

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

In the Matter of the Accusation Against:

Case No. AC 2012 4451

**NEW ENGLAND COMPOUNDING CENTER  
697 Waverly Street  
Framingham, MA 01702**

**Non-Resident Pharmacy License No. NRP 586  
Non-Resident Sterile Compounding Pharmacy  
License No. NSC 99216**

Respondent.

**DECISION AND ORDER**

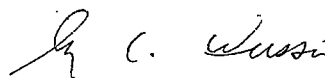
The attached Stipulated Surrender Licenses and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on September 16, 2013.

It is so ORDERED on August 15, 2013.

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 FRANK H. PACOE  
Supervising Deputy Attorney General  
3 JOSHUA A. ROOM  
Supervising Deputy Attorney General  
4 State Bar No. 214663  
455 Golden Gate Avenue, Suite 11000  
5 San Francisco, CA 94102-7004  
Telephone: (415) 703-1299  
6 Facsimile: (415) 703-5480  
*Attorneys for Complainant*

7  
8 **BEFORE THE**  
**BOARD OF PHARMACY**  
9 **DEPARTMENT OF CONSUMER AFFAIRS**  
**STATE OF CALIFORNIA**

10 In the Matter of the Accusation Against:  
11  
12 **NEW ENGLAND COMPOUNDING CENTER**  
697 Waverly Street  
13 Framingham, MA 01702  
14 **Non-Resident Pharmacy License No. NRP 586**  
**Non-Resident Sterile Compounding Pharmacy**  
15 **License No. NSC 99216**  
16 Respondent.

Case No. AC 2012 4451

**STIPULATED SURRENDER OF  
LICENSES AND ORDER**

17 In the interest of a prompt and speedy resolution of this matter, consistent with the public  
18 interest and the responsibility of the Board of Pharmacy of the Department of Consumer Affairs,  
19 the parties hereby agree to the following Stipulated Surrender of Licenses and Order which will  
20 be submitted to the Board for approval and adoption as the final disposition of the Accusation.

21 PARTIES

22 1. Virginia Herold (Complainant), Executive Officer of the Board of Pharmacy, brought  
23 this action solely in her official capacity and is represented herein by Kamala D. Harris, Attorney  
24 General of the State of California, by Joshua A. Room, Supervising Deputy Attorney General.

25 2. New England Compounding Pharmacy dba New England Compounding Center,  
26 Carla Conigliaro, President, Barry Cadden, Pharmacist in Charge (Respondent) is represented in  
27 this proceeding by Paul Cirel, of COLLORA LLP, 100 High Street, Boston, MA 02110-2321.

28 ///





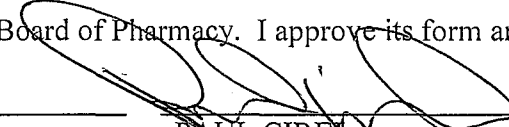


1 7. If Respondent should ever apply or reapply for a new license or certification, or  
2 petition for reinstatement of a license, by any other health care licensing agency in the State of  
3 California, all of the charges and allegations contained in Accusation No. AC 2012 4451 shall be  
4 deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of  
5 Issues or any other proceeding seeking to deny or restrict licensure.

6  
7 ACCEPTANCE

8 I have read and fully discussed with Respondent the terms and conditions and other matters  
9 contained in this Stipulated Surrender of Licenses and Order. Respondent understands the  
10 stipulation and the effect it will have on Respondent's Non-Resident Pharmacy License, and its  
11 Non-Resident Sterile Compounding Pharmacy License. Respondent enters into this Stipulated  
12 Surrender of Licenses and Order voluntarily, knowingly, and intelligently, and agrees to be bound  
13 by the Decision and Order of the Board of Pharmacy. I approve its form and content.

14 DATED: 3/11/13

  
15 PAUL CIREL  
16 COLLORA LLP  
17 Attorneys for Respondent

18 ENDORSEMENT

19 The foregoing Stipulated Surrender of Licenses and Order is hereby respectfully submitted  
20 for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

21 Dated: 3/18/2013

Respectfully submitted,

22 KAMALA D. HARRIS  
23 Attorney General of California  
24 FRANK H. PACOE  
25 Supervising Deputy Attorney General

  
26 JOSHUA A. ROOM  
27 Supervising Deputy Attorney General  
28 Attorneys for Complainant

SF2012403128  
40663558.doc

**Exhibit A**

**Accusation No. AC 2012 4451**

1 KAMALA D. HARRIS  
Attorney General of California  
2 FRANK H. PACOE  
Supervising Deputy Attorney General  
3 JOSHUA A. ROOM  
Deputy Attorney General  
4 State Bar No. 214663  
455 Golden Gate Avenue, Suite 11000  
5 San Francisco, CA 94102-7004  
Telephone: (415) 703-1299  
6 Facsimile: (415) 703-5480  
*Attorneys for Complainant*

7  
8 **BEFORE THE**  
**BOARD OF PHARMACY**  
9 **DEPARTMENT OF CONSUMER AFFAIRS**  
**STATE OF CALIFORNIA**

10 In the Matter of the Accusation Against:

Case No. AC 2012 4451

11 **NEW ENGLAND COMPOUNDING CENTER**  
12 **697 Waverly Street**  
13 **Framingham, MA 01702**

**A C C U S A T I O N**

14 **Non-Resident Pharmacy License No. NRP 586**  
15 **Non-Resident Sterile Compounding Pharmacy**  
16 **License No. NSC 99216**

Respondent.

17 Complainant alleges:

18  
19 PARTIES

20 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity  
21 as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

22 2. On or about April 28, 2004, the Board issued Non-Resident Pharmacy License No.  
23 NRP 586 to New England Compounding Pharmacy dba New England Compounding Center,  
24 Carla Conigliaro, President, Barry Cadden, Pharmacist in Charge (Respondent). The License was  
25 in force and effect at all times relevant herein, and will expire on April 1, 2013, unless renewed.

26 3. On or about June 1, 2004, the Board issued Non-Resident Sterile Compounding  
27 License No. NSC 99216 to Respondent. The License was in force and effect at all times relevant  
28 herein, and will expire on April 1, 2013, unless renewed.



JURISDICTION

1  
2       4.     This Accusation is brought before the Board of Pharmacy (Board), Department of  
3 Consumer Affairs, under the authority of the following laws. All section references are to the  
4 Business and Professions Code (Code) unless otherwise indicated.

5       5.     Section 4011 of the Code provides that the Board shall administer and enforce both  
6 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances  
7 Act [Health & Safety Code, § 11000 et seq.].

8       6.     Section 4300(a) of the Code provides that every license issued by the Board may be  
9 suspended or revoked.

10       7.     Section 118(b) of the Code provides, in pertinent part, that the suspension, expiration,  
11 surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a  
12 disciplinary action during the period within which the license may be renewed, restored, reissued  
13 or reinstated. Section 4402(e) of the Code provides that any non-pharmacist license issued by the  
14 Board may be canceled by the Board if not renewed within 60 days after its expiration, and any  
15 license canceled in this fashion may not be reissued but will instead require a new application.

STATUTORY AND REGULATORY PROVISIONS

16  
17       8.     Section 4301 of the Code provides, in pertinent part, that the Board shall take action  
18 against any holder of a license who is guilty of "unprofessional conduct," defined to include, but  
19 not be limited to, any of the following:

20           (j) The violation of any of the statutes of this state, of any other state, or of the United  
21 States regulating controlled substances and dangerous drugs.

22           (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the  
23 violation of or conspiring to violate any provision or term of this chapter or of the applicable  
24 federal and state laws and regulations governing pharmacy, including regulations established by  
25 the board or by any other state or federal regulatory agency.

26       9.     Health and Safety Code section 109970, in pertinent part, defines "manufacture" to  
27 mean "the preparation, compounding, propagation, processing, or fabrication of any food, drug,  
28 device, or cosmetic."



1 16. A contemporaneous multi-agency investigation involving, among others, the Board,  
2 other California state and local agencies, the Massachusetts Board of Registration in Pharmacy  
3 and/or Department of Public Health, state or local agencies from other states, and the federal  
4 Food and Drug Administration (FDA) and Centers for Disease Control (CDC), confirmed fungal  
5 and/or bacterial contamination of MPA, BS, and CS drug products that had been compounded by  
6 Respondent in or between in or about July 2012 and September 2012. The contaminants found in  
7 the drug products compounded by Respondent included the fungus *Exserohilum rostratum*, and  
8 the bacteria *Paenibacillus pabuli/amolyticus*, *Bacillus idriensis*, *Bacillus flexus*, *Bacillus simplex*,  
9 *Lysinibacillus sp.*, *Bacillus niabensis*, *Bacillus circulans*, *Bacillus lentus*, *Bacillus halmapalus*,  
10 and *Brevibacillus choshinens*. Other findings from the investigation included:

- 11 • That Respondent engaged in large-scale batch compounding of sterile drug products
- 12 for distribution directly to facilities without patient-specific prescriptions;
- 13 • That Respondent failed to follow adequate procedures for sterilizing drug products, or
- 14 for maintaining or validating sterilization and anti-contamination equipment; and
- 15 • That visible black particulate matter was visible in several recalled vials of MPA.

16 17. The total number of patients affected is not known, but to date the investigation has  
17 identified at least four hundred eighty (480) cases in nineteen (19) states, and thirty-three (33)  
18 deaths. At least four (4) facilities in California received contaminated and/or recalled product.

#### 19 CAUSE FOR DISCIPLINE

20 (Manufacturing, Compounding and/or Dispensing Adulterated Drug Product(s))

21 18. Respondent is subject to disciplinary action under section(s) 4301(j) and/or (o) of the  
22 Code, by reference to Health and Safety Code section(s) 109970, 111255, and/or 111295, and/or  
23 21 U.S.C. §§ 331 and/or 351(a), in that, as described above in paragraphs 14 to 17, Respondent  
24 manufactured, compounded, and/or dispensed, caused to be manufactured, compounded, and/or  
25 dispensed, attempted to manufacture, compound, and/or dispense, assisted or abetted in the  
26 manufacture, compounding, and/or dispensing, and/or conspired to manufacture, compound,  
27 and/or dispense, in interstate commerce, preparations or drugs that were adulterated.

28

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 Non-Resident Pharmacy License No. NRP 586, issued to New England Compounding Pharmacy dba New England Compounding Center, Carla Conigliaro, President, Barry Cadden, Pharmacist in Charge (Respondent);

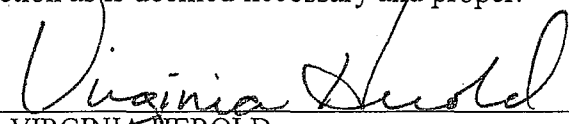
2. Revoking or suspending Non-Resident Sterile Compounding License No. NSC 99216, issued to Respondent;

3. Ordering Respondent to pay the Board the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

4. Taking such other and further action as is deemed necessary and proper.

DATED: \_\_\_\_\_

1/7/13



VIRGINIA HEROLD  
Executive Officer  
Board of Pharmacy  
Department of Consumer Affairs  
State of California  
*Complainant*

SF2012403128  
10996112.doc