



Chairman Robert Aderholt

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

FY 2017 Budget Hearing
Food and Drug Administration
February 24, 2016
Opening Statement As Prepared

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 2017 budget request. In addition to this Committee's review of the budget request, the Members of the Subcommittee will 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 Acting Commissioner of the Food and Drug Administration, Dr. Stephen Ostroff. He is joined by Mr. Jay Tyler, the Chief Financial Officer of FDA. I would note that we were pleased to see the Senate confirm Dr. Califf yesterday for the permanent position of FDA Commissioner. During the transition period between Dr. Ostroff and Dr. Califf, I believe we are in good hands today.

As I have mentioned in previous hearings, I have established four primary goals for this Subcommittee as we progress through the fiscal year 2017 appropriations process. The first goal is increasing oversight, efficiency, and the need for effective outcomes, 2) keeping rural America vibrant, 3) supporting American farmers, ranchers and producers, and 4) protecting the health of people, plants and animals.

Given the myriad of responsibilities assigned to the FDA by Congress, there is a constant need for this body to increase our oversight. Our oversight not only covers the expenditure of resources, but also the corresponding activities, the efficiency in delivering those services, and the degree to which the agency delivered or failed to deliver meaningful outcomes. At the end of the day, our constituents demand that limited resources are spent wisely.

For example, the FY 2016 omnibus bill provided FDA's full funding request to continue implementation of the Food Safety Modernization Act (FSMA). Your FY 2017 budget request proposes a total programmatic increase of \$212 million for food safety, yet the Committee is still in need of the proper accounting for food safety expenditures in the for the current and past years. While you have provided us with more detail on your spending plans than in the past, we will continue to require regular updates on your use of these funds and what you are accomplishing.

FDA's FY 2017 request includes modest increases in budget authority that more closely reflect the debt crisis facing our nation. Our Nation's over \$19 trillion debt requires us to trim

government spending or decrease the growth of government at a minimum. FDA is proposing discretionary increases of \$31.2 million and reductions in the amount of \$21.1 million for a net increase of \$10.1 million. It is worth noting that total programmatic resources in this request represent a 21 percent increase above the FY 2012 budget request.

In looking at the proposed user fees, FDA is again proposing to collect and spend \$202.3 million for new, 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 to demonstrate that current efforts are effective in assisting the intended beneficiaries and that the resources requested for new user fees will result in better services for the customers.

In addition to the President's FY 2017 budget request, Congress received the Administration's request for approximately \$1.9 billion in emergency appropriations in response to the spread of the Zika virus. I want to echo the remarks made by Chairman Rogers and two of our other Subcommittee Chairmen that the most expeditious way to respond to the disease is to use unobligated funds previously provided for Ebola response in FY 2015. In fact, in January of 2016, FDA had far more unobligated funds leftover from the Ebola appropriation than the total request for the Zika virus. This is yet another example of a situation in which the Administration should utilize existing resources rather than run to Congress for more money that compounds the Nation's debt.

Another goal for the Subcommittee is protecting the health of people, plants and animals, which is also the main mission of the FDA. The United States has one of the safest medical product markets, and the safest, most highly productive food and agriculture sectors in the world. The U.S. government plays a unique role in ensuring that all of these sectors maintain their current vitality. We must continue to explore ways by which FDA can fulfill its public health mission successfully but do so in a way that the regulated industry has clarity on the rules of the road and they are not burdened with unnecessary regulation.

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 any additional 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.

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. As noted in a December 2015 GAO Report, FDA's IT strategic plan does not identify results-oriented goals and performance measures and milestones, or targets for measuring the extent to which outcomes of IT initiatives support FDA's ability to achieve agency-wide goals and objectives.

In closing, I want to note that the work you and your colleagues perform at FDA touches the lives of every American, and we appreciate your dedicated service. You have no shortage of work as there are many challenges facing the FDA today – from food safety to opioid abuse to

antimicrobial resistance – just to name a few. We look forward to hearing from you today about your funding proposals for the future and what you are doing with available resources in the current year.

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