THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

May 21, 2013

To: Members, Subcommittee on Health

From: Majority Staff

Re: Hearing Entitled "Examining Drug Compounding"

On Thursday, May 23, 2013, at 10:00 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled "Examining Drug Compounding." This will be an informational hearing to better understand the current state of drug compounding in America. The following provides background on the witnesses and drug compounding.

I. WITNESSES

Panel I

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
Food and Drug Administration (FDA)

Panel II

Scott Gottlieb, M.D.
Resident Fellow
American Enterprise Institute

Joseph H. Harmison
Owner, Harmison Pharmacies
On behalf of National Community Pharmacist Association

Gerry Migliaccio
Quality Systems Consultant
Migliaccio Consulting

Elizabeth Scott (Scotti) Russell
Government Affairs Manager
National Association of Boards of Pharmacy

Gabrielle Cosel
Manager, Drug Safety Project
Pew Health Group, The Pew Charitable Trusts

II. COMPOUNDING

Traditional drug compounding provides a valuable medical service to patients across the country. According to FDA, it "regards traditional pharmacy compounding as the combining or altering of ingredients by a licensed pharmacist, in response to a licensed practitioner's prescription for an individual patient, which produces a medication tailored to that patient's special medical needs."[1]

In the summer and fall of 2012, a Massachusetts company, the New England Compounding Center (NECC), shipped over 17,000 vials of an injectable steroid solution from three contaminated lots to health care facilities across the country. After receiving injections of NECC's contaminated steroid, over 50 people died from complications associated with fungal meningitis. Further, almost 700 others were stricken with meningitis or other persistent fungal infections. The outbreak ranks as one of the worst public health crises associated with contaminated drugs in the history of the United States.[2]

In order to determine how to stop the outbreak and future outbreaks, the Energy and Commerce Committee pursued an investigation of the problems caused by NECC. As part of the investigation, the Committee sent a letter to FDA on October 17, 2012, asking for documents related to the outbreak. FDA did not fully comply until March 21, 2013, over five months after the Committee's document request.[3]

The Oversight and Investigations Subcommittee (O&I Subcommittee) held its first hearing on the outbreak on November 14, 2012, entitled "The Fungal Meningitis Outbreak: Could It Have Been Prevented?" The O&I Subcommittee held a second hearing on the outbreak on April 16, 2013, entitled "A Continuing Investigation into the Fungal Meningitis Outbreak and Whether It Could Have Been Prevented." In conjunction with the second hearing, the O&I Subcommittee produced a report on its investigation and concluded that "it can and should be stipulated that the fungal meningitis outbreak would not have occurred if not for the company whose management was willing to consistently cut corners and prioritize the expansion of their business over the safety of their products. That being said, NECC was not operating in the shadows. NECC had been on FDA's radar since 2002."[4]

During this hearing, the Health Subcommittee will hear from FDA and health care experts regarding the importance of drug compounding to patients and the current regulation of compounding on the Federal and State levels.

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[1] http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/Hearings/OI/20121114/HHRG-112-IF02-WState-HamburgM-20121114.pdf.

[2] For additional information, please see the following: http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/analysis/20130416Meningitis.pdf.

[3] Ibid.

[4] Ibid.

III. STAFF CONTACTS

Should you have any questions regarding the hearing, please contact Paul Edattel or Carly McWilliams at (202) 225-2927.