STATEMENT OF
THE HONORABLE BART STUPAK
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS
"AMERICAN LIVES STILL AT RISK: WHEN WILL FDA'S FOOD PROTECTION PLAN BE FULLY FUNDED AND IMPLEMENTED?"

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Today, this Subcommittee is holding another in a series of hearings examining the adequacy of the efforts of the Food and Drug Administration to protect Americans from unsafe food. In fact, today's hearing is our eighth on this topic since January of last year. The purpose of today's hearing is to receive important testimony from the FDA regarding how the Agency plans to address its many weaknesses concerning its ability to protect our food supply.

To date, our investigation and hearings have uncovered a multitude of problems regarding FDA's food safety efforts including poor policy choices, questionable management decisions, and a lack of resources. Collectively, FDA's failed regulation of domestic food producers, its ill-conceived plan to close laboratories and reorganize field staff, and its inability to ensure the safety of imported food have suggested the Agency's food safety system is broken.

Outside experts have also found that FDA's food safety system is in trouble. In fact, in January 2007, GAO added the federal oversight of food safety to its High-Risk series and called for a government wide reexamination of this country's food safety system. GAO found numerous concerns with the present food safety system including inconsistent oversight, ineffective coordination, and incomplete program planning. Last year, FDA's own Science Board issued a scathing assessment of FDA's food protection abilities concluding the agency "does not have the capacity to ensure the safety of food for the nation." In April of this year, Trust for America's Health, a major public health watchdog organization, issued yet another report which also found a number of deficiencies in the ability of FDA to safeguard the Nation's food supply.

Throughout all of these evaluations one common theme has emerged: FDA's resources are so stretched that its ability to protect Americans from unsafe food is seriously jeopardized. Perhaps the Science Board said it best in its report concluding, "In contrast to previous reviews that warned crises would arise if <u>funding issues</u> were not addressed, recent events and our findings indicate that some of those crises are now realities and American lives are at risk." Indeed, the events of the past eighteen months, with recall after recall, demonstrate these concerns have now become a reality.

In response to the multitude of food-borne contamination outbreaks and concerns about its ability to protect Americans from unsafe food, in November of last year, FDA

released a document entitled, "Food Protection Plan: An Integrated Strategy for Protecting the Nation's Food Supply." The *Food Protection Plan* lays out a blueprint for addressing food safety and food defense for both domestic and imported food. The plan attempts to prevent contamination by pursuing safety measures that will address risk through the life cycle of food products, but more importantly, to identify potential food hazards and counter them before they can do harm.

The *Food Protection Plan* is very appealing on paper and appears to be a positive first step toward creating a stronger food safety system. Nonetheless, this Subcommittee and the many experts that will testify today are concerned that key specifics and the resources required to implement this plan remain elusive. As reported by GAO at our January 29th hearing, while acknowledging it will need additional funding, "FDA has not provided specific information on the resources it anticipates the agency will need to implement this plan." Over four months later, this Committee, GAO, and others are still attempting to obtain basic data on what resources are needed and how they will be used to implement the plan.

As of Monday, it appeared that the President's budget provided only minimal support for making this plan a reality. The President's Fiscal Year 2009 budget originally asked for a mere $51 million in new budgetary authority for all programs within FDA. Approximately $42 million of this would go towards food safety. Because of cost-of-living salary adjustments, only about $30 million would be available for implementing the *Food Protection Plan*.

This is in stark contrast to the Science Board's recommendations. In a letter to Members of this Committee, it recommended that an additional $375 million be provided to FDA across all programs in FY 2009, including $128 million for food safety, and $75 for needed IT enhancements. With the President's original budget offering only $30 million additional dollars for food safety in FY 2009, one had to ponder how serious the Administration was in implementing the *Food Protection Plan*--as experts suggested the agency would need far more.

Fortunately, just days before this hearing, the Administration apparently grasped the obvious: FDA was strapped for resources and $30 million was not enough to credibly advance the *Food Protection Plan*.

On Monday evening, the HHS Secretary and the FDA Commissioner scheduled a conference call to announce that the Administration would amend FDA's FY 2009 budget request to Congress and ask for an additional $275 million in new funding. Approximately $125 million of this would go to food safety efforts. I strongly applaud this request, but we need to know far more details about how this money will be spent.

Despite the administration's revised budget request, a major concern of the Subcommittee and others is that the agency lacks a meaningful <u>strategic plan</u> detailing what the *Food Protection Plan* will cost to implement, when key milestones will be achieved, and what they are expected to accomplish.

Initially, a smattering of spreadsheets and other documents were provided to the Subcommittee by FDA that attempted to detail what parts of the plan would be implemented this year. These plans fell short in that they did not show what the overall plan would cost to execute, nor did they prioritize which features were most critical in fixing existing food safety shortcomings. Moreover, the vague plans that were provided to the Subcommittee were based on earlier budget requests; not the new request made this week.

To this point, FDA's strategic plan for implementing the *Food Protection Plan* appears almost entirely budget driven. Rather than articulating what truly needs to be fixed, why it needs to be fixed, and how fixing it would positively affect the current food safety system, FDA has instead tailored its implementation plan to match the meager resources offered in the President's original budget proposal of just $30 million for food safety.

Because both the implementation goals and funding of the *Food Protection Plan* remains a moving target, I will today' seek from Dr. Acheson information on whether the Administration intends to submit a comprehensive strategic plan based on not just today's budget request, but one based on the expected costs of the plan's full implementation. In short, if FDA is going to be successful in getting this effort funded, it must be prepared to detail the plan's expected costs, strategies, milestones and results on food safety. So far, the plan proposes a number of lofty ideals, but important specifics remain undefined.

Today, I look forward to hearing what progress has been made toward implementing the Administration's *Food Protection Plan*. Additionally I want to understand what aspects of this plan are most critical to achieve, what they would accomplish, and what they are expected to cost beyond the ever-changing budget requests that come from the Administration. As the Agency stated in its *Food Protections Plan*, "FDA recognizes the need to partner with Congress to make the changes necessary to transform the safety of the nation's food supply." I am hoping today that FDA will finally be willing to enter into this partnership with us and provide a credible and honest answer as to what is needed to realistically safeguard the Nation's food supply.

Lastly, I would be remiss if I did not mention the current Salmonella Saint Paul outbreak that that has led to 167 illnesses in 17 states. This outbreak is particularly frustrating given the fact that today marks the 1 year anniversary of the FDA's Tomato Safety Initiative, which was supposed to lead to better safety standards and improved notification and tracking of tomato outbreaks. It appears that despite one full year having passed, we are no safer today than we were a year ago.

At a minimum, the FDA and USDA should require immediate implementation of Country Of Origin Labeling for all fruits and vegetables sold in the United States. Country Of Origin Labeling will provide consumers with more information about where their food is coming from and would also help federal and state officials more quickly narrow down source locations of contaminated fruits and vegetables.