

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case No. 2012-170
Nonresident Pharmacy License of)	
NEW ENGLAND COMPOUNDING)	STATEMENT OF CHARGES
CENTER)	& NOTICE OF HEARING
License No. 3535,)	
Respondent.)	

COMES NOW the Iowa Board of Pharmacy (Board) and files this Notice of Hearing and Statement of Charges pursuant to Iowa Code sections 17A.12(2) and 17A.18(3). Respondent was issued Iowa nonresident pharmacy license 3535. Respondent's license is currently active.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on April 23, 2013, before the Iowa Board of Pharmacy. The hearing shall be held during the afternoon session, beginning at 1:00 p.m. and shall be located in the Board conference room located at 400 S.W. 8th Street, Des Moines, Iowa.

Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the board at hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 Iowa Administrative Code rule 35.19. At hearing you will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf, cross-examine witnesses, and examine any documents introduced at hearing. You may appear personally or be represented by counsel at your own expense. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The office of the Attorney General is responsible for representing the public interest (the State) in this proceeding. Pleadings shall be filed with the Board and copies should be provided to counsel for the State at the following address.

Meghan Gavin
Assistant Attorney General
Iowa Attorney General's Office
2nd Floor Hoover State Office Building
Des Moines, Iowa 50319.

Ms. Gavin can also be reached by phone at (515)281-6736 or e-mail at Meghan.Gavin@iowa.gov.

Communications. You may contact the Board office (515)281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. However, you may NOT contact individual members of the Board to discuss these proceedings by phone, letter, facsimile, email, or in person. Board members can only receive information about the case when all parties have notice and an opportunity to participate, such as at the hearing or in pleadings you file with the Board office and serve upon all parties in the case. You may also direct questions relating to settlement of these proceedings to Assistant Attorney General Meghan Gavin at (515)281-6736.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2011).

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 17A, 147, 148C, and 272C (2011) and 657 Iowa Administrative Code chapter 36.

Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 Iowa Administrative Code rule 35.21.

C. CHARGES

Count I

FAILURE TO COMPLY WITH LAWS AND RULES OF THE HOME STATE

Respondent is charged with repeated failing to comply with the pharmacy laws and rules of its home state of Massachusetts in violation of Iowa Code sections 155A.13A(1)(b) and 155A.15(2)(c) and 657 Iowa Administrative Code rules 19.10 and 36.(4)(ad).

Count II

FAILURE TO COMPLY WITH IOWA PHARMACY RULES AND COMPOUNDING REQUIREMENTS

Respondent is charged with failing to comply with Iowa pharmacy rules and compounding requirements in violation of Iowa Code sections 155A.13A(1)(b) and 155A.15(2)(c) and 657 Iowa Administrative Code rules 19.3, 20.1, 20.3, 20.10, 20.12, and 36.1(4)(j).

Count III
**HAVING A LICENSE TO PRACTICE PHARMACY ISSUED BY ANOTHER STATE
CANCELED, REVOKED, OR SUSPENDED**

Respondent is charged with having its license to practice pharmacy issued by another state canceled, revoked, or suspended for conduct substantially equivalent to any grounds for disciplinary action in Iowa in violation of Iowa Code sections 155A.13A(1)(b) and 155A.15(2)(c) and 657 Iowa Administrative Code rules 19.3 and 36.4(ae).

D. FACTUAL CIRCUMSTANCES

1. Respondent holds Iowa nonresident pharmacy #3535. At all times material to the charges, Respondent operated a nonresident pharmacy at 697 Waverly St., Framingham, Massachusetts 01702.

2. On September 24, 2012, the Massachusetts Department of Public Health (MDPH) was notified by the Tennessee Department of Health about a cluster of six rare fungal meningitis cases.

3. The patients had each received an epidural injection of steroid compounded at New England Compounding Center.

4 MDPH initiated an investigation of Respondent's pharmacy on September 25.

5. The following day, MDPH instituted a recall of all suspect lots of methylprednisolone acetate. The suspected product was distributed to more than 14,000 patients in 23 states, for a total of 17,676 doses.

6. On October 2, MDPH and Federal Drug Administration (FDA) investigators observed black particulate matter in sealed vials (of purportedly sterile methylprednisolone acetate) returned to New England Compounding Center.

7. On October 3, the Massachusetts Board of Pharmacy accepted New England Compounding Center's voluntary surrender of its pharmacy license.

8. On October 18, the FDA released laboratory confirmation of the presence of fungal contaminants in sealed vials of methylprednisolone acetate in a suspect lot prepared by the Respondent.

9. The MDPH's preliminary investigative report concluded the Respondent violated various laws and rules related to the practice of pharmacy, including:

a. The Respondent distributed large batches of compounded sterile products directly to facilities apparently for general use rather than requiring a prescription for an individual patient.

b. The Respondent distributed two of the recalled lots of methylprednisolone prior to receiving the results of the sterility testing.

c. Final sterilization of product did not follow proper standards for autoclaving pursuant to United States Pharmacopeia Standard 797 and the Respondent's own operating procedures.

d. The Respondent did not conduct validation of autoclaves.

e. Visible black particulate matter was seen in several recalled sealed vials of methylprednisolone acetate.

f. Powder hoods, intended to protect pharmacists from inhaling substances during medication preparation, within sterile compounding area were not thoroughly cleaned pursuant to law.

g. Condition of "Tacky" mats, which are used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry were sub-standard.

h. A leaking boiler adjacent to the requisite clean room created an environment susceptible to contaminant growth.

10. The outbreak of fungal meningitis attributable to the Respondent has affected 693 people in at least 19 states and is alleged to have caused the death of 45 patients.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 Iowa Administrative Code rule 36.3. If you are interested in pursuing settlement of this matter, please contact Assistant Attorney General Meghan Gavin.

F. PROBABLE CAUSE FINDING

On this 30th day of January, 2013, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



SUSAN M. FREY, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Meghan Gavin
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case No. 2012-170
Nonresident Pharmacy License of)	
NEW ENGLAND COMPOUNDING)	SETTLEMENT AGREEMENT
CENTER)	& FINAL ORDER
License No. 3535,)	
Respondent.)	

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2013), the Iowa Board of Pharmacy and the New England Compounding Center, Respondent, enter into the following Settlement Agreement and Final Order to settle a licensee disciplinary proceeding currently pending before the Board.

The allegations contained in a Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent holds Iowa nonresident pharmacy #3535. At all times material to the charges, Respondent operated a nonresident pharmacy at 697 Waverly St., Framingham, Massachusetts 01702.

2. A Statement of Charges & Notice of Hearing was filed against the Respondent on January 30, 2013.

3. The Board has jurisdiction over the parties and the subject matter of these proceedings.

4. Respondent does not admit that any of the allegations in the Statement of Charges are true, but for the purposes of this matter only has chosen not to contest the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case

proceeding, would constitute grounds for the discipline agreed to in this Order. It is expressly understood this agreement is not an admission of liability on the part of NECC.

5. Respondent agrees to **PERMANENTLY VOLUNTARILY SURRENDER** its nonresident pharmacy license.

6. Respondent agrees not to engage in any aspect of the practice of pharmacy in Iowa after the date of his signature on this Order.

7. This voluntary permanent surrender is considered a revocation of license under Iowa Administrative Code rule 657—36.15. Respondent agrees, however, that this surrender is permanent and it shall not be eligible for reinstatement under that rule.

8. Should Respondent violate the terms of this Settlement Agreement and Final Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2013) and Iowa Administrative Code chapter 657—36.

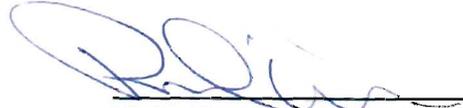
9. This Settlement Agreement and Final Order is the resolution of a contested case. By entering into this Settlement Agreement and Final Order, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Settlement Agreement and Final Order.

10. The State's legal counsel may present this Settlement Agreement and Final Order to the Board *ex parte*.

11. This Settlement Agreement and Final Order is subject to approval by a majority of the full Board. If the Board fails to approve this settlement, it shall be of no force or effect to either the Board or Respondent. If the Board approves this Settlement Agreement and Final Order, it shall be the full and final resolution of this matter.

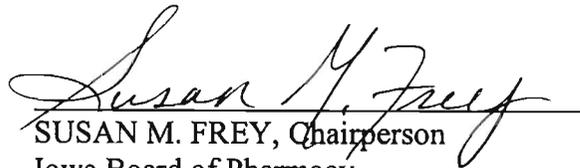
12. The Board's approval of this Settlement Agreement and Final Order shall constitute a **FINAL ORDER** of the Board.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 20th day of March 2013.



NEW ENGLAND COMPOUNDING CENTER
Respondent

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the 23rd day of April 2013.



SUSAN M. FREY, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Meghan Gavin
Assistant Attorney General
Office of the Attorney General
Hoover State Office Building
Des Moines, Iowa 50319