

Opening Statement of the Honorable Joseph R. Pitts
Subcommittee on Health
Hearing on “Examining the Implementation of the Tobacco Control Act”
April 8, 2014

(As Prepared for Delivery)

The Tobacco Control Act (TCA) was signed into law on June 22, 2009.

The TCA established the Center for Tobacco Products (CTP) within FDA and gave FDA authority over the regulation of tobacco products, including restricting their sale, distribution, advertising, and promotion. In addition, FDA has the authority to require changes in the design and characteristics of current and future tobacco products, such as the reduction or elimination of harmful ingredients and additives.

The sole funding source for CTP is user fees assessed on tobacco manufacturers and importers.

GAO has conducted a comprehensive study on the law’s implementation, and, in September 2013, it released a report entitled “New Tobacco Products: FDA Needs to Set Time Frames for Its Review Process.”

The report examines CTP’s review of new tobacco product submissions, responses to meeting requests, and use of its user fees.

Among its findings, GAO reports that CTP lacks basic performance measures “like time frames for reviews of...submissions” and that this “limit[s] CTP’s ability to evaluate policies, procedures, and staffing resources in relation to CTP’s submission review process and, in turn, limit[s] CTP’s ability to reasonably assure efficient operations and effective results.”

GAO concludes that “[a]n entity that is limited in its ability to evaluate its performance will be hard-pressed to determine what adjustments it should make to its operations or how to plan for the future.”

This report raises troubling concerns about CTP’s performance and its ability to effectively implement the Tobacco Control Act and respond to the thousands of new product submissions it has received in a timely manner.

As the Subcommittee with oversight of FDA and the Center for Tobacco Products, Dr. Marcia Crosse of GAO is here today to walk us through the report and GAO’s ongoing efforts to oversee implementation of the Act.

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