

Statement By

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Alliance for a Stronger FDA

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## **INTRODUCTION**

Mr. Chairman and members of the Committee, I am William K. Hubbard. Before my retirement after 33 years of Federal service, I served for many years with the U.S. Food and Drug Administration, and for my last 14 years was an FDA Associate Commissioner responsible for, among other things, FDA's regulations and policy development. Today, I serve as an advisor to The Alliance for a Stronger FDA, a consortium of patient, public interest, and industry organizations whose mission is to urge that FDA's appropriations be increased. The Alliance and its constituent members are greatly concerned that FDA's resource limitations have hampered the agency's ability to ensure the safety of our food and drug supply. Today's hearing is focused on the recent salmonella outbreak that been so costly to the public, the produce industry, and the government agencies involved, and is thus an appropriate subject for your attention.

## **BACKGROUND**

As you know, Congress established the Food and Drug Administration in 1906 as a result of concerns about the safety of our food supply. In those days, it was common for foods to be subjected to all manner of problematic practices—filthy, unsanitary conditions were common in food processing facilities; talcum powder, sawdust and many other contaminants were added to deceptively increase the weight or value of foods; and chemical preservatives were used in food that were untested and often highly toxic. As the 20<sup>th</sup> Century progressed, FDA's scientists and those in the emerging food processing industry slowly built a food safety infrastructure for the United States that enabled us to

claim that we had the safest food supply in the world. And the standards established by the FDA for the production of safe foods became the model for protection around the globe. Throughout the last century, there was steady progress in the food safety system – in learning how to protect food from contamination and in implementing procedures to translate that knowledge into safer food production. But, unfortunately, that progress appears to have largely ground to a halt, at least when it comes to the ability of FDA to effectively oversee improvements in food safety.

And that slowdown in FDA's role –some would even say reversal – has come at the worst possible time. That is because today the need for effective management of food safety is greater than ever before, as evidenced by:

- The emergence of new pathogens, some unknown to science in years past, such as E Coli 0157:H7, that are especially lethal when they contaminate our food;
- The substantial public health and economic costs imposed on our society from the steady – and increasing – numbers of foodborne disease outbreaks in the United States;
- The steady growth in the number of domestic food producers and, even more importantly, the tremendous increase of imported food from other countries -- particularly developing countries in Latin America and Asia, where food safety standards are often lax or unenforced; and

- The increasing desire among our citizens for fresh fruits and vegetables throughout the year, necessitating a complex system of produce production and distribution, often across long distances and through many hands.

### **THE SALMONELLA SAINTPAUL OUTBREAK**

The occasion for this hearing is, of course, the recent (and perhaps ongoing) series of cases of Salmonella Saintpaul linked to fresh produce. With over a thousand illnesses reported, and many more likely not documented; costs to the tomato industry in excess of \$100M; and consumer access to one of our favorite foods seriously disrupted, it is a significant event in our national life.

The questions raised by this outbreak are numerous:

- 1) Is the Federal government properly organized to manage an outbreak of this nature?
- 2) Is the questionnaire process used by the Centers for Disease Control and Prevention, which led FDA to spend weeks seeking contaminated tomatoes, perhaps in vain, flawed as an outbreak management tool?
- 3) Are the various government entities involved in foodborne disease outbreaks – Federal, state, and local -- adequately coordinated?
- 4) Is FDA's management of food safety too fragmented, with no central focus of authority?
- 5) Are FDA's investigative procedures too outdated to rapidly track a major ongoing foodborne disease outbreak?

- 6) Did food distributors have adequate records when FDA investigators sought to trace the movement of suspect produce?
- 7) What are the effects of the recent budget cuts in FDA's food safety program on its ability to respond to foodborne disease outbreaks?
- 8) Did public health officials have sufficient laboratory capacity and rapid screening technology to quickly analyze samples for Salmonella Saintpaul?
- 9) Does FDA have sufficient authority to effectively and rapidly identify and control threats to our food? and
- 10) What if the salmonella outbreak had been the result of intentional contamination of our food supply by forces intent on harming large numbers of our citizens, or if that day does come, will we be prepared for it?

We have, as a nation, simply not demonstrated that we take the threat to our food supply seriously. We talk a great deal about the need to improve food safety, and wring our hands over each major outbreak that occurs, costing lives and industry resources. But our actions have not been consistent with our rhetoric. Let me explain.

### **FDA FOOD SAFETY PROGRAM DECIMATED BY BUDGET CUTS**

First, there is the matter of FDA's capacity to protect the food supply. In 2003, FDA had just over 4000 field investigators to inspect our food facilities and track down problems like the current salmonella outbreak. Entering 2008, that force had been reduced to 3354, a loss of almost 700 inspectors. The cadre of food scientists in FDA headquarters underwent a 20% reduction during that time (from 950 to 782). And this occurred as the

number of major foodborne disease outbreaks more than doubled. These recent trends are part of a larger scenario over many years, in which we have declined to provide the FDA with robust capacity to oversee the safety of our food. Indeed, when I began at FDA in the 1970s, the agency inspected each of the then-70,000 US food processing facilities on average every two years. But today, we give FDA the resources to inspect the now-120,000 domestic facilities at a rate of only every decade or longer. And, of course, that doesn't count the 200,000 foreign facilities making food for our market, which are almost never inspected by the FDA.

### **FDA DENIED IN ITS EFFORTS TO IMPROVE PRODUCE SAFETY**

Second, FDA has not been permitted to act upon its knowledge and desire to improve upon the food safety threats we face. The best recent example is its attempt to have fruit and vegetable producers adopt preventive controls for produce. Early last year, following on successful efforts to require such controls for seafood and fruit juices, agency food scientists presented to the Department of Health and Human Services a comprehensive analysis of the risks posed by contamination from bacterial pathogens on produce, and a proposal to significantly reduce those risks. In essence, they were predicting the very problems we are encountering now with the current salmonella Saintpaul outbreak. Let me describe their thinking.

- First, they listed the enormous public health problems posed by unsafe food, with CDC estimating that there are 76 million foodborne disease cases in the US each year, 325,000 of which result in hospitalization and 5,000 in death.

The economic costs to consumers, industry and the health care industry are believed to range as high as \$83 billion annually

- Next, add in the fact that foodborne disease outbreaks are today averaging about 350 in number per year, as opposed to about 100 15 years ago. Then factor in the emergence of the new foodborne pathogens that are especially dangerous to the very young and the elderly.
- Also consider that fresh produce is a particularly vulnerable commodity. It is subject to contamination because it is grown in a natural environment, and further at risk of bacterial contamination via the ways we pack and handle produce. And, of course, it is increasingly attractive to consumers as a healthy product that is eaten raw (and thus not decontaminated through cooking). Tomato outbreaks from several different salmonella strains were described as a particular problem likely to reoccur regularly.
- The agency then argued that the previous voluntary efforts to protect produce had been ineffective and that a national solution, focused on preventive controls, was called for. They estimated that such interventions could cut the toll of death, disease, and economic disruption from produce outbreaks by at least 50%, and probably far more – thus saving not only lives but also hundreds of millions of dollars each year in industry losses.
- But, despite support from major segments of the produce industry, the Administration rejected the proposal, not even allowing the agency to seek public input into whether a preventive controls approach should be considered.

- If FDA's recommendation had been accepted, we would now have a proposed rule published and commented on by industry and the public, with a final rule protecting fruits and vegetables possible this year. Thus, we would have in our sights a major improvement in produce safety. But, instead, we are essentially nowhere, with any solutions years away from implementation.
- In fact, not one single food safety regulation has emerged from the FDA during this Administration (with the exception of a few specifically mandated by Congress).

### **FDA'S REGULATION IMPLEMENTING THE BT ACT'S RECORDKEEPING REQUIREMENT**

The third and last FDA action that I will comment on today deals with the regulations governing recordkeeping by food producers. As you know, after the September 11 attacks seven years ago, Congress was concerned that the food supply could be vulnerable to terrorism, and enacted the Bioterrorism Act of 2002 (formally titled the Public Health Security and Bioterrorism Preparedness and Response Act). One provision of that statute required food firms to establish and maintain records detailing the movement of food through the supply chain, with the intention of giving FDA the ability to rapidly trace sources of contamination; and thereby blunt the potentially devastating effects of intentionally contaminated food.

Unfortunately, the transition from what was believed needed right after 9/11 to what they agency actually got months later when it promulgated its regulations on recordkeeping is

a virtual case study in how to weaken a regulation to the point of being indistinguishable from the original intent. Indeed, if we were to consider the tomato/pepper salmonella search as a test of the recordkeeping rule, I think it's fair to conclude that the grade would be a fairly clear "F." Let me explain, and in so doing describe why the old axiom of not wanting to watch laws or sausages being made can also apply to implementing regulations.

Below is a brief "side-by-side" analysis of some of the key weak points introduced into the original legislation and regulation as it was being reviewed and considered by Administration reviewers:

<u>What FDA wanted/needed</u>	<u>Final Rule Provisions</u>
Records by all sources/recipients	Farms and restaurants excluded
Foreign firms as well as U.S.	Foreign firms dropped
Complete record of a food's movements	Only "one forward, one back"
Lot numbers for each shipment	Denied
Electronic records (for speed)	Denied
Records access within 4 hours	Extended to 24 hours
Consistent record format	Denied
Authority to verify keeping of records	Denied
Authority to enforce requirement	Only (mostly enforceable) "prohibited act"

In sum, the theory after 9/11 was that the agency needed rapid access to complete and useable records of a food's origins and movements, to deter and react to a terrorist attack.

What it ended up with was a requirement for partial records, made available in no particular hurry, from some people but not others, without a requirement that a given shipment be well identified, and in a format that could (and does) include the back of a plain brown paper bag. Further, the word quickly went out among the industry that FDA could only check on a firm's adherence to the recordkeeping requirement if a food connected to the firm was the subject of a serious ("Class I") recall and that the firm was unlikely to be punished if it ignored the recordkeeping requirement entirely.

One reason that the recordkeeping requirements were so watered down was the fear that they would be too costly for the food industry, with some estimates that the rules could cost processors \$140 million per year. But, of course, the produce industry lost that much in the 2006 E Coli outbreak and is on track for similar losses in the ongoing Salmonella Saintpaul investigation. While our reluctance to impose regulatory costs is understandable, it may also be contributing to an ineffective regulatory structure and, in turn, the destruction of industries that rely on regulators to make rapid and accurate decisions about public health threats.

### **ACCURATE PRODUCT TRACING IS ACHIEVABLE**

As you may hear today, Mr. Chairman, there are technological solutions that could, if utilized, solve a big piece of the current problem – rapid and accurate traceback of a food's movement through the supply chain. We are all familiar with the fact that FedEx and UPS can tell us in real time where a package has been, is now, and will arrive at its destination. The military is using Radio Frequency Identification (RFID) technology to

track everything from tanks to toilet paper, and Walmart and other major retailers are moving in that direction. The drug industry is slowly adopting RFID tracking for their products, to protect against counterfeiting and illegal diversion. Some U.S. tomato producers are implementing track and trace systems that can track a single tomato back to the farm worker that picked it. Outside the continental U.S., food producers are using or experimenting with a variety of tracking technologies, for example,

- A Dutch pilot program for produce has just been completed, illustrating how fresh produce can be effectively tracked throughout the supply chain using RFID -- not only providing for traceability but also demonstrating how such technology can improve quality and availability of fresh fruits and vegetables.
- The Hawaii Department of Agriculture is beginning an electronic program for tracking tomatoes, onions, mushrooms and other produce that will enable producers to track the movement of their products in real time and, if necessary, to initiate a recall of some foods within minutes.
- The Canadian government has recently begun a “proof of concept” traceability program for beef and pork that will become a national standard for electronic traceability from farm to restaurant or retailer.
- The Japanese have a national traceability law for cattle that uses bar code technology to track every cow and its byproducts from birth to eventual consumption as human food.
- This year, Norway’s largest food supplier will begin using an IBM-based RFID tracing system for all poultry and meat products, again, not just for

recall and traceback purposes, but to also introduce operational efficiencies and thus lower costs for producers and consumers.

While the various tracking systems in place or in development use different software and hardware, all should be able to provide the kind of rapid information that is needed to permit rapid traceback in the event of a foodborne disease outbreak. And in doing so, such systems would provide FDA with the records it needs to carry out its responsibilities. There are two keys to success in utilizing technology for effective traceback, in my opinion:

- 1) One is whether we will give FDA the authority to require adequate traceback information. This should be done using a performance standard approach, rather than asking FDA to choose among various hardware and software vendors, so as to allow the best technologies to be developed and implemented.
- 2) A second is the need to deal with the cost burden on small producers. We have seen time and gain how large food producers can implement state-of-the-art food safety and information systems. But the system is only as strong as its weakest link, and an outbreak of disease from a small producer that takes weeks to find can seriously harm an entire industry. Currently, FDA is forced to consider the effects of its actions on small producers, and that is certainly understandable, but we need to find a way to assist small producers in adopt the best new technologies for making our food safe and tracking its movement.

## **A NEED TO MOVE FROM TALK TO ACTION**

In conclusion, Mr. Chairman, today's hearing is another in a series that you have held to highlight instances where FDA needs to improve, and I agree with your concerns that FDA is not as effective as it can and should be. In the case of food, we have a real dichotomy between our rhetoric and our action. As I noted earlier, we say we want a strong FDA and a strong food safety system, but our actions belie that stated objective. We have not given FDA the authority and resources it needs to be the agency we want it to be, and then we are critical of it when it fails to meet expectations. When I first arrived at FDA in the 1970s, the food program was one-half of the agency's budget, yet today it is less than one-fourth, despite the fact that the problems on the food side of the agency have grown in numbers and intensity over those years. And the agency's recent experience with recordkeeping and its attempt to improve produce safety demonstrate that the agency is hobbled by decision makers higher up its chain of authority that will not support the agency's efforts to do better. I sincerely hope that you will agree with my conclusions and resolve to act upon them.

Thank you for giving me the opportunity to provide my views on this subject.