Opening Statement of the Honorable Gregg Harper
Subcommittee on Oversight and Investigations
"Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's Food-Recall Process."
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The Subcommittee convenes this hearing entitled "Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's Food-Recall Process."

Disease outbreaks from tainted food are an ongoing public health challenge. The Centers for Disease Control (CDC) estimates that each year one in six Americans – 48 million people – get sick from foodborne illness, 128,000 are hospitalized, and 3,000 die. The number of multistate food illness outbreaks is increasing, affecting greater numbers of Americans. And the number of vulnerable people, older and immune-compromised individuals, is growing.

The threat of foodborne illness persists, even though we have gotten better at detecting and investigating outbreaks. And through the implementation of the Hazard Analysis and Critical Control Point (HACCP) rules over the last two decades, CDC trend data indicates major reductions in the incidence of foodborne disease. Yet the problem remains significant.

When contaminated food reaches store shelves, the FDA is the public's last line of defense. The FDA needs to be able to quickly and effectively help remove dangerous foods from commerce and protect consumers. In 2010, Congress gave FDA more power to recall tainted food. The FDA Food Safety Modernization Act (FSMA) was enacted to provide FDA with the authority to mandate a food recall. In addition to this law, previous audits by both the HHS Office of Inspector General (OIG) and the Government Accountability Office (GAO) made recommendations to FDA to improve its food-recall program.

How has FDA performed with food-recalls in recent years with the new law and these recommendations? Over the last two years, the HHS OIG looked at this question and last month released a report that contains findings and recommendations for FDA.

The OIG report looked at 30 voluntary food-recalls overseen by FDA between October 2012 and May 2015. The FDA has used its mandatory recall authority only two times since the enactment of FSMA **[FIS-MA]** and not at all over the last four years. In some cases, the FDA was slow to evaluate health hazards. It took FDA an average of 47 days to complete an evaluation after learning of a planned or in-progress food-recall.

The OIG found that FDA was woefully slow in starting recalls. The average length before a recall began once FDA knew of the safety issue was 57 days.

The report also raises questions about the FDA's ability to cope with uncooperative companies. In one case involving a dietary supplement company, it took 10 months after FDA issued a warning letter about unlisted ingredients before the firm finally pulled the product. In another case, a recall of nut butter began more than five months after the FDA had traced the salmonella outbreak to the source facility. There were 14 illnesses in 11 states during that time.

A series of recalls of cheese products contaminated with listeria took 81 days to complete. Nine people got sick, including one infant who died and two fetal losses linked to illness. During that time, the firm owner lied to the FDA saying that the firm would suspend the manufacturing and distribution of cheese. However, the owner, despite knowing that the product tested positive for listeria, continued to allow the product to be distributed. The owner later pleaded guilty to FDA crimes and went to prison. Justice was done, but FDA needed to find a way to detect such deception sooner.

The OIG also found that FDA did not have a reliable system for accessing the recall initiation date or the date FDA became aware of potentially hazardous food products. More than a third of the recalls reviewed had the wrong initiation date entered into FDA's electronic data system called the Recall Enterprise System (RES). The electronic data system also did not include when FDA first found out about the suspect food products. Worse, FDA does not collect sufficient or accurate data so that the agency can measure its performance to tell whether their food-recall performance is improving.

In addition to the OIG findings, FDA told Committee staff in a briefing that there are concerns about the turnaround time it takes to get test results from FDA labs that are used to make an evaluation of the seriousness of the food hazard. To ensure the FDA labs are performing properly, FDA needs to provide independent funding and permanent staff to its Office of Laboratory Science and Safety. This

office has not been fully stood up and has been unable to inspect FDA labs. FDA should follow the example of the CDC. The CDC's Office of Lab Science and Safety has dedicated funding and permanent staff to overseeing CDC's own labs.

The enactment of the FSMA **[FIS-MA]** provided FDA mandatory recall authority and imposed more legal obligations on food manufacturers and distributors. FDA has the tools, but the OIG's findings and FDA's own assessments show that the FDA needs to reform itself to get this right.

I am heartened that the FDA Commissioner has recognized that even just a handful of problematic recalls are too many, because lives are at stake. I am also glad that the Commissioner has announced that FDA is looking at ways to improve the timeliness and scope of information provided to the public about FDA-regulated food-recalls.

I welcome and thank the witnesses, and look forward to their testimony.