



Chairman Robert Aderholt

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

FY 2019 Budget Hearing Opening Statement (as prepared) Food & Drug Administration – Commissioner Scott Gottlieb April 17, 2018

The Subcommittee will come to order.

Good Afternoon. I want to welcome all of you to today's hearing. Our primary goal this afternoon is to examine the Food and Drug Administration's fiscal year 2019 budget while also reviewing the use of funds past and present. Our witness is the Commissioner of the Food and Drug Administration, Dr. Scott Gottlieb.

Commissioner Gottlieb, you have not reached your first year anniversary yet, but you have already accomplished or made progress in a number of high priority public health initiatives – from the record number of generic drug approvals to a first time gene therapy for cancer to new strategies in combatting addictions. While I and my colleagues will not agree with you 100 percent of the time on the agency's regulatory actions, you have overwhelmingly gained bi-partisan support for the way you have handled difficult policy matters. This is a real feat in Washington these days, and so I want to commend you for your leadership. You lead an agency that touches the lives of every single American every day and millions of the consumers across the globe annually whether it is through human and animal foods, human and animal drugs, medical devices, vaccines, or cosmetics. The Agency can no longer be called a simple regulator of goods and services. We appreciate what you and your folks have accomplished and strive to accomplish on the front lines of public health.

As noted, we have not always agreed with FDA's level of regulatory enforcement. However, I want to recognize your actions and efforts towards providing flexibility in a number of regulatory actions. As we have seen many times in the past, FDA employees can sometimes become a bit too zealous and inflexible in their development and implementation of rules. You have wisely recognized the

negative impact of rigid regulations a number of times this past year and allowed the regulated industries more time to comply with those rules. As long as you don't sacrifice safety and public health, which I trust you will not, I encourage you to continue to provide regulatory relief where feasible for the sake of small and medium size businesses as well as maintaining jobs in or bringing jobs back to the United States.

FDA's budget and workforce continue to grow substantially despite what some people claim. It is difficult to say with full certainty what the right size is. We will need to deliberate on this matter while developing the FY 2019 appropriation. We do know that the reasons for growth vary.

First, the cost of paying, training and supporting scientific and medical experts is on the rise. Secondly, FDA is a regulator of products sourced all over the world and the complex nature of an international marketplace is resource intensive. Thirdly, Congress continues to place more requirements and responsibility on the Agency – sometimes too much. Lastly, Congress and the private sector continue to invest more in medical research and development. This Congress added \$3 billion to NIH research last year alone and with a total of \$37 billion in NIH research in FY 2018, we will eventually see medical breakthroughs which need to go through FDA before they can reach the marketplace. To put FDA's growth in context, when you last worked at FDA in 2007, Congress funded FDA at \$1.79 billion. FDA's FY 2019 budget request before us today stands at \$5.8 billion.

The Trump Administration's FY 2019 budget request for FDA is likely the boldest and largest funding request in recent memory and maybe ever. I count nine different funding initiatives plus requests for agency infrastructure. The discretionary budget seeks an increase in excess of \$400 million or approximately a 16 percent increase. When Secretary Perdue appears before this Subcommittee tomorrow, he may wish he was in your position to be asking for such an increase when the Administration proposed a comparable level of decrease.

The wide assortment of medical product initiatives go beyond FDA's typical regulatory boundaries. For example, FDA seeks \$12 million for an initiative entitled "Bring MedTech Manufacturing Home: Advance Medical Device Manufacturing and Quality". The Agency requests \$100 million alone for the "New Medical Data Enterprise." One more example involves promoting domestic manufacturing for \$58 million. This latter initiative involves the concept of "continuous manufacturing" – a production process that could be revolutionary if adopted by medical product companies on a large scale. While FDA's narrative

seeks to address real world problems, this Committee must make some major decisions on whether or not to invest in these initiatives and if so, at what cost.

I also hope to touch upon the funding and policy decisions included in the FY 2018 Omnibus bill enacted last month. The Members of this Subcommittee were key players in an appropriation which targeted increases to several of the Nation's highest priorities – food safety, drug compounding, the Oncology Center of Excellence, and the opioid epidemic impacting every community across the Nation. The opioid increase of \$94 million should help FDA go after illegal and counterfeit drugs entering this country through International Mail Facilities. We hope to hear from you today and over the second half of the fiscal year on FDA's performance with these new resources.

I am also aware that you have unveiled a Nutrition Innovation Strategy that includes issues of interest to this Subcommittee such as standards of identity for food products, providing nutritional information to consumers, and recommendations for sodium levels. I look forward to discussing these items as well as the continual implementation of the Food Safety Modernization Act, FSMA.

As we conduct our oversight responsibilities and craft the Agriculture & FDA Appropriations bill for FY 2019, I want to outline my goals for the Subcommittee. The first goal is to Bolster Prosperity and Economic Well Being in Rural America and the Farm Economy; the second is to Conduct Fair and Transparent Oversight of Agency Activities and Public Resources; the third is to Promote Economic Growth through Effective and Efficient Regulation and Minimization of Regulatory Overreach; and the last goal is to Protect the Health and Safety of People, Plants, & Animals.

As we move forward, we will use these goals to guide us as we consider the budget request and adequately fund critical programs. We will find resolutions to effectively meet the needs of the public health community; effective, common sense regulation that does not create barriers to economic prosperity; and investments in those areas that lead to the delivery of safe and effective products and services. Our objective is to craft a spending bill that is fiscally responsible, reflecting the needs of the American people while protecting the science and ingenuity of Americans here at home.

The aforementioned items just scratch the surface of the issues to discuss today and in the months ahead. As a Committee we must analyze the request and focus on allocating funds using the goals that I have outlined to target the most effective, highest priority programs.

Again, I want to thank you for being with us today, and I look forward to today's discussion.

###