

**Statement by
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Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Committee on Appropriations, U.S. House of Representatives**

Chairman Bishop, Ranking Member Fortenberry, and Members of the Committee:

The 35-day lapse in appropriations that began on December 22 was a significant operational challenge for FDA. Through the collective efforts of the professional staff of the agency, we maintained our critical public health functions, safeguarded the public health and safety, averted challenges to our public health protection role, and continued to perform review activities supported by user fees.

But even as we maintained our most important obligations that we owe to the American people, it was hardly business as usual at the agency.

We were at partial strength. Many programs, where the primary support is through budget authority rather than user fees, faced substantial furloughs. Our strength is our people. And many of our people were not at their posts.

These include many people in our food program, our inspectorate, our Center for Veterinary Medicine, and our blood program, to name some of the parts of the agency that were impacted the most by the lapse in funding.

Equally challenging, many of the policy, legal, administrative and communications staff that support the entire agency, and help advance our mission across our entire public health portfolio, were also on furlough. The absence of so many valued colleagues and the critical functions that they play was notable.

Many of our professional staff that continued to carry out critical activities did so unpaid. Our field force continued to perform inspections of foreign and domestic high-risk food and medical product facilities and our special agents continued their criminal investigations, even while they were unpaid and accruing per diem expenses on their government travel cards. Our operations staff and many other key functions faced significant furloughs even while their skills were in greatest need during the lapse. But working together, we maintained our vigilance.

We tracked outbreaks and addressed them; we continued import entry review making admissibility decisions and key sampling of imports at our ports of entry; we maintained post market safety assignments across our medical product centers, and so much more.

A unique spirit of public health mission guides the FDA. It animates our efforts. It binds our staff in a common mission. And gives purpose to our collective work.

The agency's staff knows how important their efforts are. They know that each one of them plays a critical role in the exercise of our expansive mission, whether they're on the front lines inspecting a manufacturing plant, analyzing data as part of a review function, providing administrative and logistical support that makes all of these and many other efforts possible, or performing one of the many other roles that advance our key public health functions.

Everyone at the FDA is essential to our collective mission.

Even though the lapse in appropriations has ended, we are still responding to its effects. During the 35-day lapse, we could not accept new medical product applications that required a user fee. As a result, we could not initiate the review of medical product applications from sponsors that we received during the lapse. With continued hard work and careful planning by our medical product centers, we will work to review this bolus of drug and medical device applications in timeframes that are consistent with our user fee goals. Despite the impacts of the lapse, we will endeavor to mitigate any observable impacts on our review performance goals in the coming year. We're committed to making sure that patients continue to have access to the treatments they need, and never wavering from our gold standard for safety and effectiveness.

We're lowering our inspectional and import and field sampling goals for the year. We won't be able to conduct as many inspections of food and medical product facilities, and reviews of imports, as we had originally planned. This is because we focused on the highest risk establishments during the lapse, and many other types of inspections didn't take place. The effected programs include human and animal food, biologics, and devices.

In setting new targets for the year, we'll use our risk-based approach, focusing on high-risk products, facilities that were never inspected, and firms with troubling compliance records, so that we can continue to protect consumers and carry out our public health mission. We believe we'll still hit our original goals for pharmaceutical and compounding inspections. And across all products, we'll continue to safeguard the public by targeting our efforts around high-risk inspections.

Certain policy work will also be delayed, especially in our food and animal health programs. Because protection of "animal health" does not often meet the Anti-Deficiency Act standard of "imminently threaten the safety of human life or the protection of property," work that impacts animal life and health generally was not permissible during the lapse.

Ultimately, FDA's greatest strength is its people. I've spent much of my time talking to our staff about the impact of the lapse in appropriations on their work and their personal lives. I know they're relieved to be back at work, and dedicated to FDA's mission. But I also know that Federal service is hard. The FDA can be hard. There's a lot at stake in the work that we do. That's what gives our work its purpose. But it also adds to the challenges that we face every day in performing our serious obligations.

Supporting the men and women of FDA, and improving our hiring process, has been one of my top priorities. So, in the coming weeks, a significant part of my focus is going to be on continuing to solidify our hiring and retention efforts, in supporting the men and women of the FDA, and doing my best to remind the people of the FDA how critical they are to the collective mission of one of the most vital agencies in the federal government.

Our work helps consumers expand opportunities to improve their health and happiness, improves animal health, and quite literally can save lives. These are just some of the obligations we perform on behalf of Americans. It's what makes our mission so challenging, but also what makes service at the FDA so rewarding. I hope you'll join me in saluting the professional staff of the agency for their dedication, perseverance, and expert execution during a challenging moment in the agency's storied history. I appreciate the opportunity to testify today about our work during the lapse, and look forward to answering your questions.