

November 27, 2012

Michael N. Souranis, President
Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, Maryland 21215

RE: Surrender of Permit to Operate Pharmacy
Permit Number: P03113
Case Number: PI-13-057/13-457

Dear Mr. Souranis and Members of the Board:

I am retained counsel to New England Compounding Center ("NECC"), and I am authorized to act on behalf of NECC in regards to the above mentioned Maryland Pharmacy Permit. NECC has made the decision to **SURRENDER** its permit (P03113) to operate a pharmacy in the State of Maryland.

I understand that the surrender of NECC's permit means that NECC may not operate a pharmacy, as it is defined in the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. ("H.O.") § 12-101 *et seq.* (2009 Repl. Vol.).

This Letter of Surrender shall become effective immediately upon the date of acceptance by the Maryland Board of Pharmacy (the "Board"). I understand that this Letter of Surrender is a **PUBLIC** document and on the Board's acceptance becomes a **FINAL ORDER** of the Board.

NECC surrender of its permit to operate a pharmacy in the State of Maryland has been prompted by an investigation by the Board and the Office of the Attorney General into NECC's Massachusetts license which was surrendered by NECC pursuant to the attached agreement with the Massachusetts Board of Pharmacy. (**Attachment A.**) NECC, a non-resident pharmacy under H.O. § 12-101(m), is required under H.O. § 12-403 to maintain "a valid, unexpired permit to conduct a pharmacy in compliance with the laws of the state in which it is located." NECC no longer meets this requirement. As a result, on October 5, 2012, the Board issued an Order for Summary Suspension for NECC's permit. The Board's Order for Summary Suspension is attached and incorporated hereto as **Attachment B.**

NECC has surrendered its permit to operate a pharmacy in the State of Maryland in order to resolve this investigation without requiring prosecution of the charges against it

Letter of Surrender
New England Compounding Center
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by the Board. I acknowledge that the Office of the Attorney General has legally sufficient evidence to prove by a preponderance of the evidence at an administrative hearing that NECC is no longer licensed to operate in its home state of Massachusetts.

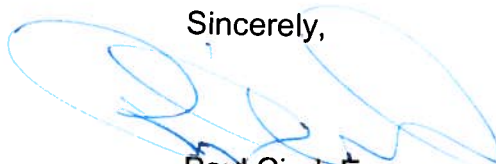
I understand that by executing this Letter of Surrender NECC is waiving any right to contest any charges that otherwise would issue from the Board's investigative findings and its vote to issue charges in a formal evidentiary hearing at which NECC would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on its behalf and all other substantive and procedural protections provided by law, including the right to appeal.

The Board will advise the Health Care Integrity Data Bank, and any other required entities of this Letter of Surrender, and in response to any inquiry, will advise that NECC has surrendered its license in lieu of disciplinary action under the Act as a resolution of the matters pending against it. In the event that NECC would apply for a permit in any form in any other state or jurisdiction, that this Letter of Surrender, and all underlying documents, may be released or published by the Board to the same extent as a Final Order that would result from disciplinary action pursuant to Md. State Gov't Code Ann. § 10-611 *et seq.* (2009 Repl. Vol. and 2010 Supp.). Finally, I have been informed that this Letter of Surrender is considered a disciplinary action by the Board.

NECC acknowledges that it may not rescind this Letter of Surrender in part or in its entirety for any reason whatsoever. NECC understands both the nature of the Board's actions and this Letter of Surrender fully. NECC acknowledges that it understands and comprehends the language, meaning and terms and effect of this Letter of Surrender. NECC makes this decision knowingly and voluntarily.

I acknowledge, on behalf of NECC, that this Letter of Surrender becomes effective immediately upon acceptance by the Board.

Sincerely,

A handwritten signature in blue ink, appearing to read "Paul Cirel", is written over a light blue circular stamp or watermark.

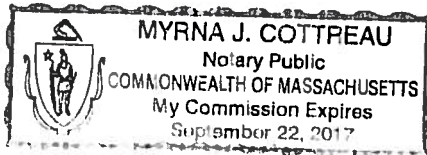
Paul Cirel, Esq.
Counsel and Representative for NECC

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NOTARY SEAL

STATE OF MASSACHUSETTS
CITY/COUNTY: Suffolk

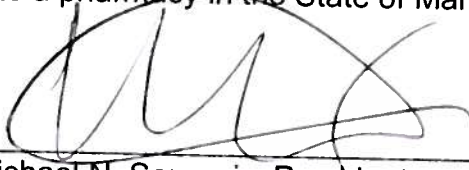
I HEREBY CERTIFY that on this 27th day of November, 2012, before me, a Notary Public of the State and City/County aforesaid personally appeared Paul Cirel, Esq., and declared and affirmed under the penalties of perjury that signing the foregoing Letter of Surrender was his voluntary act and deed on behalf of NECC.



Myrna J. Cottreau
Notary Public

ACCEPTANCE

On behalf of the Maryland Board of Pharmacy, on this 19th day of DECEMBER, 2012, I accept New England Compounding Center's **PUBLIC SURRENDER** of its permit to operate a pharmacy in the State of Maryland.



Michael N. Souranis, President
Maryland Board of Pharmacy

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of
NEW ENGLAND
COMPOUNDING CENTER
Pharmacy Registration No. 2848

Docket No. PHA-2012-0204

VOLUNTARY SURRENDER AGREEMENT

The Board of Registration in Pharmacy (Board) and New England Compounding Center, a pharmacy licensed by the Board (Pharmacy Registration No. 2848), located at 697 Waverly Street in Framingham, Massachusetts (Pharmacy), do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the file of the Pharmacy that is maintained by the Board:

1. The parties enter into this Voluntary Surrender Agreement (Agreement) relating to matters pending before the Board as Docket No. PHA-2012-0204 (Complaint) concerning:
 - (a) an inspection conducted on October 2, 2012; and
 - (b) the sterility of certain drug products compounded and dispensed by the Pharmacy; specifically, methylprednisolone acetate.
2. The Pharmacy acknowledges and agrees to surrender Pharmacy Registration No. 2848 to the Board, effective October 3, 2012 (the Effective Date of the Agreement).
3. The parties acknowledge and agree that the period of Pharmacy license surrender shall continue until such time as the Board has determined that it is in the best interest of the public health and safety for the Pharmacy to resume operations.
4. The Pharmacy agrees to immediately commence recall procedures regarding ALL in use date:
 - (a) methylprednisolone acetate; and
 - (b) other drug products prepared for intrathecal administration.
5. The Pharmacy acknowledges and agrees that the quarantine of:
 - (a) methylprednisolone acetate (commenced September 26, 2012) shall continue in effect, in accordance with the Quarantine Notice issued by the Board on October 1, 2012; and
 - (b) all other drug products on Pharmacy premises shall immediately commence and be subject to the terms and conditions of the October 1, 2012 Quarantine Notice.
6. The Agreement and its contents shall be incorporated into the records maintained by the Board. The Agreement is a public record subject to disclosure to the public and equivalent state licensing boards.

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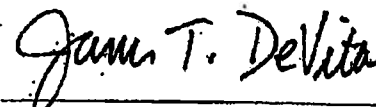
ATTACHMENT A

7. The Board agrees that in return for the Pharmacy execution of this Agreement, the Board will not initiate proceedings pursuant to G.L. c. 94C, s. 14 and G.L. c. 112, s. 40; any and all other rights of the Board to take action within the scope of its authority are expressly reserved.
8. The Pharmacy understands and agrees that the decision to enter into this Agreement is a final act and is not subject to reconsideration or judicial review.
9. The Agreement is neither an admission of liability or wrongdoing.
10. The Pharmacy states that the Pharmacy has used legal counsel in connection with the decision to enter into this Agreement or, if the Pharmacy did not, that the Pharmacy had an opportunity to do so.
11. The Pharmacy and the duly authorized representative executing this Agreement on behalf of the Pharmacy, certifies that the representative has read this document entitled "Voluntary Surrender Agreement" and understands that, by executing this Agreement, the Pharmacy is waiving any and all right to a formal hearing at which the Pharmacy would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to provide testimony on its own behalf, to contest the allegations, to present oral argument, to appeal to court in the event of an adverse ruling, and all other rights set forth in G.L. c. 30A and 801 CMR 1.01 *et seq.*

**NEW ENGLAND
COMPOUNDING CENTER**

By: 
Barry J. Cadden, President
Date: October 3, 2012

**BOARD OF REGISTRATION
IN PHARMACY**


James T. DeVita, R.Ph.
President
Date: October 3, 2012

Effective Date: October 3, 2012

Decision No. 3066

IN THE MATTER OF
NEW ENGLAND COMPOUNDING CENTER

PERMIT No: P03113

Respondent-Pharmacy

BEFORE THE
MARYLAND BOARD
OF PHARMACY

CASE NO.: PI-13-057/13-457

ORDER FOR SUMMARY SUSPENSION

Pursuant to Md. State Govt. Code Ann. §10-226 (c) (2009 Repl.), the Maryland Board of Pharmacy (the "Board") hereby **SUMMARILY SUSPENDS** the permit to operate as a pharmacy in the State of Maryland issued to **NEW ENGLAND COMPOUNDING CENTER, Permit Number P03113**, (the "Respondent-Pharmacy") under the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. §§ 12-101 et seq. (2009 Repl. Vol.). This Order is based on the following investigative findings, which the Board has reason to believe are true:

FINDINGS OF FACT

1. At all times relevant hereto, the Respondent-Pharmacy was authorized to operate a pharmacy in the State of Maryland. The Respondent-Pharmacy currently holds a permit to operate a pharmacy under permit number P03113. The Respondent-Pharmacy was first issued a permit on March 13, 2003, and its current permit will expire on December 31, 2013.

¹ The statements regarding the Respondent-Pharmacy are only intended to provide the Respondent-Pharmacy with notice of the basis for the Board's action. They are not intended as, and do not necessarily represent a completed description of the evidence, either documentary or testimonial, to be offered against the Respondent-Pharmacy in this matter.

2. The Respondent-Pharmacy is located at 697 Waverly Street, Framingham, Massachusetts 01702 and, until recently, was permitted to distribute prescription medications in all 50 states.

3. On or about October 3, 2012, the Respondent-Pharmacy voluntarily ceased operation after a fungal meningitis outbreak was traced to a steroid produced at the facility.

4. As of October 2012, at least thirty-five people in six states have become ill from the steroid and five people have died, including one person in Maryland.

5. The Respondent-Pharmacy voluntarily surrendered its Massachusetts Pharmacy permits.

6. On or about October 4, 2012, the North Carolina Board of Pharmacy issued an order summarily suspending the Respondent-Pharmacy's permit to practice pharmacy.

7. Based on the above-investigative findings, the Board has a basis to charge the Respondent-Pharmacy for violating the following:

Md. Health Occ. Code Ann. § 12-403

(f) A nonresident pharmacy shall:

(4) Maintain at all times a valid, unexpired permit to conduct a pharmacy in compliance with the laws of the state in which it is located[.]

Md. Health Occ. Code Ann. § 12-409

(b) Non-resident pharmacy. (1) A nonresident is subject to the disciplinary actions stated in this subsection.

(2) The Board may fine a nonresident pharmacy in accordance with § 12-410 of this subtitle or deny, revoke, or suspend the permit of a nonresident pharmacy for any violation of § 12-403 (d) through (g) of this subtitle.

CONCLUSIONS OF LAW

Based on the foregoing, the Board concludes as a matter of law that the public health, safety or welfare imperatively requires emergency action, pursuant to Md. St. Gov't. Code Ann. § 10-226(c)(2) (2009 Repl. Vol.).


ORDER

Based on the foregoing, it is therefore this 5th day of October 2012, by a majority vote of a quorum of the State Board of Pharmacy, by authority granted to the Board by Md. St. Gov't. Code Ann. §, 10-226(c)(2) (2009 Repl. Vol.), hereby:

ORDERED that the permit issued to the Respondent-Pharmacy to operate a pharmacy in the State of Maryland under Permit Number P03113 is hereby **SUMMARILY SUSPENDED**; and be it further

ORDERED that the Respondent-Pharmacy shall return its wall certificate and wallet-sized permit to the Board, within five days of the date this Order is signed by the Board; and be it further

ORDERED, that this document constitutes a final Order of the Board and is therefore a public document for purposes of public disclosure, as required by Md. State Gov't Code Ann. § 10-617(h) (2009 Repl. Vol. and 2011 Supp.).



LaVerne G. Naesea, Executive Director
Maryland Board of Pharmacy

NOTICE OF AN OPPORTUNITY FOR A HEARING

In accordance with the Act and the Administrative Procedures Act, Md. State Govt. Code Ann. §§ 10-201 *et seq.*, the Board hereby notifies the Respondent-Pharmacy of an opportunity for a non-evidentiary Show Cause hearing to show cause why the Board should lift the summary suspension. The Respondent-Pharmacy must request a hearing in writing **WITHIN THIRTY (30) DAYS** of service of this Notice. The written request must be made to:

LaVerne Naesea, Executive Director
Maryland Board of Pharmacy
4201 Patterson Avenue 21215
(410) 764-4755

with copies mailed to:

Tracee Orlove Fruman, Assistant Attorney General
Administrative Prosecutor
Office of the Attorney General
300 West Preston Street, Room 201
Baltimore, Maryland 21201

Linda Bethman, Assistant Attorney General
Board Counsel
Office of the Attorney General
300 West Preston Street, Room 302
Baltimore, Maryland 21201

If a request for a Show Cause hearing is made, a hearing will be scheduled before the Board.