

JOHN D. DINGELL  
15TH DISTRICT, MICHIGAN

COMMITTEE ON  
ENERGY AND COMMERCE

CO-CHAIR

HOUSE GREAT LAKES  
TASK FORCE

MEMBER

MIGRATORY BIRD  
CONSERVATION COMMISSION

Congress of the United States  
House of Representatives  
Washington, DC 20515-2215

October 17, 2012

WASHINGTON OFFICE:

ROOM 2328  
RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-2215  
(202) 225-4071

DISTRICT OFFICES:

19855 WEST OUTER DRIVE  
SUITE 103-E  
DEARBORN, MI 48124  
(313) 278-2936

23 EAST FRONT STREET  
SUITE 103  
MONROE, MI 48161  
(734) 243-1849

301 WEST MICHIGAN AVENUE  
SUITE 305  
YPSILANTI, MI 48197  
(734) 481-1100

The Honorable Fred Upton  
Chairman  
House Committee on Energy and Commerce  
2125 Rayburn House Office Building  
Washington, D.C. 20515

Dear Chairman Upton:

I write to you today to urge that the Committee hold hearings on the ongoing fungal meningitis outbreak caused by a epidural steroid injections, as well as the recent announcement by the U.S. Food and Drug Administration (FDA) that other products produced by the New England Compounding Center (NECC) are also sickening patients. As you well know, our home state of Michigan has the second highest number of patients impacted by these contaminated products, and this outbreak only continues to spread throughout the Nation.

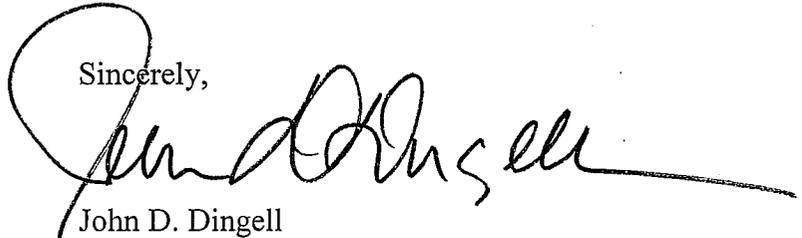
Thus far, contaminated methylprednisolone acetate produced by NECC has sickened 233 patients and resulted in 15 deaths in 15 states. CDC has noted that up to 14,000 patients in 23 states may have been exposed to this steroid. Further, it is still unclear how many patients may have been exposed to other contaminated products made by NECC, which underscores the need for the Committee to hold hearings with all due speed.

I happen to believe that compounding pharmacies do serve a public health need when they are operating in the traditional sense – providing individual patients with the drug products needed to suit their unique needs. However, this case has shown that not all compounding pharmacies are operating in this manner. It is clear to me that NECC was acting as a drug manufacturer under the guise of compounding pharmacy. NECC produced over 17,000 vials of the steroid thought to be at the root of the fungal meningitis outbreak without individual patient prescriptions as required under state regulations, shipped to 76 different facilities in 23 states, and has even reportedly solicited bulk orders from health providers. Both FDA and state boards of pharmacies are the regulatory bodies responsible for overseeing compounding pharmacies, and yet NECC flagrantly ignored warning letters by FDA and its own state regulations. Though the investigation around this particular outbreak by FDA, the Centers for Disease Control and Prevention (CDC), and the Massachusetts Department of Public Health is still ongoing, it is critical that the Committee must examine the policy issues surrounding this case to ensure that it does not happen again.

A hearing would help this Committee to better determine the causes of the outbreak, as well as the cures, and I urge you to schedule hearings immediately when Congress is back in session this November. Further, I ask that we work in a bipartisan manner on legislation that will ensure the continued safety of our drug supply, should our Committee investigation find that additional federal authorities are warranted.

With every good wish,

Sincerely,

A handwritten signature in black ink, appearing to read "John D. Dingell". The signature is fluid and cursive, with a large initial "J" and a long horizontal stroke at the end.

John D. Dingell  
Member of Congress

cc: The Honorable Henry Waxman, Ranking Member  
Committee on Energy and Commerce

The Honorable Joseph R. Pitts, Chairman  
Committee on Energy and Commerce  
Subcommittee on Health

The Honorable Frank Pallone, Jr., Ranking Member  
Committee on Energy and Commerce  
Subcommittee on Health

The Honorable Cliff Stearns, Chairman  
Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

The Honorable Diana DeGette, Ranking Member  
Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations