Chairman Robert Aderholt

Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
House Committee on Appropriations

FY 2016 Budget Hearing – Food and Drug Administration
March 4, 2015
Opening Statement As Prepared

Good Morning. I want to welcome all of you to today's hearing. The intent of this hearing is to examine the Food and Drug Administration's fiscal year 2016 budget request. In addition to this Committee's review of the budget request, the Members will likely seek information on the agency's use of current and past resources, including the activities, policies, and practices supported with appropriated funds.

Our witness today is the Commissioner of the Food and Drug Administration, Dr. Margaret Hamburg. She is joined by Norris Cochran, Deputy Assistant Secretary for Budget of the Department of Health and Human Services; and Jay Tyler, the Chief Financial Officer of FDA.

As your testimony notes, you will be stepping down at the end of this month. You have not only lasted six years in one of the most challenging and demanding jobs of the Federal government, but you have served with great success on behalf of your dedicated staff and the American people. We may have differing opinions on policies, regulations, and funding, but there is bipartisan and bicameral respect for the way you have provided leadership to this vitally important public health agency.

As I have mentioned in previous hearings, I have established three primary goals for this Subcommittee as we progress through the fiscal year 2016 appropriations process. The first goal is to improve the management of the agencies and programs within our purview. Continuing to build upon efforts in previous years, our goal is enhancing accountability in spending of the taxpayer's dollars through improved agency governance processes and internal controls, and ensuring transparent decision making. FDA has vast authorities and regulations to properly oversee various efforts under its jurisdiction – from the safety of food and medical products, to the effectiveness of drugs and devices, to the safety of vaccines and the blood supply. With these responsibilities, FDA needs to utilize their oversight capabilities in all areas to better ensure that our limited resources are spent wisely. FDA must also tighten controls for areas subject to large expenditures with unclear results and where performance tasks or milestones are not met, such as information technology. To assist Congress in monitoring the use of scarce resources, we authorized the transfer of $1.5 million in FY 2015 to the Department of Health and Human Services' Office of the Inspector General.

The second goal is to target funds to the most important programs and functions. This bill contains vast and diverse responsibilities and a limited amount of resources. It would be impossible to meet the full demands of any one agency so there are tough decisions to be made by this Subcommittee. I want to continue to be sure that we make wise decisions in allocating the funding. We will continue to invest in programs that prove effective and have broad support, such as FDA's Medical Counter Measure initiative, WIC, and rural development programs. We should also support programs that have a clear and distinct reason for using federal funding, such as addressing emerging agricultural pest and disease threats across the nation or the monitoring of safety issues with food or medical products. In order to fund these programs, we must reduce or eliminate funding for lower priority, less effective or duplicate programs.

The third goal is to promote U.S. agriculture, free and fair markets, and safe food and medicines. The United States has one of the safest medical product markets and safest, most highly productive food and agriculture sectors in the world, and the U.S. government plays a unique role in ensuring that all of these sectors main their current vitality. For instance, we support a vibrant rural economy by investing in infrastructure, such as water and waste and housing programs. We fund FDA's efforts to oversee a growing number of drugs and drug ingredients produced outside of our borders. We also promote a free and fair international trade regime that allows U.S. commodities and products to be sold around the world. As you remind us in your testimony, FDA regulates over 20 percent of every consumer dollar spent on products in the United States. This Subcommittee must continually remind FDA and this Administration that they need to be very aware of the comprehensive economic impact of their regulatory decision making so that the path to greater safety and effectiveness of products under their jurisdiction is not littered with lost jobs and struggling small businesses. The Agency's approval of 51 new molecular entities and biological products as well as a record number of orphan drugs in a single year are commendable, but we just remind you that regulations have the potential to limit both scientific discovery and ingenuity.

The size of FDA's FY 2016 request includes increases for budget authority that disregard the debt crisis facing our nation. The agency is proposing large increases using scarce discretionary resources. Since FDA is informing Congress that Food Safety, Medical Product Safety, and Rent and Infrastructure needs are their highest priorities this year, it will be incumbent upon FDA to prove to Congress that such priorities cannot be funded out of base resources first. In addition, the Agency must demonstrate that all efforts have been made to review current operations for potential savings and efficiencies. Lastly, the Subcommittee and the American public need assurance that the agency is coordinating and not duplicating other efforts across HHS, USDA and elsewhere to ensure the most efficient means of accomplishing its mission. We hope to touch upon each and all of these issues in more detail during our questions.

In looking at the proposed user fees, FDA is again proposing to collect and spend $198.6 million for new and unauthorized programs. While there is a time and place for user fees as demonstrated by the success of most of FDA's user fee programs, FDA provides no evidence that demonstrates current efforts are effective in assisting the beneficiaries and that the resources for new efforts will result in better services for the customers.

The Ryan Murray budget deal signed into law in 2013 caps overall spending as well as defense and non-defense spending. I anticipate that the Subcommittee's funding levels will remain relatively flat at best. FDA's request for budget authority exceeds the 2015 enacted funding level by six percent. Today and in the months ahead, we must analyze the request and focus on allocating the funding using the goals that I have outlined above to the most effective, highest priority programs.

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