

**STATE OF RHODE ISLAND AND
PROVIDENCE PLANTATIONS**

**RHODE ISLAND
DEPARTMENT OF HEALTH**

**MICHAEL FINE, M.D., IN HIS CAPACITY
AS DIRECTOR OF HEALTH,
STATE OF RHODE ISLAND**

V

PHARMERICA (License #PHA00446, CPHA00446)

IMMEDIATE COMPLIANCE ORDER

Now comes the Director of Health of the State of Rhode Island and, pursuant to Rhode Island General Laws §§ 23-1-21 and 5-19.1-7, -8, -12, -13, makes the following Findings of Fact and Order:

FINDINGS OF FACTS

1. Pharmerica (hereinafter "Respondent") is licensed as a retail pharmacy and holds license number PHA00446 and controlled substances registration CPHA00446 and has a registered location as set forth below.
2. On January 4, 2013 at approximately 4:40 PM, Board of Pharmacy inspectors responded to Respondent Pharmacy, located at 83 Vermont Avenue, Unit 2, Warwick, Rhode Island and determined the following:
3. Respondent on multiple occasions permitted unlicensed individuals to practice as pharmacy technicians and engage in the compounding of sterile pharmaceutical compounds in violation of R5-19.1-PHAR-27.1(9);
4. Respondent failed to maintain the anteroom and sterile room in a clean, sanitary, and orderly manner in violation of R5-19.1-PHAR-13.4;
5. Respondent failed to conduct environmental surface and air monitoring for viable microorganisms on a monthly basis as required for medium risk sterile compounding in violation of R5-19.1-PHAR-19.28;
6. Respondent failed to submit documentation that Respondent Pharmacy's anteroom meets the minimum standards of an ISO class 8 environment in violation of R5-19.1-PHAR-19.26;

7. Respondent failed to conduct and maintain annual training competencies for staff performing sterile compounding prior to 2012 in violation of R5-19.1-PHAR-19.19;
8. Pharmerica also operates a pharmacy in Brockton, MA and on or about December 27, 2012 the Massachusetts Board of Pharmacy issued a cease and desist regarding the compounding of sterile medications and the distribution of compounded sterile medications from the Brockton location;
9. On or about December 28, 2012, the Pharmacist-In-Charge of the Brockton Pharmerica ordered the Brockton compounding be done in the Warwick Pharmerica location due to the restrictions placed upon the Brockton Pharmerica by the MA Board of Pharmacy. Sterile compounded medications were subsequently transported from the Warwick Pharmerica to the Brockton Pharmerica and dispensed from the Brockton location.
10. Respondent failed to maintain invoices/records denoting drug transfer between the Brockton and Warwick Pharmerica in violation of R5-19.1-PHAR-27.1(11).
11. On January 10, 2013 Michael Fine, MD, Director, RI Department of Health did summarily suspend the registered pharmacist license of Richard Mancini, RPh, the Pharmacist-In-Charge of Pharmerica.

ORDER

After consideration of the above findings and a review of Department of Health records that demonstrate the accuracy of the above findings, it is hereby ordered that:

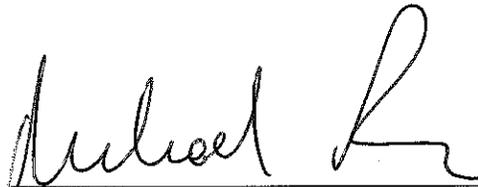
1. Respondent and its owners and employees shall cease and desist the compounding of any and all sterile pharmaceuticals.
2. Respondent and its owners and employees shall cease and desist the dispensing or distribution of any and all compounded sterile pharmaceuticals.
3. Respondent and its owners and employees shall complete the following prior to any request for rescission or vacation of this Order:
 - a. Produce a current report generated by an external, independent environmental cleaning and/or monitoring entity that demonstrates that a viable and nonviable microorganism surface and air testing was conducted of the sterile compounding area and anteroom that shows compliance with acceptable standards outlined in the Rhode Island Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers and Distributors;
 - b. Hire at its own expense an external, independent environmental cleaning and/or monitoring entity to perform cleaning of the pharmacy sterile compounding area and anteroom that is in compliance with acceptable standards outlined in the

Rhode Island Rules and Regulations Pertaining to Pharmacists, Pharmacies and
Manufacturers and Distributors;

- c. Produce a written attestation by the external, independent environmental cleaning and/or monitoring entity that avers that such cleaning and testing was done.
 - d. Make any and all necessary repairs to the sterile compounding room to prevent exposure of the area to non-sterile environments.
4. Respondent is hereby ordered to employ a new Pharmacist-In-Charge by 4:30pm on January 10, 2013. If Respondent fails to submit a new Pharmacist-In-Charge to the Department, Respondent shall not be permitted to engage in practice as a retail pharmacy in this State.
 5. That should Respondent violate any terms of this Immediate Compliance Order, Respondent shall be subject to further disciplinary sanctions.

Date Entered: January 10, 2013

By:



Michael Fine, M.D.
Director
Rhode Island Department of Health

CERTIFICATION OF SERVICE

A copy of the within Immediate Compliance Order was hand delivered to Pharmerica, 83 Vermont Avenue, Unit 2, Warwick, RI, by the undersigned on this 10th day of January, 2013.



witness


 Ian Lubinski