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8	BEFORE THE		
9	BOARD OF PHARMACY		
	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
10			
11	In the Matter of the Accusation Against:	Case No. 5973	
12	DECAL DDICC INC. DDA.		
13	DESAI DRUGS, INC., DBA: GUARDIAN PHARMACY,	ACCUSATION	
14	BHAVESH JAYATI DESAI 1823 Commercenter West		
15	San Bernardino, CA 92408		
16	Pharmacy Permit No. PHY 48241		
17	BHAVESH JAYATI DESAI		
18	1823 Commercenter West San Bernardino, CA 92408		
19			
20	Pharmacist-in-Charge No. RPH 53625		
21	Respondents.		
22			
23	Complainant alleges:		
24	<u>PARTIES</u>		
25	1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity		
26	as the Executive Officer of the Board of Pharmacy	as the Executive Officer of the Board of Pharmacy ("Board"), Department of Consumer Affairs.	
27	2. On or about October 30, 2006, the Board issued Pharmacy Permit Number PHY		
28	48241 to Desai Drugs Inc dba Guardian Pharmacy, Bhavesh Jayati Desai, Sumit C. Desai		
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	(DESAI DRUGS INC DBA GUARDIAN PHARM	ACY, BHAVESH JAYATI DESAI, SUMIT C. DESAI) ACCUSATION	

("Respondent Guardian"). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2017, unless renewed.

3. On or about August 21, 2002, the Board issued License Number RPH 53625 to Bhavesh Jayati Desai ("Respondent Bhavesh Desai"). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2017, unless renewed. Respondent Bhavesh Desai was Pharmacist-in-Charge ("PIC") for Respondent Guardian from March 27, 2014 to September 5, 2016.

### **JURISDICTION**

- 4. This Accusation is brought before the 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.
- 5. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.]
- 6. Code section 4300(a) provides that "[e]very license issued may be suspended or revoked."
  - 7. Code section 4300.1 provides:

The expiration, cancellation, forfeiture, or suspension of a Board-issued license, the place 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.

- 8. Code section 118 provides:
- (b) The suspension, expiration, or forfeiture by operation of law of a license issued by a Board in the Department, or its suspension, forfeiture, or cancellation by order of the Board or by order of a court of law, or its surrender without the written consent of the Board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the Board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.

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(c) As used in this section, Board includes an individual who is authorized by any provision of this code to issue, suspend, or revoke a license, and license includes certificate, registration, and permit.

## STATUTORY PROVISIONS

# 9. Code section 4036.5 provides:

Pharmacist-in-charge means a pharmacist proposed by a pharmacy and approved by the Board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

## 10. Code section 4119.5 provides:

- (a) A pharmacy can transfer a reasonable supply of dangerous drugs to another pharmacy.
- (b) A pharmacy may repackage and furnish to a prescriber a reasonable quantity of dangerous drugs and dangerous devices for prescriber office use.

# 11. Code section 4126.5 provides:

- (a) A pharmacy may furnish dangerous drugs only to the following:
- (1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.
- (2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.
  - (3) A licensed wholesaler acting as a reverse distributor.
- (4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
- (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.
- (6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.
  - (7) To another pharmacy under common control.
- (b) Notwithstanding any other provision of law, a violation of this section may subject the person or persons who committed the violation to a fine not to

exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

- (c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.
- (d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means."

## 12. Code section 4301 provides, in pertinent part:

The Board shall take action against any holder of a license who is guilty of unprofessional conduct .... Unprofessional conduct shall include, but is not limited to, any of the following:

- (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
- (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

## 13. Code section 4307, subdivision (a), provides:

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.

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14. Health and Safety Code section 11173, subdivision (a), provides that "[n]o person shall obtain or attempt to obtain controlled substances, (1) by fraud, deceit, misrepresentation, or subterfuge; or (2) by the concealment of a material fact."

### CONTROLLED SUBSTANCE / DANGEROUS DRUGS

15. Code section 4021 provides:

Controlled substance' means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code.

16. Code section 4022 provides, in pertinent part:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:

- (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "RX only," or words of similar import.
- (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

### **COST RECOVERY PROVISION**

17. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to 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.

#### FRAUD INVESTIGATION

- 18. On April 27, 2015, the Board received a referral from an investigator of SCAN Health Plan's Special Investigations Unit alleging that Guardian Pharmacy telephonically provided false patient diagnosis to SCAN Health Plan. The investigator indicated that the false information resulted in the payment of an expensive drug, Fentora, an opioid pain reliever used to manage breakthrough cancer pain in adults with cancer.
- 19. On June 23, 2015, based on the referral, Board Inspector Randall commenced an investigation at Guardian Pharmacy. Inspector Randall's investigation confirmed that on September 26, 2014, a staff member at Guardian Pharmacy placed a phone call to Express

Scripts' Prior Authorization Department and provided a false diagnosis of osteosarcoma for patient MJ.

- 20. The prescription was electronically prescribed on September 26, 2014. The prescription was written for "Fentora 400 mcg buccal tablets," quantity 120 for a 30 day supply. Guardian Pharmacy dispensed 112 tablets for a 28 day supply. The prescription document did not list a diagnosis.
- 21. Inspector Randall's contact with patient MJ's physician's office confirmed that it had no record of any prior authorization of a prescription of Fentora to Express Scripts for patient MJ. The physician's office confirmed that patient MJ did not have cancer.
- 22. Inspector Randall subpoenaed Respondents' phone records which revealed phone calls made from Guardian Pharmacy's phone number on September 26, 2014 to Express Scripts' "physician prior authorization approval line."
- 23. Guardian Pharmacy's prescription label affixed to the prescription indicated that Guardian Pharmacy was paid \$7,097.37 for this prescription on September 24, 2014.
- 24. The patient history indicates that MJ subsequently received six additional prescriptions for Fentora covered by SCAN Health Plan.
- 25. Respondents fraudulently obtained a benefit to which the pharmacy otherwise would not have been entitled. This was a violation of Pharmacy Law.

#### **INSPECTION LEADING TO AUDIT**

- 26. On August 28, 2015, during an inspection at Alliance Pharmacy (PHY 51160), Board Inspector Randall identified invoices showing sales of dangerous drugs from Respondent Guardian Pharmacy to Alliance Pharmacy. The majority of the sales were for promethazine with codeine.
- 27. On September 17, 2015, Board Inspector Randall conducted an inspection at Respondent Guardian Pharmacy located at 1823 Commercenter West, San Bernardino, CA 92408. Respondent Bhavesh Desai was the Pharmacist-in-Charge.
- 28. During this inspection, Pharmacist Sumit Desai (RPH 53579) confirmed that sales were made to Alliance Pharmacy. RPH Sumit Desai and Pharmacy Manager Bautista provided

invoices documenting these sales. RPH Sumit Desai said that the promethazine with codeine may have been unavailable from Alliance Pharmacy's primary wholesalers when the sales were made. He further stated that he and Respondent Bhavesh Desai were friends with Joseph Cherian (RPH 51944), the owner and Pharmacist-in-Charge of Alliance Pharmacy. RPH Sumit Desai said he believed Alliance Pharmacy was unable to obtain a sufficient quantity of the promethazine with codeine to fulfill its prescription orders.

### AUDIT OF SALES

29. Based on Inspector Randall's audit of Respondent Guardian's invoices for the period between January 9, 2015 and July 2, 2015, Respondent Guardian sold the following dangerous drugs to Alliance Pharmacy:

Date	Promethazine/Codeine	Relyyks Patches (15 per box)	Cyclobenzaprine 7.5 mg tablets
01/00/0015	473 mL	(15 her nox)	//:3 mg tablets
01/09/2015	20 bottles	101 (1	-
01/26/2015	25 bottles	10 bottles	
02/06/2015	20 bottles		
02/16/2015		10 bottles	
02/23/2015	20 bottles	,	
03/09/2015	20 bottles		
03/13/2015	20 bottles		
04/07/2015	20 bottles	10 bottles	
04/21/2015	20 bottles		
05/07/2015	20 bottles		300 tablets
05/14/2015		20 bottles	
05/21/2015	20 bottles		
06/18/2015	20 bottles		
07/02/2015		120 bottles	
Total	225 bottles / 106,425 mL	170 boxes / 2,550 patches	300 tablets

- 30. Respondent Guardian and Alliance Pharmacy were not under common control and the sales in question were made pursuant to invoices, not prescriptions. Inspector Randall also determined that the sales were not due to temporary shortages of the medications in question. While the medications may have been unavailable to Alliance Pharmacy through its typical wholesalers, the medications were not unavailable in the market in general.
- 31. In pharmacy practice, a "shortage" typically means there are not enough units of medication in the market as a whole to meet the demands of patients. When one pharmacy is out of a medication, the drug is typically considered "out of stock" at the pharmacy in question.

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Inspector Randall accessed the Food and Drug Administration (FDA)'s website and searched for documented drug shortages. There were no current or resolved market shortages listed on the FDA's database for promethazine/codeine syrup, Relyyks patches, or cyclobenzaprine 7.5 mg tablets.

#### FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Act of Dishonesty, Fraud, Deceit)

32. Respondent Guardian and Respondent Bhavesh Desai are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301(f), and/or Health and Safety Code section 11173(a), in that on September 26, 2014, Respondents committed an act involving moral turpitude, dishonesty, fraud, deceit, or corruption when Respondents' staff telephonically transmitted a false authorization for a prescription of Fentora to patient MJ's insurance carrier, as set forth above in paragraphs 17 through 24, which are incorporated by reference.

## SECOND CAUSE FOR DISCIPLINE\

(Unprofessional Conduct -- Furnishing Dangerous Drugs by Pharmacy)

33. Respondent Guardian and Respondent Bhavesh Desai are subject to disciplinary action for unprofessional conduct pursuant to Code sections 4301(j) and 4126.5(a), in that between January 9, 2015 and July 2, 2015, Respondents furnished dangerous drugs, to wit: 106,425 mL of promethazine/codeine syrup, 2,550 Relyyks patches, and 300 cyclobenzaprine 7.5 mg tablets to Alliance Pharmacy, a pharmacy not under common control, in the absence of a documented shortage of any of the medications, as set forth above in paragraphs 25 through 30, which are incorporated by reference.

#### OTHER MATTERS

34. Pursuant to Code section 4307, subdivision (a), if discipline is imposed on Pharmacy Permit Number PHY 48241 issued to Desai Drugs Inc dba Guardian Pharmacy, Desai Drugs Inc 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 48241 is placed on probation or until Pharmacy Permit Number PHY 48241 is reinstated if it is revoked.

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Permit Number PHY 48241 issued to Desai Drugs Inc dba Guardian Pharmacy while Bhavesh Jayati Desai has been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Bhavesh Jayati Desai 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 48241 is placed on probation or until Pharmacy Permit Number PHY 48241 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 48241, issued to Desai Drugs Inc dba Guardian Pharmacy;
- 2. Revoking or suspending Pharmacist-in-Charge Number RPH 53625, issued to Bhavesh Jayati Desai;
- 3. Prohibiting Desai Drugs 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 48241 is placed on probation or until Pharmacy Permit Number PHY 48241 is reinstated if Pharmacy Permit Number 48241 issued to Desai Drugs Inc dba Guardian Pharmacy is revoked;
- 4. Prohibiting Bhavesh Jayati Desai from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 48241 is placed on probation or until Pharmacy Permit Number PHY 48241 is reinstated if Pharmacy Permit Number 48241 issued to Desai Drugs Inc dba Guardian Pharmacy is revoked;
- 5. 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,

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1	6. Taking such other and further action as deemed necessary and proper.
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3	DATED: 4/14/17 Viginia Heeld
4	VIRGINIA HEROLD Executive Officer
5	Board of Pharmacy Department of Consumer Affairs State of California
6	State of California  Complainant
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