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

In the Matter of the Accusation Against:

Case No. 5743

ORLANDO'S FAIRMONT PHARMACY INC. DBA FAIRMONT PHARMACY, ORLANDO HERNANDEZ 50 Bellefontaine Street, Suite 103 Pasadena, CA 91105 Original Permit No. PHY 32744,

AS TO RESPONDENT CINDY P. CHENG ONLY

ORLANDO HERNANDEZ 173 Berkley Avenue Pasadena, CA 91107 Pharmacist License No. RPH 37523,

and

CINDY P. CHENG Fairmont Pharmacy 50 Bellefontaine Street, Suite 103 Pasadena, CA 91105 Pharmacist License No. RPH 50473

Respondents.

#### **DECISION AND ORDER**

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

This Decision shall become effective at 5:00 p.m. on June 22, 2017.

It is so ORDERED on May 23, 2017.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

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Amy Gutierrez, Pharm.D. Board President

	Visuon Decembri						
1	XAVIER BECERRA Attorney General of California						
2	ARMANDO ZAMBRANO Supervising Deputy Attorney General						
3	NANCY A, KAISER Deputy Attorney General						
4	State Bar No. 192083						
5	300 So. Spring Street, Suite 1702 Los Angeles, CA 90013						
6	Telephone: (213) 897-5794 Facsimile: (213) 897-2804 Attorneys for Complainant	•					
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8	BEFORE THE						
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS						
10	STATE OF CALIFORNIA						
11	In the Matter of the Accusation Against:	Case No. 5743					
12	ORLANDO'S FAIRMONT PHARMACY INC. DBA FAIRMONT PHARMACY,	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC					
13	ORLANDO HERNANDEZ 50 Bellefontaine Street, Suite 103	REPROVAL					
14	Pasadena, CA 91105 Pharmacy Permit No. PHY 32744,	[Bus. & Prof. Code § 495]					
15	ORLANDO HERNANDEZ	4					
16	173 S. Berkley Avenue Pasadena, CA 91107						
17	Pharmacist License No. RPH 37523,						
18	and						
19	CINDY P. CHENG Fairmont Pharmacy	·					
20	50 Bellefontaine Street, Suite 103 Pasadena, CA 91105						
21	Pharmacist License No. RPH 50473						
22	Respondents.						
23		•					
24	In the interest of a prompt and speedy settlement of this matter, consistent with the public						
25	interest and the responsibilities of the Board of Pharmacy of the Department of Consumer Affair						
26	the parties hereby agree to the following Stipulated Settlement and Disciplinary Order for Public						
27	Reproval which will be submitted to the Board for approval and adoption as the final disposition						
28		·					

STIP SETTLEMENT & DISC ORDER FOR PUBLIC REPROVAL (CHENG) (5743)

of the Accusation solely with respect to Cindy P. Cheng. It does not apply to Fairmont Pharmacy and Orlando Hernandez.

#### **PARTIES**

- 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Nancy A. Kaiser, Deputy Attorney General.
- 2. Respondent Cindy P. Cheng (Respondent) is represented in this proceeding by attorney Ivan Petrzelka, whose address is: Ivan Petrzelka, Pharm D., J.D., 28, California Pharmacy Lawyers Law Office of Tony J. Park, Inc., 2855 Michelle Drive, Suite 180, Irvine, CA 92606-1027.

#### **JURISDICTION**

- 3. On or about August 31, 1998, the Board of Pharmacy issued pharmacist license RPH 50473 to Cindy P. Cheng (Respondent). The pharmacist license was in full force and effect at all times relevant to the charges brought in Accusation No. 5743 and will expire on November 30, 2017, unless renewed.
- 4. Accusation No. 5743 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on November 2, 2016. Respondent timely filed her Notice of Defense contesting the Accusation. A copy of Accusation No. 5743 is attached as exhibit A and incorporated herein by reference.

#### ADVISEMENT AND WAIVERS

- 5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5743. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.
- 6. Respondent is fully aware of her legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at

its own expense; the right to confront and cross-examine the witnesses against her; the right to present evidence and to testify on her own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

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

#### CULPABILITY

- 8. Respondent understands and agrees that the charges and allegations in Accusation No. 5743, if proven at a hearing, constitute cause for imposing discipline upon her pharmacist license.
- 9. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up her right to contest those charges. Respondent understands and agrees that should she come before the Board or any other board or bureau of the Department of Consumer Affairs in any further or future proceedings, all of the charges and allegations set forth in the Accusation shall be deemed proven without the necessity of further proof.
- 10. Respondent agrees that her pharmacist license is subject to discipline and she agrees to be bound by the Disciplinary Order below.

#### CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or her counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw her agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public

Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

- 12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.
- 13. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

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#### **DISCIPLINARY ORDER**

IT IS HEREBY ORDERED that Pharmacist License RPH 50473 issued to Respondent Cindy P. Cheng (Respondent) shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 5743, attached as exhibit A.

#### ACCEPTANCE

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

DATED: 2/12/17 CINDY P. CHENG
Respondent

I have read and fully discussed with Respondent Cindy P. Cheng the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Respondent Legentral Legentral and Disciplinary Order for Public Respondent Cindy P. Cheng the terms and conditions

Reproval. I approve its form and content.

DATED: March 4, 2017

IVAN PETRZELKA
Attorney for Respondent

#### **ENDORSEMENT**

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

Dated: April 4, 2017

Respectfully submitted,

XAVIER BECERRA Attorney General of California ARMANDO ZAMBRANO Supervising Deputy Attorney General

NANCY A KAISER

NANCY A. KAISER Deputy Attorney General Attorneys for Complainant

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Exhibit A

Accusation No. 5743

il.			
1	KAMALA D. HARRIS		
2	Attorney General of California ARMANDO ZAMBRANO		
3	Supervising Deputy Attorney General NANCY A. KAISER	<u>.</u>	
4	Deputy Attorney General State Bar No. 192083		
5	300 So. Spring Street, Suite 1702		
6	Los Angeles, CA 90013 Telephone: (213) 897-5794 Facsimile: (213) 897-2804		
7	Attorneys for Complainant		İ
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8	BOARD OF I DEPARTMENT OF C	PHARMACY	
9	STATE OF C	ALIFORNIA	
10			
11	In the Matter of the Accusation Against:	Case No. 5743	
12	Orlando's Fairmont Pharmacy, Inc. dba Fairmont Pharmacy	·	
13	PIC Orlando Hernandez, Owner/Pres. Maria A. Hernandez, Owner/Vice Pres.	ACCUSATION	
14	50 Belle Fontaine Street Pasadena, CA 91105		
15	Original Permit Number PHY 32744		
16	and		
17	Orlando Hernandez		
18	173 South Berkeley Avenue Pasadena, California 91107		
19	Pharmacist License Number RPH 37523		1
20	and		
21	Cindy P. Cheng		
22	50 Belle Fontaine Street Pasadena, CA 91105		
23	Pharmacist License Number RPH 50473		
24	Respondents		
25	The state of the s	. ·	
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(ORLANDO'S FAIRMONT PHARMACY, INC. DBA FAIRMONT PHARMACY, ET AL.) ACCUSATION

#### **PARTIES**

- 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- 2. On or about May 6, 1986, the Board of Pharmacy issued Pharmacy Permit No. PHY 32744 to Orlando's Fairmont Pharmacy, Inc. dba Fairmont Pharmacy (Respondent Pharmacy), located at 50 Belle Fontaine Street, Pasadena, California. Orlando Hernandez, RPH 37523 has been the President and a 50% owner of Respondent Pharmacy since May 6, 1986. Maria Hernandez has been a 50% owner and Vice President of Respondent Pharmacy since May 6, 1986. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2017, unless renewed.
- 3. On or about July 1, 2003, the Board of Pharmacy issued Sterile Compounding Permit Number LSC 99057 to Orlando's Fairmont Pharmacy, Inc. dba Fairmont Pharmacy, located at 50 Belle Fontaine Street, Pasadena, California. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2017, unless renewed.
- 4. On or about January 10, 1983, the Board of Pharmacy issued pharmacist license RPH 37523 to Orlando Hernandez (Respondent Hernandez). The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2018, unless renewed. Respondent Hernandez has been the designated Pharmacist-in-Charge of Respondent Pharmacy since May 6, 1986.
- 5. In a prior disciplinary action entitled In the Matter of the Accusation Against
  Orlando's Fairmont Pharmacy dba Fairmont Pharmacy and Orlando Hernandez, Case Number
  5238, the Board issued a decision, effective December 4, 2015, in which Sterile Compounding
  Permit Number LSC 99057 issued to Respondent Pharmacy and Pharmacist License Number
  RPH 37523 issued to Respondent Hernandez were revoked, the revocations were stayed, and the
  sterile compounding permit and the pharmacist license were placed on probation for five years.

6. On or about August 31, 1998, the Board of Pharmacy issued pharmacist license RPH 50473 to Cindy P. Cheng (Respondent Cheng). The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2017, unless renewed.

#### **JURISDICTION**

- 7. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.
- 8. Section 4300 of the Code provides, in part, that every license issued by the Board is subject to discipline, including suspension or revocation.
  - 9. Section 4302 of the Code states:

"The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee."

- 10. Section 4113 of the Code states, in part:
- "(b) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."
  - 11. 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."

12. Section 4307, subdivision (a), of the Code states, in pertinent part:

"Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of

any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

- (1) Where a probationary license is Issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.
- (2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated."

#### STATUTORY PROVISIONS

#### 13. Section 4301 states:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been produced 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."

#### 14. Section 4342 states:

"(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

Brand Name(s)	Generio Name	Dangerous Drug Per Bus. & Prof. Code § 4022	Scheduled Drug per Health & Safety Code (HSC)	Indications For Use
Motilium	Domperidone	Not FDA Approved	No	Domperidone is available via an Investigational New Drug Application (IND) with the FDA for severe gastrointestinal disorders

- 20. The United States Food and Drug Administration (FDA) does not approve the drug domperidone for human use because of the potential of serious health risks associated with its use, which include cardiac arrhythmias, cardiac arrest, and sudden death. The higher the blood levels of domperidone, the higher the risk. The FDA does not permit the compounding of domperidone in the United States, with the exception of an investigational new drug (IND) application filing with the FDA. Currently, only Dougherty's Pharmacy located in Dallas, Texas, is approved by the FDA to compound domperidone.
- 21. On April 14, 2015, the Board issued a subscriber alert that stated that "Domperidone is not FDA-approved for any use in humans in the United States". It provided that the FDA permits patients with certain gastrointestinal conditions to be treated with domperidone through an Expanded Access Program, and physicians must file an IND application to the FDA to obtain expanded access for domperidone. The alert also noted that "[c]urrently, no pharmacies are authorized to compound domperidone under the Expanded Access program."

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#### CAUSE FOR DISCIPLINE

#### (Unlawful manufacturing and sales of misbranded drugs)

22. Respondents are subject to disciplinary action under sections 4300 and 4301, subdivision (a), in that they violated section 4169, subdivision (a)(3) and Health and Safety Code section 111375, subdivision (e). The circumstances are that between on or about May 27, 2015, and on or about July 21, 2015, while working as a pharmacist at Respondent Pharmacy's facility, located at 50 Belle Fontaine Street, Pasadena, California, Respondent Cheng compounded domperidone 10mg capsules and dispensed to patient D.F. four (4) domperidone prescriptions (800 capsules in total), which were compounded from the unapproved drug, domperidone. Respondents failed to warn patient D.F. of the unapproved and possible unsafe dosage status with the FDA. Respondents continued to dispense domperidone even after the Board's warning on April 14, 2015.

#### DISCIPLINE CONSIDERATIONS

- 23. To determine the degree of discipline, Complainant alleges that:
- a. In a prior disciplinary action entitled In the Matter of the Accusation Against Orlando's Fairmont Pharmacy dba Fairmont Pharmacy and Orlando Hernandez, Case Number 5238, the Board issued a decision, effective December 4, 2015, in which Sterile Compounding Permit Number LSC 99057 issued to Respondent Pharmacy and Pharmacist License Number RPH 37523 issued to Respondent Hernandez were revoked, the revocations were stayed, and the sterile compounding permit and the pharmacist license were placed on probation for five years. The discipline was imposed for violating California Code of Regulations, title 16, section 1751.7 (Violation of Compounding Requirements), Section 4342 (Production of Nonconforming Compound Drugs), and California Code of Regulations, title 16, section 1735.3, subdivision (a)(1) (Violation of Compounding Recordkeeping Requirements). That decision is now final and is incorporated by reference as if fully set forth.
- b. On or about January 21, 2010, a representative of the Board inspected Respondent Pharmacy's facility and issued to Respondent Pharmacy LSC 99057 administrative Citation No. CI 2008 38908 with \$1,000 fine for violating California Code of Regulations, title 16, sections

1716.2, subdivision (a)(3) (Compounding for Future Use) and 1751.7, subdivision (c) (Failure to Comply with Sterile Injectable Compounding Quality Assurance and Process Validation). The Citation is final.

- c. On or about January 21, 2010, a representative of the Board inspected Respondent Pharmacy's facility and issued to Respondent Pharmacy PHY 32744 administrative Citation No. CI 2009 42712 with \$1000 fine for violating Section 4342 and California Code of Regulations, title 16, section 1716 (Variation from Prescriptions). The Citation is final.
- d. On or about January 21, 2010, a representative of the Board inspected Respondent Pharmacy's facility and Issued to Respondent Hernandez, Pharmacist License Number RPH 37523 administrative Citation No. CI 2009 42713 with \$2000 fine for violating Business and Professions Code section 4342 and California Code of Regulations, title 16, sections 1716.2, subdivision (a)(3) (Compounding for Future Use) and 1751.7, subdivision (c) (Failure to Comply with Sterile Injectable Compounding Quality Assurance and Process Validation Requirements). The Citation is final.

#### OTHER MATTERS

- 24. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 32744 issued to Orlando's Fairmont Pharmacy, Inc. dba Fairmont Pharmacy (Respondent Pharmacy), Respondent Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 32744 is placed on probation or until Pharmacy Permit Number PHY 32744 is reinstated if it is revoked.
- 25. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit
  Number PHY 32744 issued to Respondent Pharmacy while Orlando Hernandez has been an
  officer and owner and had knowledge of or knowingly participated in any conduct for which the
  licensee was disciplined, Orlando Hernandez shall be prohibited from serving as a manager,
  administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
  Pharmacy Permit Number PHY 32744 is placed on probation or until Pharmacy Permit Number
  PHY 32744 is reinstated if it is revoked.

26. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit
Number PHY 32744 issued to Respondent Pharmacy while Maria Hernandez has been an officer
and owner and had knowledge of or knowingly participated in any conduct for which the licensee
was disciplined, Maria Hernandez shall be prohibited from serving as a manager, administrator,
owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy
Permit Number PHY 32744 is placed on probation or until Pharmacy Permit Number PHY 32744
is reinstated if it is revoked.

#### PRAYER

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

- 1. Revoking or suspending Pharmacy Permit Number PHY 32744, issued to Orlando's Fairmont Pharmacy, Inc. dba Fairmont Pharmacy;
- Revoking or suspending Pharmacist License RPH 37523 issued to Orlando
   Hernandez;
  - 3. Revoking or suspending Pharmacist License RPH 50473 issued to Cindy P. Cheng;
- 4. Prohibiting Orlando's Fairmont Pharmacy, Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 32744 is placed on probation or until Pharmacy Permit Number PHY 32744 is reinstated, as applicable, if Pharmacy Permit Number PHY 32744 issued to Orlando's Fairmont Pharmacy, Inc. dba Fairmont Pharmacy is revoked;
- 5. Prohibiting Orlando Hernandez from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 32744 is placed on probation or until Pharmacy Permit Number PHY 32744 is reinstated, as applicable, if Pharmacy Permit Number PHY 32744 issued to Orlando's Fairmont Pharmacy, Inc. dba Fairmont Pharmacy is revoked;
- 6. Prohibiting Maria A. Hernandez from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 32744 is placed on probation or until Pharmacy Permit Number PHY 32744 is

(ORLANDO'S FAIRMONT PHARMACY, INC. DBA FAIRMONT PHARMACY, ET AL.) ACCUSATION