

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH PROFESSIONS
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

New England Compounding Pharmacy
d/b/a New England Compounding Center
License Nos. 53-01-007871 and 53-15-016810

Complaint No. 53-12-126156

ADMINISTRATIVE COMPLAINT

Attorney General Bill Schuette, through Assistant Attorney General Wanda M. Stokes and Assistant Attorney General Kelly K. Elizondo, on behalf of the Department of Licensing and Regulatory Affairs, Bureau of Health Professions (Complainant), files this complaint against New England Compounding Pharmacy d/b/a New England Compounding Center (Respondent), alleging upon information and belief as follows:

1. The Board of Pharmacy (Board), an administrative agency established by the Public Health Code (Code), 1978 PA 368, as amended, MCL 333.1101 *et seq*, is empowered to discipline licensees under the Code through its Disciplinary Subcommittee.

2. The Board of Pharmacy has been designated the administrator of the controlled substance provisions in Article 7 of the Code and is empowered to discipline licensees under the controlled substance provisions of the Code through its DSC.

3. Respondent is currently licensed by the Board as a pharmacy and holds a controlled substance license issued by the administrator pursuant to the Code. Respondent was first issued a pharmacy and controlled substance license on February 12, 2004.

4. Section 16233(5) of the Public Health Code provides for the summary suspension of a license, reading in pertinent part, as follows:

After consultation with the chair of the appropriate board or task force or his or her designee, the department may summarily suspend a license or registration if the public health, safety, or welfare requires emergency action in accordance with section 92 of the administrative procedures act of 1969, MCL 24.292. If a license or registrant is convicted of a felony; a misdemeanor punishable by imprisonment for a maximum term of two years; or a misdemeanor involving the illegal delivery, possession, or use of a controlled substance, the department shall find that the public health, safety, or welfare requires emergency action and, in accordance with section 92 of the administrative procedures act of 1969, MCL 24.292, shall summarily suspend the licensee's license or the registrant's registration.

5. Section 7311(6) of the Code provides that a license under section 7306 to manufacture, distribute, prescribe, or dispense a controlled substance is automatically void if the licensee's license to practice is suspended or revoked under article 15.

6. Section 17768(1) of the Code provides that: "In a manner consistent with part 161, the board may fine, reprimand, or place on probation a person licensed under this part (part 177), or deny, limit, suspend, or revoke a person's license or order restitution or community service for a violation of this part or rules promulgated under this part."

7. Section 17706(1) of the Code defines a manufacturer as: "a person who prepares, produces, derives, propagates, compounds, processes, packages, or repackages a drug or device salable on prescription only, or otherwise changes the container or the labeling of a drug or device salable on prescription only, and who supplies, distributes, sells, offers for sale, batters, or otherwise disposes of that drug or device and any other drug or device salable on prescription only, to another person for resale, compounding, or dispensing."

8. Section 17748 of the Code provides: "a pharmacy, manufacturer, or wholesale distributor of prescription drugs, whether or not located in this state but doing business in this state, shall be licensed by the board in accordance with this part."

9. Section 17764(2)(b) of the Code provides: "a person shall not knowingly or recklessly do either of the following:

(a) Adulterate, misbrand, remove, or substitute a drug or device knowing or intending that the drug or device shall be used.

(b) Sell, offer for sale, cause to be sold, or manufacture for sale an adulterated or misbranded drug.”

10. Section 17764 provides the following penalties for a violation of section 17764(2)(b):

(3) Except as otherwise provided in this section, a person who violates subsection (2) is guilty of a felony punishable by imprisonment for not more than 2 years or a fine of not more than \$1,000.00, or both.

(4) A person who violates subsection (2), which violation results in personal injury, is guilty of a felony punishable by imprisonment for not more than 4 years or a fine of not more than \$4,000.00, or both.

(5) A person who violates subsection (2), which violation results in serious impairment of a body function, is guilty of a felony punishable by imprisonment for not more than 5 years or a fine of not more than \$5,000.00, or both. As used in this subsection, “serious impairment of a body function” means that term as defined in section 58c of the Michigan vehicle code, 1949 PA 300, MCL 257.58c.

(6) A person who violates subsection (2), which violation results in death, is guilty of a felony punishable by imprisonment for not more than 15 years or a fine of not more than \$20,000.00, or both.

(7) A person who violates subsection (2) with the intent to kill or to cause serious impairment of a body function of 2 or more individuals, which violation results in death, is guilty of a felony punishable by imprisonment for life without the possibility of parole or life without the possibility of parole and a fine of not more than \$40,000.00. It is not a defense to a charge under this subsection that the person did not intend to kill a specific individual, or did not intend to cause serious impairment of a body function of 2 or more specific individuals.

(8) This section does not prohibit an individual from being charged with, convicted of, or punished for any other violation of law that is committed by that individual while violating this section.

11. Section 1106 defines person to mean “an individual, partnership, cooperative, association, private corporation, personal representative, receiver, trustee, assignee, or other legal entity. Person does not include a governmental entity unless specifically provided.”

12. 1979 AC, R 338.478 defines the word person: “the word ‘person,’ as used in all statutes, and regulations relating to the profession of pharmacy, shall be construed to include individuals, partnerships, firms, corporations, associations, and governmental institutions.”

FACTUAL ALLEGATIONS

13. Respondent is a compounding pharmacy licensed in the State of Michigan, with its principal place of business in Massachusetts. Respondent holds both a Michigan pharmacy license and controlled substance license, which allow Respondent to prepare a medication for a single patient pursuant to a prescription.

14. At all times relevant hereto, Respondent compounded an epidural (spinal) steroid injection (methylprednisolone acetate) which is commonly used for the treatment of back pain.

15. On September 21, 2012, the Center for Disease Control and Prevention (CDC) was notified that a patient in Tennessee had developed the onset of fungal

meningitis approximately 19 days following a spinal injection of methylprednisolone acetate compounded by Respondent.

16. Following this initial notification, the CDC and Food and Drug Administration (FDA) became aware of numerous cases of patients developing fungal meningitis after receiving spinal steroid injections of methylprednisolone acetate compounded by Respondent.

17. A CDC and FDA investigation determined that patients received injections with one of three lots of preservative-free methylprednisolone acetate compounded by the Respondent, which had been contaminated.

18. On September 25, 2012, Respondent recalled the three lots of contaminated product associated with the development of fungal meningitis.

19. The Michigan Department of Community Health received a list from the CDC identifying Michigan facilities that had received shipments of the contaminated lots.

20. The four Michigan facilities known to have received shipments of the recalled, contaminated lots are: Michigan Neurological Institute in Grand Blanc;

Michigan Pain Specialists in Brighton; Neuromuscular and Rehabilitation in Traverse City; and Southeast Michigan Surgical Hospital in Warren.

21. The above referenced clinics utilized the spinal steroid injections and 1,900 individuals received contaminated injections prior to the recall.

22. As of October 11, 2012, more than thirty (30) cases of fungal meningitis have been confirmed in Michigan, and three deaths have been identified as a result of the adulterated steroid injections. Of the deaths all were females who were aged 57, 67 and 78. All cases are linked to the four facilities that received the contaminated product lots.

23. While the facilities that received the contaminated lots have been identified, other Michigan facilities have received products from Respondent, and as the source of contamination has not been identified, there is the potential that other unidentified products received by Michigan facilities have been contaminated. Respondent's reckless act in allowing an adulterated product to be shipped to Michigan clinics has led to an imminent public health threat in the State of Michigan as infected patients have become ill and more could become ill approximately one to four weeks following a contaminated injection.

24. Respondent did not have the required manufacturing license at the time steroid injections were shipped to Michigan. Respondent was producing the injections and shipping same in vials for general use by the clinics, and not as individual prescriptions for an identified patient. Respondent's pharmacy license did not allow it to ship large quantities for general use.

25. In order to protect the public health, safety & welfare Respondent's pharmacy and controlled substance licenses must be summarily suspended pursuant to the Board's authority under sections 16233(5), 7311(6) and 17768(1).

COUNT I

Respondent's conduct as set forth above constitutes a violation of section 17748 of the Code, contrary to section 17768(1) of the Code.

COUNT II

Respondent's conduct as set forth above constitutes a violation of section 17764(2)(b) of the Code, contrary to section 17768(1) of the Code.

WHEREFORE, Complainant requests that a hearing be scheduled pursuant to the Administrative Procedures Act of 1969, MCL 24.201 et. seq.; the Public Health Code, and the rules promulgated thereunder, to determine whether disciplinary action should be taken against Respondent for the reasons set forth

above.

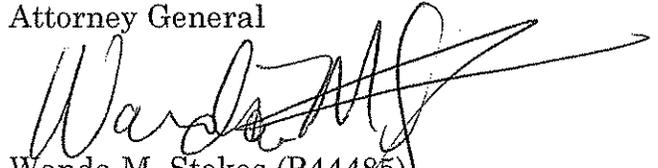
FURTHER, pending a hearing and final determination in the within cause, and pursuant to sections 16233(5), 7311(6) and 17768(1) of the Public Health Code, supra, Complainant states that the public health, safety and welfare requires emergency action and Respondent's pharmacy and controlled substance licenses should be summarily suspended.

THEREFORE, Complainant requests that this complaint be served upon Respondent and that Respondent be offered an opportunity to show compliance with all lawful requirements for retention of the aforesaid licenses. If compliance is not shown, Complainant further requests that formal proceedings be commenced pursuant to the Public Health Code, rules promulgated pursuant to it, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 *et seq*; MSA 3.560(101) *et seq*.

RESPONDENT IS HEREBY NOTIFIED that, pursuant to section 16231(7) of the Public Health Code, Respondent has 30 days from receipt of this Administrative Complaint to submit a written response to the allegations contained in it. The written response shall be submitted to the Bureau of Health Professions, Department of Licensing & Regulatory Affairs, P.O. Box 30670, Lansing, Michigan, 48909, with a copy to the undersigned assistant attorney general. Further, pursuant to section 16231(8) of the Public Health Code, failure to submit a written

response within 30 days shall be treated as an admission of the allegations contained in the Administrative Complaint and shall result in transmittal of the Administrative Complaint directly to the Board's Disciplinary Subcommittee for imposition of an appropriate sanction.

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