COMMITTEES

NATURAL RESOURCES
RANKING DEMOCRAT

ENERGY AND COMMERCE

EDWARD J. MARKEY
7TH DISTRICT, MASSACHUSETTS

2108 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–2107
(202) 225–2836

DISTRICT OFFICES:

5 HIGH STREET, SUITE 101
MEDFORD, MA 02155
(781) 396–2900

188 CONCORD STREET, SUITE 102
FRAMINGHAM, MA 01702
(508) 875–2900

http://markey.house.gov

Congress of the United States
House of Representatives
Washington, DC 20515–2107

October 16, 2012

The Honorable Eric H. Holder, Jr.
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

Dear Attorney General Holder:

I write to request that you commence an investigation into whether the New England Compounding Company (NECC), alleged to be responsible for a deadly outbreak of fungal meningitis caused by contaminated spinal injections, also has violated laws and regulations related to the manner in which controlled substances can be sold. The list of recalled NECC drug products[1] appears to include nearly 1,000 specific formulations that contain controlled substances that fall under the purview of the Drug Enforcement Agency (DEA), including substances such as cocaine, morphine, hydromorphone, meperidine, sufentanil, fentanyl, and ketamine. I have prepared a list of NECC's recalled drugs highlighted to indicate my preliminary assessment of which drugs also may be subject to DEA regulations.[2]

As of today, the nearly 18,000 vials of the contaminated steroid drug have been shipped to 76 healthcare facilities in 24 states. The Centers for Disease Control and Prevention (CDC) has estimated that 14,000 people have been injected with the contaminated steroid that has already sickened 214 people and killed fifteen. Two of the cases of fungal meningitis resulted from this medication being injected into a peripheral joint, rather than directly into the spine. Just yesterday, the Food and Drug Administration (FDA) and CDC said that they are investigating a case of fungal meningitis that may have also been caused by a different pain-relieving steroid, as well as a fungal infection in one heart transplant patient who received a cardiac medication[3], with these additional cases also involving medications manufactured by NECC. The FDA has also warned that patients receiving NECC drugs for the eye or in conjunction with eye surgery may also be at risk of infection.[4]

---

[1] http://www.neccrx.com/List_of_all_products_manufactured_since_January_2012.pdf
[2] http://markey.house.gov/document/2012/list-recalled-necc-drugs
[3] http://www.fda.gov/Drugs/DrugSafety/UCM322734.htm and http://www.cnn.com/2012/10/15/health/meningitis-outbreak-duplicate-2/index.html
[4] http://www.fda.gov/Drugs/DrugSafety/UCM322734.htm

PRINTED ON RECYCLED PAPER

According to DEA regulations, retail pharmacies that compound or sell controlled substances must be registered with the DEA and are only permitted to sell compounds containing controlled substances directly to the end user (i.e. patient) and only in response to a patient-specific prescription (where the prescriber is also a DEA registrant), unless the pharmacy also has registered as a DEA manufacturer (and then it can distribute the drugs only to DEA-registered buyers). According to the DEA,[5] "compounding a controlled substance other than pursuant to a valid patient-specific prescription or medical order, is manufacturing." According to an October 16, 2012 conversation between my staff and staff at the DEA, NECC is not registered with the DEA as a manufacturer.

Reports have indicated that despite the fact that NECC was registered with the Massachusetts Department of Public Health as a pharmacy, the company was not operating in compliance with state law because it was providing drugs to pain facilities and hospitals without requiring individual patient prescriptions.[6] This calls into question whether the pharmacy was also operating in contravention of DEA regulations for controlled substances, which require that pharmacies dispense compounded controlled substances in response to a patient-specific prescription or medical order, unless the pharmacy is also registered as a manufacturer with DEA. Additionally, if the NECC was selling controlled substances to an authorized prescriber, such as a physician, rather than a patient, the authorized prescriber must also be registered with the DEA.

This is a matter that I believe requires further investigation by the DEA to ensure that this facility, already believed to have broken Massachusetts state law, has not also skirted federal law related to controlled substances. I ask that the Department provide me with responses to the following questions and requests for information:

1. As a retail pharmacy, what types of controlled substances was NECC authorized to use to compound drugs under DEA regulations? Has the DEA issued any guidance for compounding pharmacies in handling controlled substances? If so, please provide me with a copy of any such guidance, and describe how this information has been distributed.

2. For each drug that is on both the NECC recall list and DEA's list of controlled substances, please indicate whether NECC sold each substance (or compounded drug made using the substance) in compliance with all applicable DEA regulations.

---

[5] June 19, 2012 letter from John W. Partridge, Chief Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Authority to David Miller, Executive Vice President, International Academy of Compounding Pharmacists. See: http://markey.house.gov/document/2012/dea-letter-iacp-compounding

[6] See: http://www.reuters.com/article/2012/10/13/us-usa-health-meningitis-pharmacy-idUSBRE89C0FL20121013 and http://www.bostonglobe.com/lifestyle/health-wellness/2012/10/10/gov-deval-patrick-accuses-massachusetts-compounding-pharmacy-misleading-regulators/DJFqjQ5HtrVu3NrDLqVSTM/story.html

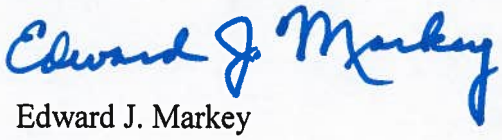
3. For each of the past ten years, please indicate a) how many DEA enforcement actions were brought against pharmacies that failed to comply with DEA's regulations related to controlled substances, and b) for each such case, the name and location of the pharmacy, the regulation that was violated and the resolution of the enforcement action (i.e. registration suspended, fines levied, warning letter, etc).

4. Please describe the enforcement actions that could be taken against a pharmacy that violates DEA's controlled substances regulations (maximum fines, penalties, sanctions, or other available actions).

5. Does the Department believe it has sufficient statutory authority and resources to perform its oversight and enforcement responsibilities with respect to compounding pharmacies? If not, what recommendations does the Department have to strengthen its capabilities to perform its duties in this area?

Thank you for your consideration and assistance in this matter. Please provide your response no later than Friday November 2, 2012. Should you have any questions about this request, please have your staff contact Dr. Avenel Joseph of my staff or Dr. Michal Freedhoff at (202) 225-2836.

Sincerely,



Edward J. Markey