
Dingell Continues to Fight for Answers on Infectious Outbreak Investigation

FDA believes number of contaminated drugs could be greater than expected

Washington, D.C. – Congressman John D. Dingell (D-MI15), an author of the recently enacted Food and Drug Administration Safety and Innovation Act, continues to question the U.S. Food and Drug Administration (FDA) upon a recent discovery that patients who have been treated during eye operations and open-heart surgeries with New England Compounding Center (NECC) products may have been exposed to contaminated pharmaceuticals. According to officials at the FDA, there is a possibility the multi-state outbreak of meningitis reported last week could now include other types of infections. Michigan alone has seen 46 sickened and 3 deaths due to this outbreak, and remains having the second largest concentration of cases nationwide.

“It is clear that NECC has disregarded state regulations and warnings laid forth by the FDA,” said Dingell. “Although this investigation is moving forward, this latest information adds to my deep concern that additional contaminated pharmaceuticals are still being used in hospitals and clinics across the country. We must move swiftly to ensure no more lives are lost to this preventable outbreak.”

As FDA’s investigation into NECC moves forward, Dingell will continue to ask tough questions and keep Michiganders informed of any other potentially contaminated drugs distributed by the compounding pharmacy. Six states, including Michigan, have suspended NECC’s company license.

The text of the letter is below and a copy can be viewed [here](#).

October 16, 2012

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Hamburg:

I write to you in regards to the most recent update on the U.S. Food and Drug Administration's (FDA) investigation of the contaminated products at the New England Compounding Center (NECC).

On Monday, FDA noted that additional products produced at NECC may have sterility issues. This includes a patient with possible meningitis that was injected with triamcinolone acetonide and two transplant patients who received cardioplegic solution during surgery who now have *Aspergillus fumigatus* infection. FDA has also cautioned against the use of any ophthalmic drugs that are injectable or used in conjunction with eye surgery. While I understand that FDA's investigation is still ongoing, I am greatly concerned that additional contaminated NECC products may still remain on the market and could cause harm to thousands more Americans.

Given this latest update, I respectfully request the answers to the following questions:

1. Please provide a complete list of the products produced at NECC, including the proprietary name, the nonproprietary name or common name, the quantity of doses produced, dosage forms, strengths, route of administration, and proposed indication for each of the products. How many of these products were prepared based on a prescription for a specific patient?
2. How many facilities, in how many states, have received NECC products?
3. Please provide an estimate of how many patients are at risk from infection or meningitis from the use of NECC products. How does FDA intend to notify patients that may have been treated with NECC products?
4. Do any of NECC's products remain on the market? If so, which products remain on the market? Of those that remain on the market, how many doses remain on the market? (Don't understand last question.)

As the meningitis outbreak continues to grow and now newer fungal infections are reported, I remain concerned that FDA and state regulators have not collected full and accurate information about the activities of NECC. It is clear that NECC willfully disregarded state regulations and did not properly address the concerns laid out by FDA in previous warning letters. This company's actions have shown that new authority and further oversight over compounding pharmacies is needed. I will be sending you further inquiry as to what authority, personnel, and funding is needed by FDA to better oversee compounding pharmacies.

Given the serious nature of this outbreak, I respectfully request that a response be sent to my office no later than October 30, 2012. Should you or your staff have any questions, please do not hesitate to contact me or have a member of your staff contact Kimberlee Trzeciak in my office at (202) 225-4071.

With every good wish,

Sincerely,

John D. Dingell
Member of Congress