1	Kamala D. Harris	
2	Attorney General of California KENT D. HARRIS	•
3	Supervising Deputy Attorney General PHILLIP L. ARTHUR	
4	Deputy Attorney General State Bar No. 238339	
5	1300 I Street, Suite 125 P.O. Box 944255	
6	Sacramento, CA 94244-2550	
_	Telephone: (916) 322-0032 Facsimile: (916) 327-8643	
7	E-mail: Phillip.Árthur@doj.ca.gov Attorneys for Complainant	· · ·
8	BEFOI	RETHE
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS	
10	STATE OF C	CALIFORNIA
11	In the Matter of the Accusation Against:	Case No. 4928
12	CARDINAL HEALTH	Case No. 4928
13	Cardinal Health	
14	2045 Interstate Drive Lakeland, FL 33805	ACCUSATION
15	Out of State Distributor License No. OSD	
16	4820	
17	and	
18	Joyce R. Butler	
19	1401 Holy Cow Road Polk City, FL 33868	
20	Designated Representative-in-Charge	
21	License No. EXC 20146	
22	Respondents.	
23		
24		
25	Complainant alleges:	
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.	
		1
		Accusatio

111212111

1	2.	On or about April 21, 2010, the Board of Pharmacy issued Out of State Distributor	
2	License Number OSD 4820 to Cardinal Health (Respondent Cardinal Health). The Out of State		
3	Distributor License was in full force and effect at all times relevant to the charges brought herein		
4	and will expire on April 1, 2014, unless renewed.		
5	3.	On or about May 13, 2009, the Board of Pharmacy issued Designated Representative-	
6	in-Charge l	License Number EXC 20146 to Joyce R. Butler (Respondent Butler) as a designated	
7	representat	ive in California. The EXC License was in full force and effect at all times relevant to	
8	the charges	s brought herein and will expire on May 1, 2014, unless renewed.	
9		JURISDICTION	
10	4.	This Accusation is brought before the Board of Pharmacy (Board), Department of	
11	Consumer	Affairs, under the authority of the following laws. All section references are to the	
12	Business a	nd Professions Code unless otherwise indicated.	
13	5.	Section 4300 of the Code states, in pertinent part:	
14	"(a)	Every license issued may be suspended or revoked "	
15		STATUTORY PROVISIONS	
16	6.	Section 4161 of the Code states, in pertinent part:	
17	"(a)	A person located outside this state that (1) ships, sells, mails, or delivers dangerous	
18	drugs or dangerous devices into this state or (2) sells, brokers, or distributes dangerous drugs or		
19	devices within this state shall be considered a nonresident wholesaler.		
20	··· ·		
21	(j) J	The designated representative-in-charge shall be responsible for the nonresident	
22	wholesale	r's compliance with state and federal laws governing wholesalers"	
23	7.	Section 4300.1 of the Code states:	
24	"The	e expiration, cancellation, forfeiture, or suspension of a board-issued license by	
25	operation	of law or by order or decision of the board or a court of law, the placement of a license	
26	on a retire	d status, or the voluntary surrender of a license by a licensee shall not deprive the board	
27	of jurisdic	tion to commence or proceed with any investigation of, or action or disciplinary	
28	proceedin	g against, the licensee or to render a decision suspending or revoking the license."	
		2	
	II	Accusation	

8. Section 4301 of the Code states, in pertinent part: 1 "The board shall take action against any holder of a license who is guilty of unprofessional 2 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. 3 Unprofessional conduct shall include, but is not limited to, any of the following: 4 <sup>11</sup>... 5 (n) The revocation, suspension, or other discipline by another state of a license to practice 6 pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter. 7 . ." 8 **COST RECOVERY** 9 9. Section 125.3 of the Code states, in pertinent part, that the Board may request the 10 administrative law judge to direct a licentiate found to have committed a violation or violations of 11 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and 12 enforcement of the case. 13 **RESPONDENT CARDINAL HEALTH** 14 FIRST CAUSE FOR DISCIPLINE 15 (Unprofessional Conduct–Discipline by Another State) 16 Respondent Cardinal Health is subject to disciplinary action under section 4301(n) of 17 10. the Code in that Cardinal Health's Drug Enforcement Administration (DEA) registration for its 18 19 Lakeland Distribution Center, located in Florida, has been disciplined by the United States 20 Department of Justice, Drug Enforcement Administration. The circumstances are as follows: On or about May 14, 2012, Respondent Cardinal entered into an Administrative 21 11. Memorandum of Agreement (MOA) with the United States Department of Justice, Drug 22 Enforcement Administration based upon the following facts: (1) Cardinal is registered with DEA 23 at 28 facilities as distributers of Schedule II-V controlled substances, under provisions of the 24 Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 et seq.; (2) in September 25 26 2008, Cardinal entered into a Settlement and Release Agreement and Administrative 27 Memorandum of Agreement ("2008 MOA"); (3) Cardinal's Lakeland distribution facility 28 ("Cardinal Lakeland") was registered with the DEA as a distributor of Schedule II-V controlled

3

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.

The order to show cause, referenced above, alleged that: (1) Despite the 2008 a. 3 MOA, Cardinal Lakeland failed to maintain effective controls against diversion of particular 4 controlled substances into other than legitimate medical, scientific, and industrial channels as 5 evidenced by sales to certain customers of Cardinal; (2) Cardinal Lakeland failed to report 6 suspicious orders of controlled substances as required by 21 C.F.R. § 1304.74(b); and (3) Cardinal 7 Lakeland failed to conduct meaningful due diligence of its retail pharmacies, including its retail 8 chain pharmacy customers to ensure that controlled substances were not diverted into other than 9 legitimate channels. 10

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 13 until May 14, 2017 (five years from its effective date, May 14, 2012). Under the terms of the 14 MOA, Cardinal agreed to: (1) implement various control procedures to ensure that it did not 15 commit further conduct as described in subparagraph (a) above; (2) continued suspension of its 16 authority to handle controlled substances at Cardinal Lakeland until May 15, 2014; and (3) fully 17 cooperate with the DEA. Under the terms of the MOA, the DEA agreed to lift the suspension of 18 Cardinal Lakeland's DEA registration on May 14, 2014, so long as Cardinal complied with the 19 terms of the agreement. 20

## **RESPONDENT BUTLER**

## SECOND CAUSE FOR DISCIPLINE

23

24

21

22

(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

25 || in that as the Designated Representative-In-Charge of Respondent Cardinal, Butler failed to

26 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 asfollows:

·		
1	13. Since April 21, 2010, Respondent Butler has served as the Designated	
2	Representative-In-Charge for Respondent Cardinal.	
3	14. Respondent Cardinal was disciplined by the DEA, through the MOA and as described	
4	in more particularity in paragraph 11 and all of its subparts, for violating state and federal laws	
5	governing wholesalers while Respondent Butler served as Cardinal's Representative-In-Charge.	
6	PRAYER	
7	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,	
8	and that following the hearing, the Board of Pharmacy issue a decision:	
9	1. Revoking or suspending Out of State Distributor License Number OSD 4820, issued	
10	to Cardinal Health;	
11	2. Revoking or suspending Designated Representative-in-Charge License Number EXC	
12	20146, issued to Joyce R. Butler;	
13	3. Ordering Cardinal Health and Joyce R. Butler to pay the Board of Pharmacy the	
14	reasonable costs of the investigation and enforcement of this case, pursuant to Business and	
15	Professions Code section 125.3; and	
16	4. Taking such other and further action as deemed necessary and proper.	
17		
18		
19 20	DATED: 11/4/13 VIRGINIA REPOLD	
21	Executive Officer Board of Pharmacy	
22	Department of Consumer Affairs State of California	
23	Complainant	
24	SA2013112700	
25	11176460.doc	
26		
27		
28		
	5	
[	Accusation	

Accusation