

**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.

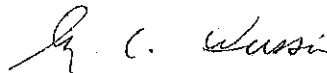
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Repeval 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



By

STANLEY C. WEISSER
Board President

1 KAMALA D. HARRIS
Attorney General of California
2 KENT D. HARRIS
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9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:

Case No. 4928

12 **CARDINAL HEALTH**
13 **2045 Interstate Drive**
14 **Lakeland, FL 33805**

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER FOR PUBLIC
REPROVAL

15 **Out of State Distributor License No. OSD**
16 **4820**

[Bus. & Prof. Code § 495]

17 **and**

18 **JOYCE R. BUTLER**
19 **1401 Holy Cow Road**
20 **Polk City, FL 33868**

21 **Designated Representative-in-Charge**
22 **License No. EXC 20146**

23 Respondents.

24 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
entitled proceedings that the following matters are true:

25 PARTIES

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
28

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

3 2. Respondent Cardinal Health (Respondent Cardinal) and Respondent Joyce R. Butler
4 (Respondent Butler) are represented in this proceeding by attorney Susan Trujillo, whose address
5 is: Quarles & Brady, LLP, Two North Central Avenue, Phoenix, AZ 85004.

6 3. On or about April 21, 2010, the Board of Pharmacy issued Out of State Distributor
7 License No. OSD 4820 to Respondent Cardinal. The Out of State Distributor License was in full
8 force and effect at all times relevant to the charges brought in Accusation No. 4928 and will
9 expire on April 1, 2014, unless renewed.

10 4. On or about May 13, 2009, the Board of Pharmacy issued Designated Representative-
11 in-Charge License No. EXC 20146 to Respondent Butler as a designated representative in
12 California. The EXC License was in full force and effect at all times relevant to the charges
13 brought in Accusation No. 4928 and will expire on May 1, 2014, unless renewed.

14 JURISDICTION

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

20 ADVISEMENT AND WAIVERS

21 6. Respondents have carefully read, fully discussed with counsel, and understand the
22 charges and allegations in Accusation No. 4928. Respondents have also carefully read, fully
23 discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary
24 Order for Public Reproval.

25 7. Respondents are fully aware of their legal rights in this matter, including the right to a
26 hearing on the charges and allegations in the Accusation; the right to be represented by counsel at
27 their own expense; the right to confront and cross-examine the witnesses against them; the right
28 to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to

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

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

6 CULPABILITY

7 9. Respondents understand and agree that the charges and allegations in Accusation No.
8 4928, if proven at a hearing, constitute cause for imposing discipline upon Respondent Cardinal
9 Health's Out of State Distributor License No. OSD 4820, and Respondent Joyce R. Butler's
10 Designated Representative-in-Charge License No. EXC 20146.

11 10. For the purpose of resolving the Accusation without the expense and uncertainty of
12 further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual
13 basis for the charges in the Accusation, and that Respondents hereby give up their right to contest
14 those charges.

15 11. Respondents agree that Respondent Cardinal Health's Out of State Distributor
16 License No. OSD 4820, and Respondent Joyce R. Butler's Designated Representative-in-Charge
17 License No. EXC 20146, are subject to discipline and agree to the issuance of a letter of public
18 reproof.

19 CONTINGENCY

20 12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents
21 understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may
22 communicate directly with the Board regarding this stipulation and settlement, without notice to
23 or participation by Respondents or their counsel. By signing the stipulation, Respondents
24 understand and agree that they may not withdraw their agreement or seek to rescind the
25 stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this
26 stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public
27 Reproof shall be of no force or effect, except for this paragraph, it shall be inadmissible in any
28

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

3 13. The parties understand and agree that Portable Document Format (PDF), electronic,
4 and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Repeval,
5 including Portable Document Format (PDF), electronic, and facsimile signatures thereto, shall
6 have the same force and effect as the originals.

7 14. This Stipulated Settlement and Disciplinary Order for Public Repeval is intended by
8 the parties to be an integrated writing representing the complete, final, and exclusive embodiment
9 of their agreement. It supersedes any and all prior or contemporaneous agreements,
10 understandings, discussions, negotiations, and commitments (written or oral). This Stipulated
11 Settlement and Disciplinary Order for Public Repeval may not be altered, amended, modified,
12 supplemented, or otherwise changed except by a writing executed by an authorized representative
13 of each of the parties.

14 15. In consideration of the foregoing admissions and stipulations, the parties agree that
15 the Board may, without further notice or formal proceeding, issue and enter the following
16 Disciplinary Order:

17 **DISCIPLINARY ORDER**

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

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

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Repeval and have fully discussed it with my attorney, Susan Trujillo. I understand the stipulation and the effect it will have on Respondent Cardinal's Out of State Distributor License and my Designated Representative-in-Charge License. I enter into this Stipulated Settlement and Disciplinary Order for Public Repeval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy. I have the authority to bind Cardinal Health to all the terms of this agreement.

DATED: 3/19/2014 Joyce R. Butler
CARDINAL HEALTH
JOYCE R. BUTLER, DESIGNATED
REPRESENTATIVE-IN-CHARGE
Respondent

DATED: 3/19/2014 Joyce R. Butler
JOYCE R. BUTLER
DESIGNATED REPRESENTATIVE-IN-CHARGE
Respondent

I have read and fully discussed with Respondents Cardinal Health and Joyce R. Butler the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Repeval. I approve its form and content.

DATED: 3/20/2014 Susan Trujillo
SUSAN TRUJILLO
Attorney for Respondent

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ENDORSEMENT

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

Dated: 3/20/14

Respectfully submitted,

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



PHILLIP 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
2 KENT D. HARRIS
Supervising Deputy Attorney General
3 PHILLIP L. ARTHUR
Deputy Attorney General
4 State Bar No. 238339
1300 I Street, Suite 125
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Sacramento, CA 94244-2550
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7 E-mail: Phillip.Arthur@doj.ca.gov
Attorneys for Complainant
8

9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:

Case No. 4928

12 **CARDINAL HEALTH**
13 **Cardinal Health**
2045 Interstate Drive
14 **Lakeland, FL 33805**

ACCUSATION

15 **Out of State-Distributor License No. OSD**
16 **4820**

17 **and**

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

20 **Designated Representative-in-Charge**
21 **License No. EXC 20146**

22 **Respondents.**

23
24 **Complainant alleges:**

25 **PARTIES**

26 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity.
27 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
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1 8. Section 4301 of the Code states, in pertinent part:

2 "The board shall take action against any holder of a license who is guilty of unprofessional
3 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.
4 Unprofessional conduct shall include, but is not limited to, any of the following:

5
6 (n) The revocation, suspension, or other discipline by another state of a license to practice
7 pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

8
9 **COST RECOVERY**

10 9. Section 125.3 of the Code states, in pertinent part, that the Board may request the
11 administrative law judge to direct a licentiate found to have committed a violation or violations of
12 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
13 enforcement of the case.

14 **RESPONDENT CARDINAL HEALTH**

15 **FIRST CAUSE FOR DISCIPLINE**

16 **(Unprofessional Conduct—Discipline by Another State)**

17 10. Respondent Cardinal Health is subject to disciplinary action under section 4301(n) of
18 the Code in that Cardinal Health's Drug Enforcement Administration (DEA) registration for its
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:

21 11. On or about May 14, 2012, Respondent Cardinal entered into an Administrative
22 Memorandum of Agreement (MOA) with the United States Department of Justice, Drug
23 Enforcement Administration based upon the following facts: (1) Cardinal is registered with DEA
24 at 28 facilities as distributors of Schedule II-V controlled substances, under provisions of the
25 Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 *et seq.*; (2) in September
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

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

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

11 .b. In the MOA, Cardinal admitted that its due diligence efforts for some pharmacy
12 customers and its compliance with the 2008 MOA, in certain respects, were inadequate.

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

21 **RESPONDENT BUTLER**

22 **SECOND CAUSE FOR DISCIPLINE**

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

24 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
27 circumstances are described with more particularity in paragraph 11, and all of its subparts, and as
28 follows:

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13. Since April 21, 2010, Respondent Butler has served as the Designated Representative-In-Charge for Respondent Cardinal.

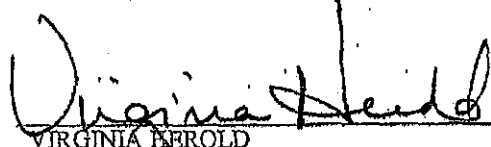
14. Respondent Cardinal was disciplined by the DEA, through the MOA and as described in more particularity in paragraph 11 and all of its subparts, for violating state and federal laws governing wholesalers while Respondent Butler served as Cardinal's Representative-In-Charge.

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;
- 2. 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 PEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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Exhibit B

Letter of Public Repeal in Case No. 4928



California State Board of Pharmacy

1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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 Reapproval
Cardinal Health, OSD 4820
Joyce Butler, EXC 20146
April 30, 2014
Page 2

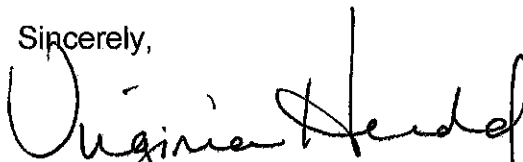
customers and its compliance with the 2008 MOA, in certain respects, were inadequate. Under the terms of the MOA, the agreement remains in full force and effect until May 14, 2017 (five years from its effective date, May 14, 2012).

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 reapproval.

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 reapproval.

Sincerely,



VIRGINIA K. HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs