1	XAVIER BECERRA Attorney General of California		
2	SHAWN P. COOK Supervising Deputy Attorney General ELAINE YAN Deputy Attorney General State Bar No. 277961 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 269-6683		
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5			
6	Facsimile: (213) 897-2804 Attorneys for Complainant		
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8	BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFEA IRS		
10	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
11	In the Matter of the Accusation Against:	Case No. 6329	
12	CARDINAL HEALTH, DBA PARMED	Cuse 140. 0329	
13	PHARMACEUTICALS, LLC 4220 Hyde Park Blvd.	FIRST AMENDED ACCUSATION	
14	Niagara Falls, NY 14305		
15	Out of State Distributor License No. OSD 4895		
16	LINDA J. DUNKLE		
17	5796 West St. Sanborn, NY 14132		
18	Designated Representative License No. EXC 21821	Designated Representative License No.	
19	Respondents.		
20			
21	Complainant alleges:		
22	PART		
23	1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity		
24	as the Interim Executive Officer of the Board of Pharmacy, Department of Consumer Affairs		
25	(Board).		
26	2. On or about May 10, 2007, the Board issued Out of State Distributor License Number		
27	OSD 4895 to Cardinal Health, d.b.a., Parmed Pharmaceuticals, LLC (Respondent Cardinal		
28	Health). The Out of State Distributor License was in full force and effect at all times relevant to		
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the charges brought herein, was cancelled on June 28, 2018, and has not been reinstated.

3. On or about September 11, 2012, the Board issued Designated Representative License Number EXC 21821 to Linda J. Dunkle (Respondent Dunkle). The Designated Representative License was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2019, unless renewed.

# **JURISDICTION**

- 4. This Accusation is brought before the Board, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.
- 5. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.
- 6. Section 4300.1 of the Code provides that the expiration, cancellation, forfeiture, or suspension of a Board-issued license, 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

7. Section 4301 of the Code 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 includes, but is not limited to, any of the following:

(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.

. . . .

(*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."

8. Section 4022.5 of the Code states, in pertinent part:

. . . .

- (b) "Designated representative-in-charge" means a designated representative or designated representative-reverse distributor, 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."
  - 9. Section 4043 of the Code, state:
- (a) "Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.
- 10. Section 4059.5, subdivision (a) of the Code, states in pertinent part that, "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."
- 11. Section 4116, subsection (a) of the Code states that, no person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the

pharmacist remains present in the pharmacy during all times as the authorized individual is present.

- 12. Section 4163, subdivision (a) of the Code, states in pertinent part: "A manufacturer, wholesaler, repackager, or pharmacy may not furnish a dangerous drug or dangerous device to an unauthorized person."
  - 13. Health and Safety Code section 11209, states, in pertinent part:
- "(a) No person shall deliver Schedule II, III, or IV controlled substances to a pharmacy or pharmacy receiving area, nor shall any person receive controlled substances on behalf of a pharmacy unless, at the time of delivery, a pharmacist or authorized receiving personnel signs a receipt showing the type and quantity of the controlled substances received. Any discrepancy between the receipt and the type or quantity of controlled substances actually received shall be reported to the delivering wholesaler or manufacturer by the next business day after delivery to the pharmacy.
  - (b) The delivery receipt and any record of discrepancy shall be maintained by the wholesaler or manufacturer for a period of three years.
  - (c) A violation of this section is a misdemeanor."

...

## **REGULATIONS**

- 14. California Code of Regulations, title 16, section 1783, states, in pertinent part:
- "(a) A manufacturer or wholesaler shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer or wholesaler shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person."

#### **COSTS**

15. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation of the licensing act to pay a sum not to exceed its reasonable costs of investigation and enforcement.

# **DISCIPLINE CONSIDERATIONS** 26. On June 18, 2018, the Board issued Citation No. CI 2017 80280 to Respondent 2 Cardinal Health. The Board cited Respondent Cardinal Health for violating California Business 3 and Professions Code section 4059.5, subdivision (a), in that Respondent Cardinal Health sold 4 and shipped dangerous drugs to a pharmacy, but the dangerous drugs were not signed for by a 5 pharmacist. The Board fined Respondent Cardinal Health in the amount of \$1,000.00. 6 **PRAYER** 7 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, 8 9 and that following the hearing, the Board of Pharmacy issue a decision: 10 Revoking or suspending Out of State Distributor License Number OSD 4895, issued to Cardinal Health, doing business as Parmed Pharmaceuticals, LLC; 11 2. Revoking or suspending Designated Representative License Number EXC 21821, 12 issued to Linda J. Dunkle; 13 2. 14 Ordering Cardinal Health, doing business as Parmed Pharmaceuticals, LLC, and Linda J. Dunkle to pay the Board of Pharmacy the reasonable costs of the investigation and 15 enforcement of this case, pursuant to Business and Professions Code section 125.3; and 16 3. Taking such other and further action as deemed necessary and proper. 17 18 19 Une Sodergram May 10, 2019 20 DATED: ANNE SODERGREN Interim Executive Officer **Board of Pharmacy** 22 Department of Consumer Affairs State of California 23 Complainant 24 25 26

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DOJ Matter ID: LA2018500075

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1	XAVIER BECERRA		
2	Attorney General of California SHAWN P. COOK Supervising Deputy Attorney General		
3	ELAINE YAN Deputy Attorney General		
4	State Bar No. 277961 300 So. Spring Street, Suite 1702		
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17	5796 West St. Sanborn, NY 14132		
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21	Complainant alleges:		
22	PAR	TIES	
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the charges brought herein and will expire on May 1, 2019, unless renewed.

3. On or about September 11, 2012, the Board issued Designated Representative License Number EXC 21821 to Linda J. Dunkle (Respondent Dunkle). The Designated Representative License was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2019, unless renewed.

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