Chairman Robert Aderholt

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

FY 2018 Budget Hearing
Commissioner of FDA Dr. Scott Gottlieb
May 25, 2017
Opening Statement As Prepared

I want to welcome all of you to today's hearing. We are pleased to have the new Commissioner of FDA, Dr. Scott Gottlieb, testifying before the Subcommittee today. Dr. Gottlieb, you are no stranger to FDA or the Department of Health and Human Services. You have served in various leadership roles and on committees that make you well qualified to lead FDA. Welcome to the Subcommittee, and we look forward to working with you and your team.

The intent of this hearing is to examine the Food and Drug Administration's fiscal year 2018 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.

As I have mentioned in previous hearings, I have established four primary goals for this Subcommittee as we progress through the fiscal year 2018 appropriations process. The first goal is evaluating and accounting for taxpayer dollars to ensure efficiency and accountability, second is investing in rural infrastructure as a catalyst for growth, third is ensuring support for American farmers, ranchers and producers, and, last and most pertinent to FDA, protecting the health and safety of people, plants, and animals.

Congress has passed a number of noteworthy pieces of legislation over the past ten years involving FDA's roles and responsibilities. These Acts include the Tobacco Control Act, the Food Safety and Modernization Act (FSMA), the Food and Drug Administration Safety and Innovation Act, the Drug Quality and Security Act, and, most recently, the 21st Century Cures Act. Each of these major Acts has resulted in new funding streams and a constant need for the Appropriations Committee to increase our oversight of the agency. Our oversight not only covers the expenditure of resources, but also the corresponding actions, the efficiency in delivering those actions, and the degree to which the agency delivered or failed to deliver meaningful and measurable outcomes. At the end of the day, our constituents demand that limited resources are spent wisely.

FDA's FY 2018 budget request is not unlike other agency budgets this year in that the Administration proposes to scale back some activities and decrease spending. As I reminded folks at the budget hearing for the Secretary of Agriculture yesterday, our nation's debt is unsustainable and it will soon exceed $20 trillion. In terms of your funding request, FDA is proposing at total of $4.9 billion at the program level for its Salaries and Expenses Account. Of

this total, $3.1 billion is derived from user fees and $1.8 billion comes from discretionary budget authority. This change in budget authority represents a decrease of $939 million. While the budget proposes to recoup $769 million from additional user fees, the agency is proposing a reduction of $171 million. We will likely have questions and comments about these proposed changes as some of the budget gimmicks of yesterday are here today.

In looking at the proposed user fees, FDA is again proposing to collect and spend $725 million in renegotiated user fees for the drugs, medical devices, generic drugs, and biosimilar user fee accounts. I give someone credit for coming up with this creative proposal, but the legislation before Congress reflects agreements that take up to two years to work out. You are asking the authorizing committees to reopen their nearly finished product and renegotiate over $700 million in user fees without any additional benefit in return. These reauthorizations need to be complete by July, or, as I understand it, FDA will begin the process of reducing their medical product review staff. At a time when the Administration is talking about speeding up medical product reviews, it would not help to lay off the very people you need to complete the reviews. Lastly, I am skeptical of FDA reopening user fee agreements for unexpired animal drug user fees to recoup an additional $53 million. This is a long way of saying that the agency's chances of offsetting budget authority with user fees faces a steep uphill battle.

FDA oversees 20 cents out of every consumer dollar, resulting in 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. On a related note, I would like to express my appreciation for the FDA's recent decisions to review the previous Administration's regulatory actions. Your agency can achieve the same ends as those required by Congress, but without the costly and burdensome means of some of FDA's previous regulatory actions.

I look forward to hearing about the Agency's new priorities as well as the continuation of past priorities such as reducing the opioid abuse or your progress in implementing the provisions of FSMA. We expect to hear more about the planned changes to the medical product review process. The agency's recent fast approval of the cancer drug Keytruda may indicate FDA's greater willingness to utilize the latest medical advances to improve your regulatory processes and make drugs accessible prior to the completion of a lengthy drug trial. I also want to open up a dialogue about the Orphan Product review process so that Congress can determine whether the underlying law or administrative changes are necessary to weed out the unscrupulous actors in this space. At the end of the day, we want to hear from you that resources are adequately aligned with policies that will advance public health.

As I and my colleagues are keenly aware, 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 drug safety and effectiveness to opioid abuse to food and animal feed safety – just to name a few. We look forward to hearing from you today about the President's budget proposal and what you are doing with newly approved resources in the current year.

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