dispensed to patients in California shall conform to the  
3 following format:

4 “(1) Each of the following items, and only these four items, shall be clustered into one area  
5 of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a  
6 12-point sans serif typeface, and listed in the following order:

7 “(A) Name of the patient

8 “(B) Name of the drug and strength of the drug. For the purposes of this section, “name of  
9 the drug” means either the manufacturer’s trade name of the drug, or the generic name and the  
10 name of the manufacturer.

11 “(C) The directions for the use of the drug.

12 “(D) The condition or purpose for which the drug was prescribed if the condition or  
13 purpose is indicated on the prescription.

14 . . . .”

15 17. California Code of Regulations, title 16, section 1714, subdivision (c) states:

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

20 18. California Code of Regulations, title 16, section 1717.3, subdivision (b) states:

21 “(b) A person may dispense a dangerous drug, that is not a controlled substance, pursuant  
22 to a preprinted multiple checkoff prescription blank and may dispense more than one dangerous  
23 drug, that is not a controlled substance, pursuant to such a blank if the prescriber has indicated on  
24 the blank the number of dangerous drugs he or she has prescribed.”

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

26 “(a) For each compounded drug product, the pharmacy records shall include:

27 . . .

28 “(2) The date the drug product was compounded.

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

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

3 ...

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

5 ...

6 “(c) Chemicals, bulk drug substances, drug products, and components used to compound  
7 drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain  
8 any available certificates of purity or analysis for chemicals, bulk drug substances, drug products,  
9 and components used in compounding. Certificates of purity or analysis are not required for drug  
10 products that are approved by the Food and Drug Administration.

11 ....”

12 20. California Code of Regulations, title 16, section 1735.6, subdivision (b) states:

13 “(b) Any equipment used to compound drug products shall be stored, used, and maintained  
14 in accordance with manufacturers' specifications.”

15 21. California Code of Regulations, title 16, section 1761 states, in part:

16 “(a) No pharmacist shall compound or dispense any prescription which contains any  
17 significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any  
18 such prescription, the pharmacist shall contact the prescriber to obtain the information needed to  
19 validate the prescription.

20 ....”

21 COST RECOVERY

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

25 RELEVANT DRUG INFORMATION

26 23. “Domperidone,” also known as motilium, is an anti-dopaminergic drug which acts as  
27 an antiemetic and a prokinetic agent. It is used in many countries for the treatment of  
28 gastroparesis, a condition in which the stomach cannot empty itself of food in a normal fashion.



1 Compounding with domperidone is not allowed in the United States with the exception of  
2 investigational new drug application filing. Only Dougherty's Pharmacy, located in Dallas,  
3 Texas, is approved to compound domperidone at this time. Distribution of any domperidone-  
4 containing products is illegal. The Federal Drug Administration ("FDA") has instructed its field  
5 personnel to detain shipments of domperidone and refuse its admission into the United States.

6 24. Domperidone is believed to promote lactation. But the drug is not approved in any  
7 country, including the United States, for promoting lactation. In fact, the FDA warns against  
8 using domperidone for promoting lactation. In particular, on June 7, 2004, the FDA published a  
9 talk paper titled "FDA Warns Against Women Using Unapproved Drug, Domperidone, to  
10 Increase Milk Production,"<sup>1</sup> in which it warns about the public risks associated with use of the  
11 drug:

12 The [FDA] is concerned with the potential public health risks associated with  
13 domperidone. There have been several published reports and case studies of  
14 cardiac arrhythmias, cardiac arrest, and sudden death in patients receiving an  
15 intravenous form of domperidone . . . . In several countries where the oral form  
16 of domperidone continues to be marketed, labels for the product contain specific  
17 warnings against use of domperidone by breastfeeding women and note that the  
18 drug is excreted in breast milk that could expose a breastfeeding infant to  
19 unknown risks. Because of the possibility of serious adverse effects, FDA  
20 recommends that breastfeeding women not use domperidone to increase milk  
21 production.

22 . . . .  
23  
24 The letters issued by FDA today stated that all drug products containing  
25 domperidone (whether compounded or not) violate the Federal Food, Drug, and  
26 Cosmetic Act (the Act) because they are unapproved new drugs and misbranded.  
27 In addition, distribution within the U.S., or importation of domperidone-  
28 containing products, violates the law. FDA informed the warning letter recipients  
that further violations of the Act may result in enforcement actions including  
seizure and injunction.

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<sup>1</sup> <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm173886.htm>

FIRST CAUSE FOR DISCIPLINE

(Sale of Misbranded Drug)

(Bus. & Prof. Code § 4169, subd. (a)(3); and Health and Safety Code §§ 111335; 111375, subd. (c); and 111400)

25. Respondents SV Pharmacy, David Matsuo, Vivian Matsuo, Foo, and Lee have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for their trade, sale, or transfer of a dangerous drug that they knew or reasonably should have known was misbranded, as defined in Health and Safety Code section 111335. (Bus. & Prof. Code § 4169, subd. (a)(3); and Health and Safety Code §§ 111335; 111375, subd. (c); and 111400). In particular:

a. From January 3, 2014 to April 8, 2015, Respondent SV Pharmacy compounded domperidone 10 mg, 20 mg, 30 mg, and 40 mg capsules and dispensed to patients approximately 393 domperidone prescriptions (42,060 capsules) which were compounded from domperidone.

b. From January 3, 2014 to April 8, 2015, Respondent David Matsuo, while working at Respondent SV Pharmacy, compounded domperidone 10 mg, 20 mg, 30 mg, and 40 mg capsules and dispensed to patients approximately 28,913 capsules which were compounded from domperidone.

c. From January 3, 2014 to April 8, 2015, Respondent Vivian Matsuo, while working at Respondent SV Pharmacy, compounded domperidone 10 mg, 20 mg, 30 mg, and 40 mg capsules and dispensed to patients 7,877 capsules which were compounded from domperidone.

d. From January 3, 2014 to April 8, 2015, Respondent Foo, while working at Respondent SV Pharmacy, compounded domperidone 10 mg, 20 mg, 30 mg, and 40 mg capsules and dispensed to patients approximately 4,120 capsules which were compounded from domperidone.

e. From January 3, 2014 to April 8, 2015, Respondent Lee, while working at Respondent SV Pharmacy, compounded domperidone 10 mg, 20 mg, 30 mg, and 40 mg capsules and dispensed to patients approximately 1,150 capsules which were compounded from domperidone.

1 f. In each of these instances, the domperidone was misbranded because  
2 Respondents SV Pharmacy, David Matsuo, Vivian Matsuo, Foo, and Lee branded, labeled, or  
3 otherwise represented to patients that the drug was appropriate for consumption by humans when  
4 they knew or reasonably should that it is not appropriate for consumption by humans.

5 SECOND CAUSE FOR DISCIPLINE  
6 (Failure to Exercise Professional Judgment)  
7 (Bus. & Prof. Code § 4306.5, subd. (b))

8 26. Respondents David Matsuo and Vivian Matsuo have subjected their Pharmacist  
9 Licenses to disciplinary action for failing to exercise or implement their best professional  
10 judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled  
11 substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.  
12 (Bus. & Prof. Code § 4306.5, subd. (b)). In particular,

13 a. From January 3, 2014 to April 8, 2015, Respondent David Matsuo, while  
14 working at Respondent SV Pharmacy, compounded domperidone 10 mg, 20 mg, 30 mg, and 40  
15 mg capsules and dispensed to patients approximately 28,913 capsules which were compounded  
16 from domperidone.

17 b. From January 3, 2014 to April 8, 2015, Respondent Vivian Matsuo, while  
18 working at Respondent SV Pharmacy, compounded domperidone 10 mg, 20 mg, 30 mg, and 40  
19 mg capsules and dispensed to patients 7,877 capsules which were compounded from  
20 domperidone.

21 c. In both instances, the bulk container of domperidone stated "Not for human  
22 use, not for use in food producing animals."

23 THIRD CAUSE FOR DISCIPLINE  
24 (Failure to Maintain Compounding Equipment)  
25 (Cal. Code Regs., title 16, § 1735.6, subd. (b))

26 27. Respondents SV Pharmacy, David Matsuo, Vivian Matsuo, and Foo have subjected  
27 their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to  
28 store, use, and maintain equipment used to compound drug products in accordance with  
29 manufacturers' specifications. In particular, since 2010, SV Pharmacy, David Matsuo, Vivian  
30 Matsuo, and Foo used and maintained a powder hood to compound domperidone, and that

1 powder hood had not been certified according to manufacturer's guidelines or certified annually,  
2 as required by the manufacturer.

3 FOURTH CAUSE FOR DISCIPLINE  
4 (Failure to Maintain Operational Standards)  
(Cal. Code Regs., title 16, § 1714, subd. (c))

5 28. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their  
6 Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to  
7 maintain the pharmacy and equipment in a clean and orderly condition. (Cal. Code Regs., title  
8 16, § 1714, subd. (c)). In particular, during an inspection of Respondent SV Pharmacy on April  
9 8, 2015, two balances located in the powder hood were discovered with a visible amount of  
10 powder residue and had not been cleaned. Respondent Vivian Matsuo, as the PIC, and  
11 Respondent David Matsuo, as a compounding pharmacist, should have made sure daily cleaning  
12 of the equipment was performed.

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14 FIFTH CAUSE FOR DISCIPLINE  
15 (Failure to Obtain Drugs from Reliable Suppliers, Acquire and Retain  
Certificates of Purity or Analysis)  
16 (Cal. Code Regs., title 16, § 1735.3, subd. (c))

17 29. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their  
18 Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to  
19 obtain chemicals, bulk drug substances, drug products, or compounds used to compound drug  
20 products from a reliable supplier and/or acquire and retain certificates of purity or analysis. (Cal.  
21 Code Regs., title 16, § 1735.3, subd. (c)). In particular, during an inspection of Respondent SV  
22 Pharmacy on April 8, 2015, a Board investigator found many bulk chemicals that had no  
23 certificate of analysis. Respondent Vivian Matsuo, as the PIC, and Respondent David Matsuo, as  
24 a compounding pharmacist, should have overseen the process and ensured each bulk chemical  
25 used in the process of compounding complied with the law.  
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SIXTH CAUSE FOR DISCIPLINE  
(Failure to Dispense Using Compliant Patient-Centered Labels)  
(Cal. Code Regs., title 16, § 1707.5, subd. (a)(1))

30. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for using non-compliant labels for drug containers dispensed to patients. (Cal. Code Regs., title 16, § 1707.5, subd. (a)(1)). In particular, during an inspection of Respondent SV Pharmacy on April 8, 2015, a Board investigator found the pharmacy's prescription labels were printed in approximately 10 point sans serif typeface, rather than 12 point as required by law. Respondent Vivian Matsuo, as the PIC, and Respondent David Matsuo, as a pharmacist, were responsible for making sure the prescription labels were compliant with the law.

SEVENTH CAUSE FOR DISCIPLINE  
(Failure to Maintain Records of Compounded Drug Products –  
Identity of Pharmacist Reviewing Final Drug Product)  
(Cal. Code Regs., title 16, § 1735.3, subd. (a)(4))

31. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to record the identity of the pharmacist reviewing final drug products. (Cal. Code Regs., title 16, § 1735.3, subd. (a)(4)). In particular, in the course of a Board investigation, it was discovered that the records for the following compounded drug products did not state the verifying final check by a pharmacist:

- a. Domperidone 10 mg on July 31, 2012; June 25, 2013; and July 5, 2013.
- b. Domperidone 20 mg on June 5, 2012; March 10, 2014; September 17, 2014; December 18, 2014; and April 2, 2015.

32. Respondent Vivian Matsuo, as the PIC, and Respondent David Matsuo, as a pharmacist, were responsible for ensuring this documentation was complete.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Compounded Drug Products –  
Identity Personnel who Compounded Drug product)  
(Cal. Code Regs., title 16, § 1735.3, subd. (a)(3))

33. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to record the identity of the pharmacy personnel who compounded drug products. (Cal. Code Regs., title 16, § 1735.3, subd. (a)(3)). In particular, in the course of a Board investigation, it was discovered that the records for the following compounded drug products did not state the identity of the personnel who compounded the drug product:

a. Domperidone 10 mg on March 20, 2015; December 18, 2013; November 29, 2013; June 30, 2010; August 10, 2011; December 22, 2011; November 9, 2011; December 20, 2010; and October 18, 2010.

b. Domperidone 20 mg on August 9, 2014; April 2, 2015; December 26, 2012; February 19, 2013; May 20, 2013; June 27, 2014; November 28, 2011; March 7, 2012; December 3, 2012; November 25, 2012; September 4, 2012; March 16, 2010; June 8, 2010; August 4, 2010; October 12, 2010; January 13, 2011; July 8, 2011; and October 5, 2011.

c. Domperidone 30 mg on April 2, 2015.

34. Respondent Vivian Matsuo, as the PIC, and Respondent David Matsuo, as a pharmacist, were responsible for ensuring this documentation was complete.

NINTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Compounded Drug Products –  
Date Drug Product Compounded)  
(Cal. Code Regs., title 16, § 1735.3, subd. (a)(2))

35. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to record the date a drug product was compounded. (Cal. Code Regs., title 16, § 1735.3, subd. (a)(2)). In particular, in reviewing the domperidone compounding records from January 5, 2010 to April 2, 2015, the following errors were discovered: February 6, 2014 was actually February 6, 2015; November 29, 2013 was actually November 29, 2012; and December 26, 2014 was

1 actually December 26, 2012. Respondent Vivian Matsuo, as the PIC, and Respondent David  
2 Matsuo, as a pharmacist, were responsible for ensuring this documentation was correct.

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4 TENTH CAUSE FOR DISCIPLINE  
(Failure to Maintain Records of Compounded Drug Products –  
5 Expiration Date)  
(Cal. Code Regs., title 16, § 1735.3, subd. (a)(8))

6 36. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their  
7 Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to  
8 record the expiration date of the final compounded drug product. (Cal. Code Regs., title 16, §  
9 1735.3, subd. (a)(8)). In particular, in reviewing the domperidone compounding records from  
10 January 5, 2010 to April 2, 2015, a Board investigator discovered that, on seven of the  
11 compounding logs, the expiration date reads “6 months” instead of the actual expiration. In  
12 addition, two domperidone compounding logs do not state an expiration date. Respondent Vivian  
13 Matsuo, as the PIC, and Respondent David Matsuo, as a pharmacist, were responsible for  
14 ensuring this documentation was correct.

15 ELEVENTH CAUSE FOR DISCIPLINE  
(Failure to Indicate Number of Drugs Prescribed)  
16 (Cal. Code Regs., title 16, §§ 1717.3, subd. (b), and 1761, subd. (a))

17 37. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their  
18 Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to  
19 indicate on a preprinted multiple check-off prescription blank the number of dangerous drugs he  
20 or she prescribed. (Cal. Code Regs., title 16, §§ 1717.3, subd. (b), and 1761, subd. (a)). In  
21 particular, during an investigation on April 8, 2015, a Board investigator discovered a preprinted  
22 check-off list prescription for a dangerous drug where the prescriber did not indicate on the blank  
23 the total number of dangerous drugs he or she has prescribed. This non-compliant prescription  
24 was accepted and dispensed by Respondent SV Pharmacy without clarification and correction.  
25 Respondent Vivian Matsuo, as the PIC, and Respondent David Matsuo, as a pharmacist, were  
26 responsible for ensuring this prescription was clarified and corrected.

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TWELFTH CAUSE FOR DISCIPLINE

(Errors in Prescriptions)  
(Cal. Code Regs., title 16, § 1761, subd. (a))

38. Respondents SV Pharmacy, David Matsuo, and Vivian Matsuo have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for dispensing prescriptions containing a significant error, omission, irregularity, uncertainty, ambiguity or alteration. (Cal. Code Regs., title 16, § 1761, subd. (a)). In particular, a Board investigator discovered the following:

a. Prescription number 5013354 did not state which pharmacist received the refill authorization from the doctor's office.

b. In prescription number 5013424, two strengths of domperidone and three quantities to dispense are written on the face of the prescription and it lacks documentation of clarification by a pharmacist.

c. In prescription number 5013166, two quantities of domperidone to dispense are written on the face of the prescription and it lacks documentation of clarification by a pharmacist.

THIRTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Violation of the Law Governing Pharmacy)  
(Bus. & Prof. Code § 4301, subd. (o); and Health and Safety Code §§ 111375, sub. (c), and 111400)

39. Respondents SV Pharmacy, David Matsuo, Vivian Matsuo, Foo, and Lee have subjected their Pharmacy Permit and Pharmacist Licenses, respectively, to disciplinary action for unprofessional conduct by violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate applicable federal and state laws and regulations governing pharmacy. ((Bus. & Prof. Code § 4301, subd. (o); and Health and Safety Code §§ 111375, sub. (c)), and 111400)). The circumstances are set forth in paragraph 23 through paragraph 38.

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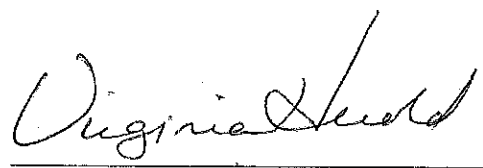
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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this Accusation, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacy Permit Number PHY 44228, issued to Respondent Silicon Valley Pharmacy;
2. Revoking or suspending Pharmacist License Number RPH 36383, issued to Respondent David S. Matsuo;
3. Revoking or suspending Pharmacist License Number RPH 36646, issued to Respondent Vivian Choi Matsuo;
4. Revoking or suspending Pharmacist License Number RPH 35288, issued to Respondent Anabella Sai-Yan Foo;
5. Revoking or suspending Pharmacist License Number RPH 39041, issued to Respondent Jennifer Hwa-Young Lee;
6. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and
7. Taking such other and further action as deemed necessary and proper.

DATED: 6/13/16



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

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