THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

February 6, 2014

To: Health Subcommittee Members

From: Majority Committee Staff

Re: Hearing entitled "Examining Drug Shortages and Recent Efforts to Address Them"

On February 10, 2014, at 2:00 p.m. in 2123 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled "Examining Drug Shortages and Recent Efforts to Address Them." This hearing will focus on issues raised, and actions taken, by the Food and Drug Administration (FDA) to prevent and mitigate shortages since enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA) (P.L. 112-114) in July 2012.

I. Witnesses

Marcia Crosse, Ph.D.
Director, Health Care
U.S. Government Accountability Office

Douglas Throckmorton, M.D.
Deputy Director of Regulatory Programs
U.S. Food and Drug Administration

II. Background

A drug shortage occurs when the current or projected demand for a drug exceeds the supply of the drug. In September 2011 and February 2012, the Committee held hearings to examine the combination of factors that may precipitate a shortage, including, but not limited to, various types of disruptions in manufacturing capacity or raw material supply, consolidation in the market or supply chain, and changes in clinical practice. In addition, the Committee heard how the number and severity of drug shortages have dramatically increased in recent years, forcing healthcare providers to devote significant resources to mitigate the often devastating impacts they can have on patients.

The Committee took bipartisan action in response. FDASIA provided FDA with additional authorities and placed new requirements on drug manufacturers intended to help prevent and mitigate drug shortages. These include the establishment of an FDA task force to develop and

implement a strategic plan,[1] the requirement for manufacturers to notify FDA at least six months prior to the date of a discontinuance or interruption in the manufacture of a life supporting drug,[2] the ability for FDA to expedite drug applications and inspections of manufacturing facilities to prevent or mitigate shortages, and the submission of an annual report by FDA to Congress.[3]

Further, FDASIA directed the Government Accountability Office (GAO) to examine several different aspects of drug shortages, including their characteristics and causes, the effect on providers, and FDA's role in resolving them. In connection with the hearing, GAO will be releasing its final report entitled "Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability."

As evidenced by the widespread intravenous saline shortages currently hitting our nation's hospitals, this is very much an ongoing issue.[4] The hearing will provide an opportunity to discuss GAO's findings, understand how FDA's recent efforts have affected the situation, and determine whether more can be done.

III. **Staff Contacts**

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

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[1] *See* U.S. FOOD & DRUG ADMIN., STRATEGIC PLAN FOR PREVENTING AND MITIGATING DRUG SHORTAGES (Oct. 2013), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf.

[2] *See* Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products, 78 Fed. Reg. 65904 (proposed Nov. 4, 2013). FDA's proposed rule implementing the notification provisions in FDASIA would require a manufacturer to notify FDA at least 6 months prior to the date of a permanent discontinuance or interruption in manufacturing, or, if 6 months' advance notice is not possible, as soon as practicable thereafter, but in no case later than 5 business days after the permanent discontinuance or interruption occurs. The comment period for this proposal closed January 3, 2014.

[3] Sec. 1002 of FDASIA requires the annual report be submitted to Congress by the end of each calendar year. FDA submitted the first annual report, for 2013, to the Committee on February 5, 2014.

[4] *See* Karen Weintraub, *Hospitals struggle with intravenous saline shortage*, USA TODAY (Jan. 27, 2014), *available at* http://www.usatoday.com/story/news/nation/2014/01/27/saline-intravenous-shortage/4944169/.