THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

April 4, 2014

To: Members, Subcommittee on Health

From: Majority Committee Staff

Re: Hearing on "Examining the Implementation of the Tobacco Control Act"

On Tuesday, April 8, 2014, the Subcommittee on Health will hold a hearing entitled "Examining the Implementation of the Tobacco Control Act." The Subcommittee will convene at 10:15 a.m. in 2322 Rayburn House Office Building. At the hearing, the Subcommittee will review work conducted by the Government Accountability Office (GAO) overseeing the regulatory activities of the Food and Drug Administration's (FDA) Center for Tobacco Products (CTP or the Center) since the Center was established in 2009 under the Family Smoking Prevention and Tobacco Control Act (TCA, P.L. 111-31).

I. WITNESS

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

II. BACKGROUND

The TCA was enacted in 2009, and granted FDA the authority to regulate the manufacturing, marketing, and distribution of tobacco products. The CTP was established under the TCA to implement the law by reviewing submissions for marketing new tobacco products, enforcing prohibitions on the sale of certain tobacco products, developing regulations and guidance, engaging in public education about the risks associated with tobacco product use, and performing other regulatory activities. Under the TCA, tobacco manufacturers and importers are assessed user fees, which provide the sole source of funding for the CTP's regulatory activities.

GAO has conducted extensive analysis on the implementation of the TCA, including a report released in September 2013 entitled "New Tobacco Products: FDA Needs to Set Time Frames for Its Review Process," which examined the status of the Center's review of new tobacco product submissions, responses to meeting requests, and use of resources. GAO also has conducted work on trade in tobacco products and issued a report in April 2012, which in part describes market shifts and differences in FDA's regulation of various types of tobacco products. Further, as mandated by section 106(b) of the TCA, GAO currently is working on a report concerning "the adequacy of [FDA's] authority and resources" as well as "any recommendations for strengthening that authority" that will be issued later this year.

III. LEGISLATION

The Subcommittee also will discuss H.R. 389, the "Transparency in Tobacco User Fees Act of 2013," which was introduced by Representative Guthrie on January 23, 2013. This bill would require FDA to submit annual reports to Congress on the use of tobacco user fees assessed and collected under the TCA.

IV. STAFF CONTACT

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