BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

Case No. 4928

CARDINAL HEALTH

2045 Interstate Drive Lakeland, FL 33805

Out of State Distributor License No. OSD 4820

and

JOYCE R. BUTLER

1401 Holy Cow Road Polk City, FL 33868

Designated Representative-in-Charge License No. EXC 20146

Respondents.

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on May 5, 2014.

It is so ORDERED on April 30, 2014.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

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By

STANLEY C. WEISSER Board President

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			
7	Telephone: (916) 322-0032 Facsimile: (916) 327-8643 Facsily Phillip Arthur (916) as gard			
	E-mail: Phillip.Arthur@doj.ca.gov Attorneys for Complainant			
8	BEFORE THE			
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	STIPULATED SETTLEMENT AND		
13	2045 Interstate Drive Lakeland, FL 33805	DISCIPLINARY ORDER FOR PUBLIC REPROVAL		
14	Out of State Distributor License No. OSD	[Bus. & Prof. Code § 495]		
15	4820			
16	and	·		
17	JOYCE R. BUTLER 1401 Holy Cow Road			
18	Polk City, FL 33868			
19	Designated Representative-in-Charge License No. EXC 20146			
20	Respondents.			
21	Tespondon.			
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23	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-			
24	entitled proceedings that the following matters are true:			
25	<u>PARTIES</u>			
26	1. VIRGINIA HEROLD (Complainant) is the Executive Officer of the Board of			
27	Pharmacy. She brought this action solely in her official capacity and is represented in this matter			
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STIPULATED SETTLEMENT (4928)

by Kamala D. Harris, Attorney General of the State of California, by Phillip L. Arthur, Deputy Attorney General.

- 2. Respondent Cardinal Health (Respondent Cardinal) and Respondent Joyce R. Butler (Respondent Butler) are represented in this proceeding by attorney Susan Trujillo, whose address is: Quarles & Brady, LLP, Two North Central Avenue, Phoenix, AZ 85004.
- 3. On or about April 21, 2010, the Board of Pharmacy issued Out of State Distributor License No. OSD 4820 to Respondent Cardinal. The Out of State Distributor License was in full force and effect at all times relevant to the charges brought in Accusation No. 4928 and will expire on April 1, 2014, unless renewed.
- 4. On or about May 13, 2009, the Board of Pharmacy issued Designated Representative-in-Charge License No. EXC 20146 to 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 in Accusation No. 4928 and will expire on May 1, 2014, unless renewed.

JURISDICTION

5. Accusation No. 4928 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs and is currently pending against Respondents. The Accusation and all other statutorily required documents were properly served on Respondents on November 25, 2013. Respondents timely filed their Notice of Defense contesting the Accusation. A copy of Accusation No. 4928 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 6. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in Accusation No. 4928. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.
- 7. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at their own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to

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compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

- 9. Respondents understand and agree that the charges and allegations in Accusation No. 4928, if proven at a hearing, constitute cause for imposing discipline upon Respondent Cardinal Health's Out of State Distributor License No. OSD 4820, and Respondent Joyce R. Butler's Designated Representative-in-Charge License No. EXC 20146.
- 10. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondents hereby give up their right to contest those charges.
- 11. Respondents agree that Respondent Cardinal Health's Out of State Distributor License No. OSD 4820, and Respondent Joyce R. Butler's Designated Representative-in-Charge License No. EXC 20146, are subject to discipline and agree to the issuance of a letter of public reproval.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any

legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

- 13. The parties understand and agree that Portable Document Format (PDF), electronic, and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including Portable Document Format (PDF), electronic, and facsimile signatures thereto, shall have the same force and effect as the originals.
- 14. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Out of State Distributor License No. OSD 4820 issued to Respondent Cardinal Health (Respondent Cardinal), and Designated Representative-in-Charge License No. EXC 20146 issued to Respondent Joyce R. Butler (Respondent Butler), shall, by way of letter from the Board's Executive Officer, be publicly reproved. The letter shall be in the same form as the letter attached as Exhibit B to this stipulation.

IT IS FURTHER ORDERED that within thirty (30) days from the effective date of this decision, Respondent Cardinal shall pay \$1,505.00 to the Board for its costs associated with the investigation and enforcement of this matter. If Respondent Cardinal fails to pay the Board costs as ordered, Respondent Cardinal shall not be allowed to renew its Out of State Distributor License until Respondent Cardinal pays costs in full.

ACCEPTANCE

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I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Susan Trujillo. I understand the ıd ıal

4	stipulation and the effect it will have on Respondent Cardinal's Out of State Distributor Licens		
5	and my Designated Representative-in-Charge License. I enter into this Stipulated Settlement a		
6	Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to b		
7	bound by the Decision and Order of the Board of Pharmacy. I have the authority to bind Cardi		
8	Health to all the terms of this agreement.		
9			
0	DATED: 3/19/2014 Juge 4. Butler		
1	CARDINAL HEALTH JÖYCE R. BUTLER, DESIGNATED REPRESENTATIVE-IN-CHARGE		
3	Respondent		
.4	DATED: 3/19/2014 Due & Barles		
5	JOYCE RBUTLER BESIGNATED REPRESENTATIVE-IN-CHARGE Respondent		
6			
7	I have read and fully discussed with Respondents Cardinal Health and Joyce R. Butler the		
8	terms and conditions and other matters contained in the above Stipulated Settlement and		
9	Disciplinary Order for Public Reproval. I approve its form and content.		
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2	DATED: 3/20/2014 Man Trujillo		
3	Altorney for Respondent		
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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 3/2014

Respectfully submitted,

KAMALA D. HARRIS Attorney General of California KENT D. HARRIS Supervising Deputy Attorney General

PHILIP L. ARTHUR
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 4928

•	, 1	KAMALA D. HARRIS
		Attorney General of California
. 1	2	KENT D. HARRIS Supervising Deputy Attorney General
•	3	PHILLIP L. ARTHUR
,		Deputy Attorney General
	.4	State Bar No. 238339
ì		1300 I Street, Suite 125
	5	P.O. Box 944255 Secrements CA 94244 2550
	6 [Sacramento, CA 94244-2550 Telephone: (916) 322-0032
		Facsimile: (916) 327-8643
•	7 (E-mail; Phillip, Arthur@doj.ca.gov
•		Attorneys for Complainant
	. 8	ינירינים איני ביי איני אויי אויי
•	9	BEFORE THE BOARD OF PHARMACY
• •		DEPARTMENT OF CONSUMER AFFAIRS
	10	STATE OF CALIFORNIA
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	11 }	
	12	In the Matter of the Accusation Against: Case No. 4928
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	13	Cardinal Health
	[2045 Interstate Drive ACCUSATION
	14	Lakeland, FL 33805
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		Out of State Distributor License No. OSD
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•	- 1	Joyce R. Butler
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	20	Polk City, FL 33868
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	21	Designated Representative-in-Charge License No. EXC 20146
t	-^ }	Livense 140, MAC 20140
•	22	Respondents.
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	24	
•		Complainant alleges:
•	25 [
•	000	PARTIES
	26	1 Nimited Time 14 (Chample Inspects Ladies at the American Ladies in Language Ladies in Ladies
,	27	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
	ľ	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
	28	The state of the s
	}	
	}	
	- 1	. Accusati

- 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 parti
- "(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."

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 DBA issued an order to show cause and immediate suspension of registration to Cardinal Lakeland.

- 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:

- 13. Since April 21, 2010, Respondent Butler has served as the Designated Representative-In-Charge for Respondent Cardinal.
- 14. Respondent Cardinal was disciplined by the DEA, through the MOA and as described in more particularity in paragraph 11 and all of its subparts, for violating state and federal laws governing wholesalers while Respondent Butler served as Cardinal's Representative-In-Charge.

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 Out of State Distributor License Number OSD 4820, issued to Cardinal Health;
- Revoking or suspending Designated Representative-in-Charge License Number EXC
 20146, issued to Joyce R. Butler;
- 3. Ordering Cardinal Health and Joyce R. Butler 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
 - 4. Taking such other and further action as deemed necessary and proper.

DATED: 11/4/13

VIRGINIA NEROLD

Executive Officer Board of Pharmacy

Department of Consumer Affairs

State of California
Complainant

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Exhibit B

Letter of Public Reproval in Case No. 4928

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

April 30, 2014

Cardinal Health 2045 Interstate Drive Lakeland, FL 33805

Joyce R. Butler 1401 Holy Cow Road Polk City, FL 33868

Re:

LETTER OF PUBLIC REPROVAL

In the Matter of the Accusation Against:

Cardinal Health, Out of State Distributor License No. OSD 4820, and Joyce R.

Butler, Designated Representative-in-Charge License No. EXC 20146

Dear Cardinal Health and Ms. Butler:

On November 4, 2013, the Board of Pharmacy, Department of Consumer Affairs, State of California, filed an Accusation against your Out of State Distributor License and Designated Representative-in-Charge License. The Accusation alleged that you engaged in unprofessional conduct under California Business and Professions Code sections 4161(j) and 4301(n). The Accusation alleged that on or about May 14, 2012, Cardinal Health entered into an Administrative Memorandum of Agreement (MOA) with the United States Department of Justice, Drug Enforcement Administration (DEA) based upon the following facts: (1) Cardinal Health is registered with the DEA at 28 facilities as distributors 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 Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA"); (3) Cardinal Health'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.

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 Health; (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. In the MOA, Cardinal Health admitted that its due diligence efforts for some pharmacy

Letter of Public Reproval Cardinal Health, OSD 4820 Joyce Butler, EXC 20146 April 30, 2014 Page 2

customers and its compliance with the 2008 MOA, in certain respects, were inadequate. 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 Health agreed to: (1) implement various control procedures to ensure that it did not commit further conduct as described 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. The conduct described above and in the MOA occurred while Joyce R. Butler served as Cardinal Health's Representative-in-Charge.

Taking into consideration that Cardinal Health and Joyce R. Butler have fully complied with the terms of the MOA, and that there are other mitigating circumstances in this case that support the determination that they are safe to practice as an Out of State Distributor and Designated Representative-in-Charge, the Board has decided that the charges warrant a public reproval.

Accordingly, in resolution of this matter under the authority provided under Business and Professions Code section 495, the Board of Pharmacy, Department of Consumer Affairs issues this letter of public reproval.

Sincerely,

VIRGINIAK. HEROLD

Executive Officer

Board of Pharmacv

Department of Consumer Affairs