Chairman Sanford D. Bishop, Jr.

"Status of Operations" Hearing

Food and Drug Administration

Commissioner Scott Gottlieb

February 27, 2019

The Subcommittee will come to order.

[Gavel.]

Good afternoon.

I want to welcome everyone to today's hearing, our first in the 116th Congress.

Before we get underway, I would like to personally welcome all the returning members to the subcommittee and our new members: Ms. Lee of California, Ms. McCollum of Minnesota, Mr. Cuellar of Texas, Ranking Member Fortenberry of Nebraska, and Mr. Moolenaar of Michigan.

I would also like to thank Mr. Aderholt for his work on this subcommittee, serving as the Chairman for the previous six years.

I look forward to working with all of you in a productive and bipartisan manner.

I also want to thank Commissioner Gottlieb for allowing us to start the hearing an hour later. We are very appreciative of your flexibility.

The work of this subcommittee touches the lives of every citizen on a daily basis, as we have said so often. Many do not recognize the far reaching jurisdictions and programs this subcommittee addresses – a little bit of everything from food safety to agriculture research to drug approval to rural development to protecting market integrity through the Commodity Futures Trading Commission.

Part of our efforts include providing necessary resources to the Food and Drug Administration, which plays a critical role in the lives of every

American. In addition, we have a duty to make sure those resources are put to the best possible use by the agency.

With that, I would like to welcome our witness, Dr. Scott Gottlieb, Commissioner of the Food and Drug Administration. We are delighted to see you.

Today we wish to discuss the status of operations at the Food and Drug Administration, including impacts and recovery from the longest and most pointless shutdown in U.S. history.

Before we begin, I would like to thank you and your committed employees for your efforts during the shutdown, many of them working without pay.

While the full impacts from the shutdown will not be known for some time, there are undoubtedly accrued backlogs of inspections, delayed drug and medical device reviews and potentially exhausted pools of user fees as a result of the shutdown. We look forward to hearing the processes put into place to work through these backlogs as efficiently as possible and other efforts to return to more standard operations.

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

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Now, let me ask our distinguished Ranking Member, Mr. Fortenberry, if he has any opening remarks.

Mr. Fortenberry?

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Next, I would like to recognize the chairwoman of the full Committee, Congresswoman Lowey, for her opening remarks.

Chairwoman Lowey?

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Before Dr. Gottlieb begins, a reminder to members that, as is customary with our subcommittee, members will be recognized by seniority for those who were here when I gaveled the hearing to order, and then in order of their arrival after that.

We will alternate majority and minority members and we will adhere to the five-minute rule.

Commissioner Gottlieb, without objection, your entire written testimony will be included in the record.

I will recognize you now for your statement, and then we will proceed with questions.

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