THE COMMITTEE ON ENERGY AND COMMERCE

Memorandum

April 14, 2013

TO: Members, Subcommittee on Oversight and Investigations

FROM: Subcommittee on Oversight and Investigations Staff

RE: Hearing on "A Continuing Investigation into the Fungal Meningitis Outbreak and Whether It Could Have Been Prevented"

On Tuesday, April 16, 2013, at 10:00 a.m. in room 2123 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled "A Continuing Investigation into the Fungal Meningitis Outbreak and Whether It Could Have Been Prevented."

This hearing is a continuation of the Subcommittee's examination of the facts surrounding the 2012 outbreak of fungal meningitis caused by contaminated steroids made and distributed by the New England Compounding Center (NECC) in Framingham, Massachusetts. As was the intent of the first hearing on November 14, 2012, the Subcommittee will examine the Food and Drug Administration's (FDA) history with NECC and its sister company, Ameridose, to determine whether this tragedy could have been prevented had the agency taken action sooner.

I. WITNESS

The Honorable Margaret A. Hamburg, MD
Commissioner
U.S. Food and Drug Administration (FDA)

II. BACKGROUND

As of April 2013, 53 people have died and almost 700 others have been stricken with meningitis or other serious fungal infections after having received contaminated injections of methylprednisolone acetate—a compounded steroid solution, 17,000 vials of which had been made by NECC and shipped to health care facilities across the country. This outbreak ranks as one of the worst public health crises associated with contaminated drugs in the history of the United States.

In early October 2012, bipartisan Committee staff received briefings from FDA and the Centers for Disease Control and Prevention (CDC), as well as from the Massachusetts Department of Public Health (MDPH), to determine how something like this could happen. Knowing that FDA had sent a Warning Letter to NECC in December 2006, on October 12, 2012,

bipartisan Committee staff requested a timeline documenting the agency's past interactions with NECC and Ameridose in order to gain a better understanding of their inspectional history and any related actions FDA had taken. This timeline was produced to the Committee on January 4, 2013, and is attached to this memorandum (see Attachment A). Prior to its November 14, 2012, hearing, the Subcommittee did not know the full extent of FDA's history with NECC leading up to the meningitis outbreak or whether the agency had received recent complaints about NECC and/or Ameridose that raised questions about the nature of their operations and the safety of their products. Neither Commissioner Hamburg's testimony nor the timeline FDA subsequently produced provided much detail about any complaints, warnings, or reports FDA received about these companies.

Following the November 2012 hearing, based on Commissioner Hamburg's testimony, the Committee sent a letter to FDA requesting memoranda and briefing materials related to FDA's assessment of its authority over compounding to determine how this influenced agency decision-making with respect to NECC and Ameridose. Over the course of the next two months, the Committee pressed FDA to produce its documents related to the fungal meningitis outbreak. On February 1, 2013, the Committee sent Commissioner Hamburg another letter regarding its document requests. In that letter, Committee Chairman Upton and Oversight Subcommittee Chairman Murphy stated that if FDA did not produce all responsive documents by February 25, 2013, the Committee would issue a subpoena. FDA finally completed its production on March 21, 2013.

Documents produced by FDA establish the following facts about the agency's history with NECC and its sister company, Ameridose:

1. FDA has known for years that NECC and Ameridose were significantly engaged in drug manufacturing activities and operating well outside the bounds of traditional pharmacy compounding.

2. FDA has also received a litany of complaints about NECC and Ameridose, a number of which directly involved the safety and sterility of the companies' products.

3. Information received by FDA about NECC and Ameridose, including complaints about the safety and sterility of their products, was not shared with State regulators.

Since the November 2012 hearing, FDA held a public meeting with the State pharmacy boards to discuss ways to facilitate increased communication and develop a framework to ensure adequate oversight. FDA has since inspected almost 50 compounding facilities. The majority of these firms were selected for inspection based on their production of sterile injectable drug products alone; however, FDA had received complaints associated with the products and practices of a number of the companies targeted. As with NECC and Ameridose, FDA had already documented serious violations of the Food, Drug, and Cosmetic Act (FDCA) at several

of these very facilities. Based on these recent inspections, FDA has issued Form 483s[1] to approximately 30 of the facilities and posted the documents on the agency's website—an additional step the agency has not typically taken in the past.

III. ISSUES

- Why did FDA decide not to reinspect NECC after stating that it would do so in a Warning Letter to the company in December 2006 and then again in related correspondence two years later?
- What did FDA know about the relationship between NECC and Ameridose?
- How did FDA protect patient safety as it grappled with its authority over drug compounding?
- What did FDA know about the nature and scope of the companies' operations and the safety of their products?
- How did such knowledge influence the agency's assessment of whether NECC and/or Ameridose should be considered a traditional compounding pharmacy versus a drug manufacturer?

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Karen Christian or John Stone with the Subcommittee on Oversight and Investigations at (202) 225-2927.

[1] FDA issues a Form 483 at the end of an inspection when the investigators believe that the observed conditions or practices, in their judgment, may indicate violations of the FDCA or any related regulations. FDA has stated that its goal in issuing a 483 is to have the company act quickly to correct potential violations. The FDA considers the 483 along with an Establishment Inspection Report (EIR), prepared by FDA investigators, and any other information, including any responses received from the company, to determine whether further action is appropriate.