



# THE COMMITTEE ON ENERGY AND COMMERCE

## MEMORANDUM

July 12, 2013

To: Members, Subcommittee on Health

From: Majority Committee Staff

Re: Hearing Entitled “Reforming the Drug Compounding Regulatory Framework”

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On Tuesday, July 16, 2013, at 3:00 p.m. in 2123 Rayburn House Office Building, the Subcommittee on Health will hold a legislative hearing entitled “Reforming the Drug Compounding Regulatory Framework.” This legislative hearing will examine various proposals for reforming the regulatory framework of the drug compounding industry. 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**

Jeffrey Francer  
Assistant General Counsel  
Pharmaceutical Research and Manufacturers of America

David Gaugh  
Senior Vice President for Sciences and Regulatory Affairs  
Generic Pharmaceutical Association

B. Douglas Hoey  
Chief Executive Officer  
National Community Pharmacists Association

David G. Miller  
Executive Vice President and CEO  
International Academy of Compounding Pharmacists

Carmen Catizone  
Executive Director  
National Association of Boards of Pharmacy

Kasey Thompson  
Vice President  
American Society of Health-System Pharmacists

Allan Coukell  
Senior Director, Drug and Medical Devices  
The Pew Charitable Trusts

## **II. DRUG 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.”<sup>1</sup>

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.<sup>2</sup>

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?” After FDA finally complied with the Committee’s document request, 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 outlining the issues caused by NECC.<sup>3</sup>

On May 23, 2013, the Health Subcommittee held a hearing entitled “Examining Drug Compounding.” The hearing provided the Subcommittee with a better understanding of the role of compounding in the U.S. health system and the challenges of regulating the compounding industry.

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<sup>1</sup><http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/Hearings/OI/20121114/HHR-G-112-IF02-WState-HamburgM-20121114.pdf>.

<sup>2</sup> For additional information, please see the following:

<http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/analysis/20130416Meningitis.pdf>.

<sup>3</sup> Ibid.

During this hearing, the Health Subcommittee will hear from FDA and health care experts regarding the legislative proposals released since the outbreak, including:

- H.R. \_\_\_ “The Compounding Clarity Act” authored by Rep. Morgan Griffith
- H.R. 2186 “Verifying Authority and Legality in Drug Compounding Act of 2013” sponsored by Rep. Ed Markey
- S. 959 “Pharmaceutical Compounding Quality and Accountability Act” sponsored by Sen. Tom Harkin

### **III. STAFF CONTACTS**

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