STATEMENT OF
THE HONORABLE BART STUPAK
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS
"THE RECENT SALMONELLA OUTBREAK: LESSONS LEARNED AND CONSEQUENCES TO INDUSTRY AND PUBLIC HEALTH."

JULY 31, 2008

Since the 110th Congress began in January 2007, this Subcommittee has been investigating the adequacy of the Food and Drug Administration's efforts to protect Americans from unsafe food.

Today, we hold the Subcommittee's ninth hearing regarding the safety and security of the Nation's food supply. The purpose of today's hearing is to examine the events surrounding the recent *Salmonella* Saintpaul outbreak. We will consider the implications to public health and industry and will examine what lessons can be learned to better safeguard our food supply.

Since April, at least 1304 people in 43 states, the District of Columbia, and Canada have been infected with *Salmonella* Saintpaul. These illnesses have resulted in at least 252 hospitalizations and may have been a contributing factor in two deaths. This outbreak is one of the largest outbreaks of *Salmonella* ever in the United States and, based on the number of confirmed cases, it is the largest foodborne outbreak in the last decade.

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have struggled to identify the cause of the *Salmonella* outbreak. Originally, CDC and FDA identified tomatoes as the most likely cause of the outbreak. However, as the outbreak continued and the number of illnesses soared, FDA was unable to definitively identify tomatoes as the source of the contamination. In late June, CDC expanded its epidemiological investigation to include food items that are commonly served in combination with tomatoes. This study found that people who became ill were more likely to have recently consumed raw tomatoes, fresh jalapeño peppers, and fresh cilantro. However, the CDC still could not determine the exact cause of the outbreak.

Finally, on July 21st - nearly two months after the outbreak was first discovered - FDA announced a "significant break" in its investigation when they confirmed the presence of *Salmonella* Saintpaul in a Mexican grown jalapeño pepper. This jalapeño had the same *Salmonella* genetic fingerprint as the strain linked to the outbreak. Despite this discovery in jalapeños, the FDA still refused

to rule out tomatoes as the original source of the outbreak, which has angered many tomato growers.

Today, we will examine why it took FDA, CDC, and State public health agencies so long to identify jalapeño peppers as a source of the *Salmonella* Saintpaul. Further, we will explore what lessons for industry and government should be garnered as a result of this outbreak. Perhaps most importantly, we will try to determine which aspects of this outbreak investigation worked well and which failed, so that regulators and the affected industry will be better prepared to rapidly respond to future outbreaks.

For example, we will examine a portion of the Bioterrorism Act of 2002, which was designed to ensure the traceability of food. The Act directed the Secretary of Health and Human Services to issue regulations regarding the establishment and maintenance of records by most people and companies that manufacture, process, pack, transport, distribute, or receive food. Most notably exempt from this requirement are farms and restaurants. The regulation requires that records must be kept to allow Federal investigators to identify the immediate previous sources and subsequent recipients of food in order to be able to quickly respond to threats to our food supply.

However, in discussions with Committee staff, Dr. David Acheson, FDA's Assistant Commissioner for Food Protection, stated that the Bioterrorism Act did not function as intended during this outbreak. Because the Bioterrorism Act does not require a particular format for maintaining records, most food companies have their own unique system of recordkeeping, which, according to FDA officials, has caused significant delays in FDA's traceback investigation. While FDA has ultimately been able to traceback commodities associated with this outbreak, it has been too time-consuming of a process requiring countless hours trying to link one company's records to the next. Today, we will explore what specific problems FDA had during its traceback investigation and whether alterations to the Bioterrorism Act or other additional regulations are needed to allow federal investigators to quickly traceback suspected commodities during an outbreak.

We will also explore what the industry can do to maintain traceability of its products. While there has been discussion by FDA and the media that loose produce, like tomatoes, are difficult to trace due to their complex processing and distribution chains, some in the industry maintain that such commodities are rapidly traceable from the farm to the end user. Indeed, some tomato companies visited by Committee staff did provide evidence that tomatoes could be rapidly traced back if the need arose. However, these sophisticated systems appear to conflict with statements by FDA officials who claim that tracing this commodity has often been a time-consuming and daunting task. Today, we will discuss whether there are particular systems that can be adopted by industry to enhance traceability, particularly for high-risk commodities.

Finally, we will also hear a host of criticisms from industry directed at FDA and CDC for the way they have conducted its outbreak investigation. For example:

- We will hear that FDA often did not share or solicit critical data and other information from state food safety agencies.

- We will hear that the way state health agencies interact and share data with key federal agencies such as the FDA and CDC is often inefficient, overly bureaucratic, and sometimes even counterproductive.

- We will hear that by failing to adequately coordinate with key State agencies, both FDA and CDC missed important opportunities to leverage scarce federal resources with State resources to conduct inspections and field work related to the investigation.

- We will hear that neither CDC nor FDA worked closely enough with State agencies to understand key produce distribution patterns and, if they had, they would have realized earlier that based on the geographic distribution patterns of the illness, the source of the *Salmonella* was likely not from Florida.

- Finally, we will hear that because there are over 3,000 local health departments and 50 state health departments working under different public health laws, there is tremendous variability in the capacity to respond to disease outbreaks, which can have profound consequences on the ability to pinpoint a contamination source.

These and other troubling issues related to this outbreak continue to be uncovered as we move forward in this investigation. While we understand that FDA's and CDC's investigation into this outbreak is ongoing, it is important to find answers and solutions to the key failures that have been identified up to this point.

At a minimum, the FDA and the CDC must convene an independent post-mortem task force which includes local, State, Federal, scientific and industry officials related to this outbreak, to study which features of the investigation broke down and how the system can be improved. While this Salmonella outbreak has sickened scores of people and caused great economic damage to the produce industry, we are fortunate that this does not appear to be an intentional contamination of our food supply. If we do not learn from this case and rapidly improve our food safety system, we will be doomed to repeat the failures of the current outbreak. The American public deserves better from industry and our local, State and Federal agencies!