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

In the Matter of the Accusation Against: **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.	Case No. AC 2012 4451 **ACCUSATION**

Complainant alleges:

PARTIES

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

2. 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 herein, and will expire on April 1, 2013, unless renewed.

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

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 sterilzation 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);

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

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