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

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By

STANLEY C. WEISSER Board President

1	Kamala D. Harris									
2	Attorney General of California FRANK H. PACOE	· ·								
3	Supervising Deputy Attorney General JOSHUA A. ROOM									
4	Supervising Deputy Attorney General State Bar No. 214663	•								
5	455 Golden Gate Avenue, Suite 11000 San Francisco, CA 94102-7004									
6	Telephone: (415) 703-1299 Facsimile: (415) 703-5480									
7	Attorneys for Complainant									
8	BEFORE									
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA									
ļ	STATE OF CAL	IFORNIA								
10	In the Matter of the Accusation Against:	Case No. AC 2012 4451								
11	NEW ENGLAND COMPOUNDING CENTER									
12	697 Waverly Street Framingham, MA 01702	STIPULATED SURRENDER OF								
13	Non-Resident Pharmacy License No. NRP 586	LICENSES AND ORDER								
14	Non-Resident Sterile Compounding Pharmacy License No. NSC 99216									
15	Respondent.									
16										
17	In the interest of a prompt and speedy resoluti	on of this matter, consistent with the public								
18	interest and the responsibility of the Board of Pharm	nacy 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	<u>PARTIES</u>									
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, Pharmac	cist in Charge (Respondent) is represented in								
27	this proceeding by Paul Cirel, of COLLORA LLP,	100 High Street, Boston, MA 02110-2321.								
28	///									

- 3. On or about April 28, 2004, the Board issued Non-Resident Pharmacy License No. NRP 586 to New England Compounding Pharmacy dba New England Compounding Center, Carla Conigliaro, President, Barry Cadden, Pharmacist in Charge (Respondent). The License was in force and effect at all times relevant to the charges brought in Accusation No. AC 2012 4451 and will expire on April 1, 2013, unless renewed.
- 4. On or about June 1, 2004, the Board issued Non-Resident Sterile Compounding Pharmacy License No. NSC 99216 to Respondent. The License was in force and effect at all times relevant to the charges brought in Accusation No. AC 2012 4451 and will expire on April 1, 2013, unless renewed.

JURISDICTION

5. Accusation No. AC 2012 4451 was filed before the Board of Pharmacy (Board),
Department of Consumer Affairs, and is currently pending against Respondent. The Accusation
and all other statutorily required documents were properly served on Respondent on January 9,
2013. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of
Accusation No. AC 2012 4451 is attached as exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

- 6. Respondent has carefully read, fully discussed with counsel, and understands the allegations in Accusation No. AC 2012 4451. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of Licenses and Order.
- 7. Respondent is fully aware of its 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 its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to 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. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

- 9. Respondent understands that the charges and allegations in Accusation No. AC 2012 4451, if proven at a hearing, constitute cause for imposing discipline upon its Non-Resident Pharmacy License and its Non-Resident Sterile Compounding Pharmacy License. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent gives up its right to contest that cause for discipline exists based on those charges.
- 10. Respondent understands that by signing this stipulation it enables the Board to issue an order accepting the surrender of its Non-Resident Pharmacy License and its Non-Resident Sterile Compounding Pharmacy License without further notice or process.

CONTINGENCY

- 11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its 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 Surrender of Licenses and Order 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.
- 12. The parties understand and agree that facsimile copies of this Stipulated Surrender of Licenses and Order, including facsimile signatures thereto, shall have the same force and effect as the originals.
- 13. This Stipulated Surrender of Licenses and Order 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 Surrender of Licenses and Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

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

ORDER

IT IS HEREBY ORDERED that Non-Resident Pharmacy License No. NRP 586, and Non-Resident Sterile Compounding Pharmacy License No. NSC 99216, each issued to New England Compounding Pharmacy dba New England Compounding Center, Carla Conigliaro, President, Barry Cadden, Pharmacist in Charge (Respondent), are each and both surrendered and accepted by the Board of Pharmacy.

- 1. The surrender of Respondent's Non-Resident Pharmacy License and Non-Resident Sterile Compounding Pharmacy License and the acceptance of the surrendered licenses by the Board constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.
- 2. Respondent shall lose all rights and privileges as a Non-Resident Pharmacy and a Non-Resident Sterile Compounding Pharmacy in California as of the effective date of the Board's Decision and Order.
- 3. Respondent shall cause to be delivered to the Board its pocket licenses, and, if they were issued, its wall certificates, on or before the effective date of the Decision and Order.
- 4. Respondent may not apply, reapply, or petition for any licensure or registration of the Board for three (3) years from the effective date of the Decision and Order.
- 5. If Respondent ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Accusation No. AC 2012 4451 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.
- 6. Respondent shall pay the Board its costs of investigation and enforcement in the amount of \$2,561.00 prior to issuance of a new or reinstated license.

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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: 31113							
15	PAUL CIREL COLLORA LLP							
16	Attorneys for Respondent							
17	ENDORSEMENT							
18	The foregoing Stipulated Surrender of Licenses and Order is hereby respectfully submitted							
19	for consideration by the Board of Pharmacy of the Department of Consumer Affairs.							
20	Dated: 3/0/2 Respectfully submitted,							
21	Dated: 5/18/2013 Respectfully submitted, KAMALA D. HARRIS							
22	Attorney General of California FRANK H. PACOE							
23	Supervising Deputy Attorney General							
24	Jul R							
25	YOSHUA A. ROOM							
26	/Supervising Deputy Attorney General Attorneys for Complainant							
27	SE2012402128							
28	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) 703-1299 Facsimile: (415) 703-5480 Attorneys for Complainant	•								
7		PUT								
8	BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS									
9	STATE OF CAL									
10	T. 1. 3. 4 1 2 1 1 1 1 1 1	G N- A G 2012 4451								
11	In the Matter of the Accusation Against:	Case No. AC 2012 4451								
12	NEW ENGLAND COMPOUNDING CENTER 697 Waverly Street	ACCTICATION								
13	Framingham, MA 01702	ACCUSATION								
14	Non-Resident Pharmacy License No. NRP 586 Non-Resident Sterile Compounding Pharmacy License No. NSC 99216									
15	License No. NSC 99216 Respondent.									
16	Respondent.									
17	Complainant alleges:									
18										
19	PARTIE	<u>ES</u>								
20	Virginia Herold (Complainant) brings th	nis 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 is	ssued 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 v	will expire on April 1, 2013, unless renewed.								
26	3. On or about June 1, 2004, the Board iss	ued Non-Resident Sterile Compounding								
27	License No. NSC 99216 to Respondent. The Licen	se was in force and effect at all times relevant								
28	herein, and will expire on April 1, 2013, unless rene	ewed.								

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 (Code) unless otherwise indicated.
- 5. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].
- 6. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.
- 7. Section 118(b) of the Code provides, in pertinent part, that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated. Section 4402(e) of the Code provides that any non-pharmacist license issued by the Board may be canceled by the Board if not renewed within 60 days after its expiration, and any license canceled in this fashion may not be reissued but will instead require a new application.

STATUTORY AND REGULATORY PROVISIONS

- 8. Section 4301 of the Code provides, in pertinent part, that the Board shall take action against any holder of a license who is guilty of "unprofessional conduct," defined to include, but not be limited to, any of the following:
- (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
- (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.
- 9. Health and Safety Code section 109970, in pertinent part, defines "manufacture" to mean "the preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic."

22.

10. Health and Safety Code section 111255 provides that a drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

- 11. Health and Safety Code section 111295 provides that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.
- 12. 21 U.S.C. § 331 prohibits, in pertinent part, the introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, the adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce, and the receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
- 13. 21 U.S.C. § 351(a) provides, in pertinent part, that a drug or device shall be deemed to be adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance; or if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

FACTUAL BACKGROUND

- 14. For an unknown period of at least several years until at least in or about September 2012, Respondent compounded sterile injectable drug products or preparations, shipping those products from its compounding facilities in Massachusetts to California and other states. Among the sterile injectable compounded products prepared by Respondent were: (1) methylprednisone acetate (MPA); (2) betamethasone solution (BS); and (3) cardioplegia solution (CS). All of these are dangerous drug (prescription-only) sterile injectable drug products.
- 15. After reports prior to and/or in September 2012 of outbreaks of fungal meningitis and other infections in patients to whom products compounded by Respondent had been administered, on or about September 26, 2012 three (3) lots of MPA compounded by Respondent were recalled. On or about October 3, 2012, Respondent voluntarily surrendered its underlying Massachusetts' license(s). On or about October 6, 2012, Respondent extended the recall to all products that had been compounded and distributed by Respondent from the Framingham, MA facility.

- 16. A contemporaneous multi-agency investigation involving, among others, the Board, other California state and local agencies, the Massachusetts Board of Registration in Pharmacy and/or Department of Public Health, state or local agencies from other states, and the federal Food and Drug Administration (FDA) and Centers for Disease Control (CDC), confirmed fungal and/or bacterial contamination of MPA, BS, and CS drug products that had been compounded by Respondent in or between in or about July 2012 and September 2012. The contaminants found in the drug products compounded by Respondent included the fungus Exserohilum rostratum, and the bacteria Paenibacillus pabuli/amolyticus, Bacillus idriensis, Bacillus flexus, Bacillus simplex, Lysinibacillus sp., Bacillus niabensis, Bacillus circulans, Bacillus lentus, Bacillus halmapalus, and Brevibacillus choshinens. Other findings from the investigation included:
 - That Respondent engaged in large-scale batch compounding of sterile drug products for distribution directly to facilities without patient-specific prescriptions;
 - That Respondent failed to follow adequate procedures for sterilizing drug products, or for maintaining or validating sterilization and anti-contamination equipment; and
 - That visible black particulate matter was visible in several recalled vials of MPA.
- 17. The total number of patients affected is not known, but to date the investigation has identified at least four hundred eighty (480) cases in nineteen (19) states, and thirty-three (33) deaths. At least four (4) facilities in California received contaminated and/or recalled product.

CAUSE FOR DISCIPLINE

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

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

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);
- Revoking or suspending Non-Resident Sterile Compounding License No. NSC 2. 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	l proper
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Executive Officer Board of Pharmacy

Department of Consumer Affairs

State of California Complainant

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