Statement By

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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 need to strengthen our nation's food safety system that has been under constant strain in recent years and is widely viewed as being in dire need of improvement. I commend the Committee for your effort to shine light on this problem and possible solutions.

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 20th 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 record of 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 the limitations under which FDA attempts to do its job have been dismayingly exposed. I will attempt to describe those limitations in this testimony, but first, let me give you my view of the risks imposed on our society by foodborne disease.

HOW RISKY IS OUR FOOD SUPPLY?

The food safety threat in the United States presents a contradiction in many ways. On the one hand, we do basically have a safe food supply. Most growers, food processors, transporters, grocers and restaurants care about the health of their customers and do a good job of practicing safe production, storage, and handling techniques. Americans can generally go about their daily lives without fear that opening a can of soup or preparing a sandwich will subject them to illness or death.

But, as recent foodborne disease outbreaks have well demonstrated, our system is only as strong as its weakest points – and there are simply too many of those. We saw this recently with the peanut butter contamination, in which a small Georgia firm's product

was sold to dozens of larger firms and ended up contaminating hundreds of different products and potentially endangering millions of our citizens. Last year's pepper contamination with Salmonella saintpaul – initially focused on tomatoes – apparently resulted from one small distributor on the U.S.- Mexico border, yet caused a nationwide panic over the safety of tomatoes and related products. In the 2006 E Coli in spinach outbreak, the entire nation's spinach crop was blamed until the source of the contamination was isolated to three farms in California.

Those peanut butter, pepper and spinach examples are just a few of the breakdowns that have caused our citizens to question their leaders' ability to carry out this most quintessential governmental function – the safety of commodities that are so necessary for a healthy society. Indeed, some argue that our food supply is becoming less safe despite the progress that has been made in science and medicine in recent decades. It is certainly clear that there are trends that cry out for intervention by the Congress, namely:

- New pathogens have emerged in foodstuffs, some unknown to science in years past, that are especially lethal when they contaminate our food. They have exotic names, such as *Enterobacter sakazakii, E Coli 0157:H7, Listeria monocytogenes, Vibrio cholerae 0139, and Salmonella Typhimurium DT104*, but they all pose a significant threat of severe illness and death when our citizens contract them. And there is an expectation among scientists that yet more of these threats will be discovered in the future.

- There are very substantial public health and economic costs imposed on our society from the steady – and perhaps increasing – numbers of foodborne disease outbreaks in the United States. The Center for Science in the Public Interest has tracked foodborne disease outbreaks for many years and their data shows outbreaks increasing from an average of 100 per year a decade and a half ago to almost 350 annually in recent years. Even if those increases are the result of better reporting of outbreaks, I know of no one who believes outbreaks are declining for foods regulated by the FDA;
- There has been a steady growth in the number of domestic food producers and, even more alarmingly, a tremendous increase in imported food from other countries -- particularly developing countries in Latin America and Asia, where food safety standards are often lax or unenforced; and
- Our system of food production and distribution in increasingly complex, often necessitating the movement of food across long distances and through many hands and into many finished products.

TOLL OF FOODBORNE ILLNESS

Even if one accepts the premise that our food supply is mostly a safe one, the impact of the food contaminations that do occur is remarkable. As you know, the Centers for Disease Control estimated in 1999 that 76 million Americans contract a foodborne illness each year. Of those, 350,000 are hospitalized, and 5,000 die. And, if we update those statistics to our current population level, as recently calculated by the Associated Press, it's likely that the current estimate would be over 87 million cases and almost 6,000

deaths. That means that we are sustaining food-related deaths of an equivalent number of our citizens to those killed in the World Trade Center attack every 6 months; yet many, if not most, of those deaths are preventable. And beyond the obvious human suffering, and the associated economic costs to sickened consumers, there are tremendous economic costs to food producers. The 2006 spinach outbreak, for example, resulted in the destruction of much of that year's spinach crop and cost producers an estimated $100 million; and last year's tomato/pepper outbreak resulted in producer losses in the hundreds of million of dollars. In fact, it is estimated that the overall negative economic impact of foodborne illness in the United States may be has high as $83 billion per year. Worse yet, these repeated outbreaks and their attendant publicity paint a picture, erroneously I believe, of a food industry that cannot assure safe products. Indeed, after the spinach outbreak, the government of Mexico – a nation derided in the past as the home of Montezuma's Revenge – announced it would evaluate whether American produce was safe to import into Mexico. And this is happening at a time in which one of America's few remaining sources of a positive trade balance is our food exports.

FDA'S FOOD SAFETY SYSTEM – BROKEN BEYOND REPAIR?

"FDA does not have the capacity to ensure the safety of food for the nation." Those are not my words, but rather the summation last year of FDA's Science Board, an advisory committee of experts from many fields of study. And that conclusion has been echoed by a cascade of expert reports in recent years, by the Institute of Medicine, the Government Accountability Office, the HHS Inspector General, the National Academies of Science, and several Congressional committees. All of those studies have concluded that the FDA

regulatory system, as currently constructed, simply cannot adequately oversee a large and diverse food production system within its current structure and resources.

Let me give you just a flavor of the metrics by which FDA's inability can be counted. When I arrived at FDA in the 1970s, the Official Establishment Inventory of food facilities subject to regulation was about 70,000, and FDA was able to conduct 35,000 inspections each year, meaning that, on average, each facility could be inspected every other year. Today, the domestic OEI is 150,000, and FDA conducts about 7,000 inspections per year. This means that FDA can realistically inspect only the 6,000 or so facilities that are designated as "high risk," which, of course, means that most food facilities never see an FDA inspector. Attached is a chart illustrating the dramatic decline in food inspections since the 1970s.

The more recent history of FDA capacity is even more disheartening. In 2003, FDA had just over 4000 field investigators and compliance officers to inspect our food facilities and carry out outbreak investigations (as well as inspect drug and medical device facilities). 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 foodborne disease outbreaks appear to have 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. And, of course, none of this counts the

216,000 foreign facilities making food for our market, of which FDA inspects only about 100 per year.

AN INEFFECTIVE PARADIGM

I will not dwell on FDA's resource woes; they have been well documented and are indisputable. The more important point is that the resource shortfalls are but one of the two principal causes of FDA's inability to protect our food supply. The other is that FDA's food safety system is a relic of the 19th century, one that should have been discarded years ago.

Let's look back to FDA's origins, in the dawn of the 20th century. Americans grew much of their food, and food that was purchased tended to come from a nearby source, such as a farm near the consumer's home. Processed foods were relatively few in number, and tended to be staple goods, such as molasses, flour, and sugar. The "state of the art" method of ensuring food safety was the visual inspection by a government official of food processing facilities and the products emanating from them. Imports were few, and were also mostly staple goods. An inspector could easily open a barrel of flour and examine it for insect or rodent infestation, mold and mildew, and other signs of contamination. So Congress embodied that concept into the original Pure Food and Drug Act of 1906. Itinerant Federal inspectors could visit facilities and examine their overall sanitation as an indicator of safe food production. With new provisions added in 1938,

those inspectors were give enforcement tools believed to be adequate for the day – prosecution of the business's chief executive, an injunction against the business to stop it from selling contaminated food, and authority to seize food found to be contaminated.

Meat, on the other hand, was considered a far riskier food in those pre-refrigeration days. That concern, combined with the need to assure export markets that U.S. beef was free of brucellosis and hoof and mouth disease, prompted Congress to require a continuous inspection model for slaughter facilities, in which Federal inspectors examine and provide a Federal stamp to every meat product as it is processed. Meat regulators were also given a range of strong enforcement tools to ensure that processors adhere to Federal standards. That system, administered by the Department of Agriculture, remains largely unchanged today.

While the meat inspection program also has its critics, the FDA food safety system has been determined to have severe flaws in its conception and implementation, in the context of the modern world, viz.,

- It is a system with random success. That is, it relies on the infrequent inspection by FDA (or perhaps a state inspector) to identify and correct deficiencies in a processing facility;
- Each FDA inspection is only a "snapshot" of the condition of the food processor the day of the visit, thus it cannot assure that the facility is operating safely at all times;

- There are few true standards by which most food processors can be judged. FDA has general "sanitation" regulations, but has not been empowered to set food-specific requirements to which producers should adhere;
- It does not take advantage of state-of-the-art food protection mechanisms, such as HACCP, that industry leaders have developed and implemented in recent years;
- Food safety inspections and oversight by state and local authorities are inadequately coordinated with the FDA; nor are training of state and local inspectors done jointly with FDA inspectors, resulting in differing inspection procedures and varying thoroughness;
- FDA lacks enforcement tools common to modern regulatory agencies, such as authority to recall contaminated food, to require periodic registration of food facilities, to fine firms failing to comply with requirements, and to require detailed records of a food's movement through commerce (so that contaminated food can be found and recalled promptly); and
- FDA lacks a modern and robust laboratory system that can effectively and rapidly test food samples for the hundreds of possible contaminants that can attack our food.

WHAT IS NEEDED – A MODERN, RISK-BASED FOOD SAFETY SYSTEM

Despite the considerable gloom we have been seeing in recent years related to the failures of our food safety system, there is great reason to be optimistic that we can successfully fix its many flaws. The key will be to move from the current reactive, fragmented system to one that is focused on prevention. FDA and the industry have already demonstrated

the possibilities, through development of procedures for preventive controls for low-acid canned foods, seafood, and juice. Under a system of preventive controls, producers undertake steps to assure the safety of their food, and whose complexity is based on the risks posed to the food:

1) Analyze hazards, that is, understand what hazards their food might be subjected to so that they can eliminate them,

2) Develop an adequate food safety plan, under which they will take the necessary steps to adequately control and monitor the identified hazards,

3) Document the steps the facility takes to implement the plan, thereby creating a record of how they successfully control the hazards, and can thus assure both regulators and their customers that they are always vigilant about food safety, and

4) Meet standards for minimizing risk in their food, such as by periodic testing for hazards to assure that the finished product is indeed uncontaminated.

Under such a new paradigm, FDA's role would shift from its current "gotcha" mode via random inspections to one in which they set the requirements for preventive controls and any necessary quantitative tolerances for contaminants; train and educate processors in the use of such controls; assess the adequacy of firms' food safety plans and their implementation of these plans; and oversee an inspection regime under which FDA, state, local, and other third-party inspectors can confirm the proper implementation of food safety plans.

WHAT IS NEEDED FROM CONGRESS

FDA cannot move to the type of modern food safety system that is needed without statutory change. Specifically, I believe the Congress should enact legislation with the following elements:

First, empower FDA to mandate preventive controls for all food. Many, if not most, large processors have already adopted some form of preventive controls, but such a system will only be as strong as its weakest link, and FDA must be specifically charged with requiring food producers to have an adequate food safety plan that assesses and controls for any risks intentionally or unintentionally present in their food or its production processes, as well as the ability to require specific preventive controls for specific foods, if appropriate. As part of that regime, FDA will need access to the firm's records documenting its adherence to its food safety plan.

Second, give FDA the resources to be successful in a new food safety system. In the 1970s, when FDA's food program was at its zenith, its budget was one-half of the agency's budget, and that could be a short term goal for restoring the program to health. Additional funding of about $500 million, or about 2 cents a week for each American, would allow FDA to begin ramping up its food safety capabilities, although additional increases will be needed over the next few years. Without the resources to strengthen the FDA, no authorities can or will bring the change that is needed, but I believe the vast majority of Americans would gladly pay a penny every few days for a safer food supply. Indeed, the cost to the taxpayer would likely be recouped by savings to consumers through the elimination of just one major outbreak a year.

Third, FDA's scientists believe they need modern enforcement authorities of the type that many other regulatory agencies possess:

a) Annual registration of food facilities – Currently, food facilities need register only once, meaning that FDA cannot keep an accurate and up to date record of who is manufacturing food. A necessary companion provision would be authority to suspend a registration if FDA determines that the facility cannot safely produce food.

b) Mandatory recall authority – Currently, FDA must cajole a firm found to have sold contaminated food to the public; while FDA can usually prevail, days can go by in which contaminated food continues to be sold and consumed. However, recall authority should be limited to instances in which the food is believed to pose a threat to human health, not for minor infractions such as harmless labeling errors.

c) Laboratory accreditation – In the recent peanut butter incident, the processor had received test results from private laboratories that found salmonella contamination; but neither the firm nor the laboratory was required to notify FDA. Agency scientists would like to have the authority to require laboratories to be accredited and access their test results.

d) Traceback – When a foodborne disease outbreak occurs, FDA must determine where the contamination originated, and where the contaminated food was sent (so as to warn consumers and have contaminated food recalled). The agency does not have sufficient authority to require food processors to keep adequate, interoperable records that quickly and accurately show the movement of food. This has been most problematic in the produce area, and the produce industry has called for enhanced product tracing.

e) Importer Requirements – Currently, authority over food imports is focused on FDA's ability to inspect an imported food as it enters the country, but the agency has resources to inspect only 6/10 of 1% of food imports. The agency needs authority to require importers to implement appropriate preventive measures so that the food they import is more likely to be safe before it ever begins on its way to the U.S.

f) Administrative Detention - Currently, FDA can detain a food in commerce only if the agency has compelling evidence that it presents a threat of serious harm. That standard is so high that they agency has never used it; a less burdensome standard like "reason to believe" that a food may be contaminated is needed.

h) Civil Money Penalties – Most regulatory agencies can fine violators, but FDA cannot fine a firm that produces or sells contaminated food. A strong CMP authority would give FDA a tool that is intermediate between prosecuting the firm and merely admonishing them, and can serve as an effective deterrent for future misconduct.

Finally, the recent peanut butter case illustrates the inconsistencies among state and Federal inspection regimes. Our food safety system needs a national food safety training Academy, analogous to Law Enforcement Training Academy in Glynco, Georgia, that will provide uniform, science-based training for all food inspectors, at all levels of government, and that can be accessed as well by private, third-party inspectors.

A NEED TO MOVE FROM TALK TO ACTION

In conclusion, Mr. Chairman, today's hearing is another in a series that Congress has 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. 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. Meanwhile, as report after report recommends dramatic change in our food safety oversight, foodborne disease outbreaks continue unabated and public confidence in our government's ability to protect us declines steadily. That is a record for which we should be truly embarrassed, and I sincerely hope that you and your colleagues 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.