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9	BEFORE THE BOARD OF PHARMACY	
10	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA	
11		·
12	In the Matter of the Accusation Against:	Case No. 4928
13	CARDINAL HEALTH Cardinal Health	
14	2045 Interstate Drive Lakeland, FL 33805	ACCUSATION
15	Out of State Distributor License No. OSD	
16	4820	
17	and	
18		
19	Joyce R. Butler 1401 Holy Cow Road	
	Polk City, FL 33868	
20	Designated Representative-in-Charge	
21	License No. EXC 20146	
22	Respondents.	·
23		
24	Complainant alleges:	
25		
26	PARTIES	
27	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity	
28	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.	
	Accusation	

Accusation

- 2. On or about April 21, 2010, the Board of Pharmacy issued Out of State Distributor License Number OSD 4820 to Cardinal Health (Respondent Cardinal Health). The Out of State Distributor License was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2014, unless renewed.
- 3. On or about May 13, 2009, the Board of Pharmacy issued Designated Representative-in-Charge License Number EXC 20146 to Joyce R. Butler (Respondent Butler) as a designated representative in California. The EXC License was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2014, unless renewed.

JURISDICTION

- 4. 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 unless otherwise indicated.
 - 5. Section 4300 of the Code states, in pertinent part:
 - "(a) Every license issued may be suspended or revoked. . . . "

STATUTORY PROVISIONS

- 6. Section 4161 of the Code states, in pertinent part:
- "(a) A person located outside this state that (1) ships, sells, mails, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler.

"...

- (j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. . . ."
 - 7. Section 4300.1 of the Code 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."

8. 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 procured by fraud or misrepresentation or issued by mistake.

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

"...

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

COST RECOVERY

9. 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.

RESPONDENT CARDINAL HEALTH

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Discipline by Another State)

- 10. Respondent Cardinal Health is subject to disciplinary action under section 4301(n) of the Code in that Cardinal Health's Drug Enforcement Administration (DEA) registration for its Lakeland Distribution Center, located in Florida, has been disciplined by the United States Department of Justice, Drug Enforcement Administration. The circumstances are as follows:
- 11. On or about May 14, 2012, Respondent Cardinal entered into an Administrative Memorandum of Agreement (MOA) with the United States Department of Justice, Drug Enforcement Administration based upon the following facts: (1) Cardinal is registered with DEA at 28 facilities as distributers of Schedule II-V controlled substances, under provisions of the Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 et seq.; (2) in September 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA"); (3) Cardinal's Lakeland distribution facility ("Cardinal Lakeland") was registered with the DEA as a distributor of Schedule II-V controlled

substances, with an expiration date of May 31, 2012; and (4) on February 2, 2012, the DEA issued an order to show cause and immediate suspension of registration to Cardinal Lakeland.

- a. The order to show cause, referenced above, alleged that: (1) Despite the 2008 MOA, Cardinal Lakeland failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels as evidenced by sales to certain customers of Cardinal; (2) Cardinal Lakeland failed to report suspicious orders of controlled substances as required by 21 C.F.R. § 1304.74(b); and (3) Cardinal Lakeland failed to conduct meaningful due diligence of its retail pharmacies, including its retail chain pharmacy customers to ensure that controlled substances were not diverted into other than legitimate channels.
- b. In the MOA, Cardinal admitted that its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate.
- c. Under the terms of the MOA, the agreement remains in full force and effect until May 14, 2017 (five years from its effective date, May 14, 2012). Under the terms of the MOA, Cardinal agreed to: (1) implement various control procedures to ensure that it did not commit further conduct as described in subparagraph (a) above; (2) continued suspension of its authority to handle controlled substances at Cardinal Lakeland until May 15, 2014; and (3) fully cooperate with the DEA. Under the terms of the MOA, the DEA agreed to lift the suspension of Cardinal Lakeland's DEA registration on May 14, 2014, so long as Cardinal complied with the terms of the agreement.

RESPONDENT BUTLER

SECOND CAUSE FOR DISCIPLINE

(Failure to Ensure Compliance With State and Federal Laws Governing Wholesalers)

12. Respondent Butler is subject to disciplinary action under section 4161(j) of the Code in that as the Designated Representative-In-Charge of Respondent Cardinal, Butler failed to ensure Cardinal's compliance with state and federal laws governing wholesalers. The circumstances are described with more particularity in paragraph 11, and all of its subparts, and as follows:

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Accusation