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1 2 3 4 5 6 7 8	XAVIER BECERRA Attorney General of California MARC D. GREENBAUM Supervising Deputy Attorney General ZACHARY T. FANSELOW Deputy Attorney General State Bar No. 274129 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 897-2562 Facsimile: (213) 897-2562 Facsimile: (213) 897-2804 Attorneys for Complainant BEFORE BOARD OF PH DEPARTMENT OF CO STATE OF CA	IARMACY NSUMER AFFAIRS
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10	In the Matter of the Accusation Against:	Case No. 5724
11 12	CARDINAL HEALTH 27680 Avenue Mentry Valencia, CA 91355 MICHAEL KAUFMAN, Chief Executive Officer	ACCUSATION
13	ERIC TORREZ, Designated Representative-in-	
14	Charge	
15	Original Wholesale Permit No. WLS 3176	
16 17	Respondent.	
18	Complainant alleges:	
19	PARTIES	
20	1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity	
21	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.	
22	2. On or about May 23, 1996, the Board of Pharmacy issued Original Wholesale Permit	
23	Number WLS 3176 to Cardinal Health, with Michael Kaufmann as the Chief Executive Officer	
24	since June 25, 2010, Jon Giacomin, Stephen Reardon, Warren Hastings, and Craig Morford as	
25	Vice Presidents since June 25, 2010, and Eric Torrez as the Designated Representative-in-Charge	
26	since October 19, 2012 ("Respondent"). The Wholesale Permit was in full force and effect at all	
27	times relevant to the charges brought herein and will expire on May 1, 2017, unless renewed.	
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		ACCUSATION

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 JURISDICTION

 3. This Accusation is brought before the Board of Pharmacy, Department of Consumer Affairs ("Board"), under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

 4. Section 4300 provides, in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

5. 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."

STATUTORY PROVISIONS

6. Section 4022 states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, 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.

"(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ______," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

"(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."

7. Section 4022.5 states:

(a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.

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(b) "Designated representative-in-charge" means a designated representative or a pharmacist proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board as the supervisor or manager responsible for ensuring the wholesaler's or veterinary food-animal drug retailer's compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

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8. Section 4059.5, subdivision (a), states:

"Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative shall sign for and receive the delivery."

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9. Section 4160, subdivision (d), states:

"Every wholesaler shall be supervised or managed by a designated representative-incharge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license without identification of an approved designated representative-incharge for the wholesaler. The designated representative-in-charge shall maintain an active license as a designated representative with the board at all times during which he or she is designated as the designated representative-in-charge."

10. 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 issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

"(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

- 8 "(j) The violation of any of the statutes of this state, of any other state, or of the United
 9 States regulating controlled substances and dangerous drugs.
- "(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."

15 11. Health and Safety Code section 11153.5, subdivision (a), states: "No wholesaler or
16 manufacturer, or agent or employee of a wholesaler or manufacturer, shall furnish controlled
17 substances for other than legitimate medical purposes."

COST RECOVERY

12. Section 125.3 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.

CONTROLLED SUBSTANCES AND DANGEROUS DRUGS

 Alprazolam, brand name Xanax, is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d)(1), and a dangerous drug pursuant to Business and Professions Code section 4022.

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14. Carisoprodol, brand name Soma, is a Schedule IV controlled substance pursuant to
 Code of Federal Regulations, title 21, section 1308.14, subdivision (c)(6), and a dangerous drug
 pursuant to Business and Professions Code section 4022, as of January 11, 2012.

15. Hydrocodone-Acetaminophen, brand name Norco, is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(I), and a dangerous drug pursuant to Business and Professions Code section 4022.

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16. Promethazine with codeine syrup is a Schedule V controlled substance pursuant to Health and Safety Code section 11058, subdivision (c)(1), and a dangerous drug pursuant to Business and Professions Code section 4022.

FIRST CAUSE FOR DISCIPLINE

(Furnishing Controlled Substances Other than for a Legitimate Purpose)

17. Respondent is subject to disciplinary action under section 4301, subdivision (e), and Health and Safety Code section 11153.5, subdivisions (a), in conjunction with section 4301, subdivisions (j) and (o), for furnishing controlled substances to a pharmacy, Pacific Plaza Pharmacy, that were not being used for legitimate medical purposes.

18. The Board's review of Respondent's sale of controlled substances to Pacific Plaza Pharmacy identified factors of irregularity, or "red flags," that either gave, or should have given, Respondent sufficient information to identify potential problems with the orders from Pacific Plaza Pharmacy and put Respondent on notice to conduct further inquiries into the legitimacy of the orders. These factors of irregularity include that, between 2013 and 2015, Respondent sold increasingly large amounts of controlled substances to Pacific Plaza Pharmacy and, in several instances, the sales of controlled substances from Respondent to Pacific Plaza Pharmacy increased significantly over a matter of months. The controlled substances sold by Respondent to Pacific Plaza Pharmacy include, but are not limited to, alprazolam 2mg, carisoprodol 350mg, hydrocodone with acetaminophen 7.5mg/325mg and 10mg/325mg, and promethazine with codeine syrup. The Board's review also identified discrepancies between the volume of controlled substances sold between lower strengths of a controlled substance and higher strengths, which are more frequently subjected to abuse.

A. Sales of Dangerous Drugs and Controlled Substances Over Time

a. Respondent sold Pacific Plaza Pharmacy a total of zero tablets of alprazolam 2mg in 2012, 1,200 tablets in 2013, and 24,200 tablets in 2014. Additionally, Respondent sold zero tablets of alprazolam 2mg to Pacific Plaza Pharmacy in January of 2014. Sales then trended upward to 5,100 tablets in May of 2014.

b. Respondent sold Pacific Plaza Pharmacy a total of 2,400 tablets of carisoprodol 350mg in 2012, 32,000 tablets in 2013, and 39,400 tablets in 2014. Additionally, Respondent sold 1,500 tablets of carisoprodol 350mg to Pacific Plaza Pharmacy in March of 2013 and sales trended upward to 4,800 tablets in June of 2013. And, after selling Pacific Plaza Pharmacy 1,000 tablets of carisoprodol 350mg in October of 2014, Respondent sold 3,000 tablets in November of 2014 and 6,000 tablets in December of 2014.

c. Respondent sold Pacific Plaza Pharmacy a total of 300 tablets of hydrocodone with acetaminophen 7.5mg/325mg in 2012, 1,700 tablets in 2013, and 25,900 tablets in 2014.
Additionally, Respondent sold zero to 200 tablets of hydrocodone with acetaminophen 7.5mg/325mg per month to Pacific Plaza Pharmacy from March of 2013 to September of 2013. Sales then trended upward to 4,000 tablets in March of 2014.

d. Respondent sold Pacific Plaza Pharmacy a total of 29,500 tablets of hydrocodone
with acetaminophen 10mg/325mg in 2012, 34,000 tablets in 2013, and 60,500 tablets in 2014.
Additionally, Respondent sold 1,500 tablets of hydrocodone with acetaminophen 10mg/325mg to
Pacific Plaza Pharmacy in March of 2013 and sales trended upward to 6,000 tablets in October of
2013, and 9,500 tablets in January of 2014.

e. Respondent sold Pacific Plaza Pharmacy a total of 70 bottles of promethazine with codeine syrup in 2012, 521 bottles in 2013, and 338 bottles in 2014. Additionally, Respondent sold 35 bottles of promethazine with codeine syrup to Pacific Plaza Pharmacy in April of 2013. Sales then increased to 55 bottles in May of 2013 and 61 bottles in June of 2013.

B. Comparison Between Strength of Controlled Substances Sold

a. Board Investigators also compared sales of alprazolam 1mg tablets and alprazolam
2mg tablets to Pacific Plaza Pharmacy between 2012 and 2014. Alprazolam is available in

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0.25mg, 0.5mg, 1mg, and 2mg tablets. Ordering significant amounts of the highest available strength compared to lower strengths is a red flag for illegitimate pharmacy dispensing.

b. Whereas Pacific Plaza Pharmacy's orders of alprazolam 2mg increased from zero tablets in 2012, to 1,200 tablets in 2013, to 24,200 tablets in 2014, Pacific Plaza Pharmacy's ordering of alprazolam 1mg during that same time period remained relatively constant, with 2,000 tablets in 2012, zero tablets in 2013, and 2,000 tablets in 2014.

SECOND CAUSE FOR DISCIPLINE

(Allowing a Non-Pharmacist to Sign for and Receive Dangerous Drugs)

19. Respondent is subject to disciplinary action under section 4059.5, subdivision (a), in conjunction with section 4301, subdivisions (j) and (o), for allowing a non-pharmacist to sign for and receive dangerous drugs. The circumstances include that Respondent delivered dangerous drugs to a pharmacy, The Prescription Shop, on April 5, 2014, August 16, 2014, January 17, 2015, and February 14, 2015, and allowed The Prescription Shop's owner, a non-pharmacist, to sign for and receive the dangerous drugs.

DISCIPLINARY CONSIDERATIONS

20. To determine the degree of discipline, if any, to be imposed on Respondent, Complainant alleges the following:

a. On or about October 18, 2012, the Board of Pharmacy issued Respondent Citation Number CI 2012 54340, with a \$3,100.00 fine. Respondent complied with the citation and it is final. The citation alleged that from on or about June 9, 2011 to on or about March 7, 2012, Respondent delivered dangerous drugs to a pharmacy and allowed a pharmacy technician to sign for and receive the dangerous drugs instead of a pharmacist, in violation of Business and Professions Code section 4059.5, subdivision (a).

b. On or about October 22, 2012, the Board of Pharmacy issued Respondent Citation Number CI 2012 54167, with a \$375.00 fine. Respondent complied with the citation and it is final. The citation alleged that on or about January 6, 2012, Respondent delivered dangerous drugs to an unlicensed pharmacy in violation of Business and Professions Code section 4169, subdivision (a)(1). c. On or about December 20, 2012, the Board of Pharmacy issued Respondent Citation
Number CI 2012 55020, with a \$5,000.00 fine. Respondent complied with the citation and it is
final. The citation alleged that from on or about January 2011 to on or about February 15, 2012,
Respondent allowed non pharmacist staff at a pharmacy to sign for dangerous drug deliveries in
violation of Business and Professions Code section 4059.5, subdivision (a).

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d. On or about July 30, 2013, the Board of Pharmacy issued Respondent Citation
Number CI 2012 57355, with a \$5,000.00 fine. Respondent complied with the citation and it is
final. The citation alleged that between 2007 and 2009, Respondent failed to ensure that
controlled substances and dangerous drugs that were delivered to a pharmacy were ordered for
legitimate medical purposes in violation of Health and Safety Code section 11153.5, subdivisions
(a) and (c).

e. On or about November 5, 2013, the Board of Pharmacy issued Respondent Citation
Number CI 2012 57421, with a \$5,000.00 fine. Respondent complied with the citation and it is
final. The citation alleged that from on or about July 22, 2010, to on or about July 13, 2012,
Respondent allowed non pharmacist staff at a pharmacy to sign for dangerous drug deliveries in
violation of Business and Professions Code section 4059.5, subdivision (a).

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 Original Wholesale Permit Number WLS 3176, issued to Cardinal Health with Michael Kaufmann as the Chief Executive Officer, Jon Giacomin, Stephen Reardon, Warren Hastings, and Craig Morford as Vice Presidents and Eric Torrez as the Designated Representative-in-Charge;

Ordering Cardinal Health 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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3. Taking such other and further action as deemed necessary and proper. 3/8/17 DATED: VIRGINIA HEROLD **Executive Officer** Board of Pharmacy Department of Consumer Affairs State of California Complainant LA2016500075 52361823.doc 17.