THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

October 1, 2013

To: Members, Subcommittee on Health

From: Majority Committee Staff

Re: Hearing Entitled "Reviewing FDA's Implementation of FDASIA"

On Thursday, October 3, 2013, at 10:00 a.m. in 2123 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled "Reviewing FDA's Implementation of FDASIA." This hearing will focus on the status of the Food and Drug Administration's (FDA) progress on the implementation of Food and Drug Administration Safety and Innovation Act (FDASIA). The following provides background on the hearing.

I. WITNESSES

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

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

II. BACKGROUND

On July 9, 2012, FDASIA was signed into law. As detailed below, FDASIA included numerous provisions to bring predictability, consistency, and transparency to FDA's regulation of drugs and devices.

Title I—PDUFA: Title I of FDASIA reauthorized the Prescription Drug User Fee Act for five years. As part of its agreement with industry, FDA committed to the following goals: (1) meeting performance metrics regarding the timely review of drug applications; (2) increasing interaction between drug sponsors and FDA during the review process; (3) improving engagement with patients, including those with rare diseases; (4) providing more granular data from its review divisions to improve transparency, and (5) undertaking an independent assessment by a third party of FDA's performance in FDA's reviewing applications for novel drugs.

Title II—MDUFA: Title II of FDASIA reauthorized the Medical Device User Fee Act for five years. Industry agreed to increase the fees it paid to FDA in return for significant changes in FDA's performance and accountability. In its agreement, FDA committed to the following:

reporting its total time for reviewing devices; increasing interaction between sponsors and the agency; contracting with an independent entity for a review of the device approval and clearance processes; and implementing a corrective action plan to address deficiencies found in the independent review.

Title III—GDUFA: Title III of FDASIA authorized the Generic Drug User Fee Act (GDUFA). Under GDUFA, the generic drug industry agreed to pay approximately $1.5 billion over five years in return for faster and more predictable review of generic drug applications and increased inspections of drug facilities.

Title IV—BSUFA: Title IV of FDASIA authorized the Biosimilars User Fee Act (BSUFA). This new user fee applies to products approved under the abbreviated approval pathway for biological products shown to be biosimilar to an FDA-licensed biologic.

Title V—BPCA and PREA: FDASIA permanently reauthorized the Best Pharmaceuticals for Children Act and Pediatric Research Equity Act, which incentivizes the testing of prescription drugs in children to allow for the safe use of these products by children.

Title VI—Medical Device Regulatory Reforms: Title VII reformed FDA's medical device review process in order to bring additional predictability, consistency, and transparency to the process. These included reforms to the Investigational Device Exemption process, 510(k) modifications guidance, least burdensome requirements, custom devices, and de novo classification process.

Title VII—Drug Supply Chain: This title included provisions to enable FDA to deal with the increased globalization of drug manufacturing.

Title VIII—Generating Antibiotic Incentives Now: Title VIII made a number of changes to support the development of new antibiotic drugs, including incentives for new qualified infectious disease products by providing an additional five years of exclusivity.

Title IX—Drug Regulatory Reforms: The legislation contained numerous provisions to improve the drug review process, including a provision to increase access to the Accelerated Approval pathway so patients could access life-saving drugs faster.

Title X—Drug Shortages: Title IX included reforms to help patients, doctors, nurses, and hospitals handle the drug shortages crisis. Included among these reforms was the FDA drug shortages list.

Title XI—Other Provisions: The last title of FDASIA made a number of important improvements, including fixing issues related to conflicts of interest, requiring notice by FDA of its intent to regulate lab-developed tests , clarifying the regulation of medical gases, and banning certain synthetic drugs.

III. STAFF CONTACTS

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