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 recent salmonella outbreak that been so costly to the public, and on what directions our food regulatory system might go to prevent further such outbreaks. 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.

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 complexity of our system of food production and distribution, which often necessitates the movement of food across long distances and through many hands and into many finished products.

THE SALMONELLA IN PEANUT BUTTER OUTBREAK

The occasion for this hearing is, of course, the recent (and perhaps ongoing) series of cases of Salmonella Typhimurium linked to peanut butter. With hundreds of illnesses, and several deaths, reported, and many more likely not documented; the recall of a wide variety of food products made by many different producers; and widespread consumer anxiety about a food commonly consumed by our children, including our new President's daughter, 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) Are the various governmental entities involved in foodborne disease outbreaks – Federal, state, and local – adequately coordinated?

3) Does FDA have the necessary authorities and resources to prevent such contaminations and outbreaks from continuing?

4) Are state food inspectors properly trained and managed to insure effective partnership with Federal food safety efforts?

5) Are FDA and industry processes for tracing the source and destination of food products adequate to ensure rapid recall of contaminated food?

I suggest, Mr. Chairman, that we, as a nation, have 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.

TOLL OF FOODBORNE ILLNESS

As you know, the Centers for Disease Control estimate that 76 million Americans contract a foodborne illness each year. Of those, 350,000 are hospitalized, and 5,000 die. That means that we are losing the equivalent of the World Trade Center attack every 8 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 inspect each of those facilities every other year (that is, 35,000 inspections per year). Today, the 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," meaning that most food facilities never see an FDA inspector. [Peanut butter has not

been considered a high risk food.] Attached is a chart illustrating the dramatic decline in food inspections since the 1970s.

This also means that in the days when FDA's food program was adequately resourced, FDA would have likely inspected the Blakely, Georgia peanut butter processor with some regularity, but today the chances of FDA routinely visiting that facility are virtually nil. And, of course, it further means that there could be, and likely are, many other facilities around the country with similar problems awaiting their turn in the limelight.

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 track down problems like the current salmonella outbreak (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 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 secondary to the real problem, which 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. Some of the most lethal bacterial "pathogens" that worry us today, such as E Coli 0157:H7, were unknown to nature and thus no threat to humans. 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. 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; that system 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 (e.g., 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;

- It 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. Known generally as Hazard Analysis Critical Control Points, or HACCP, it is a methodology under which producers undertake four 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 a food safety plan under which they will take the necessary steps to control 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.

These are often fairly simple, common sense steps, but they have shown a remarkable capacity to effectively prevent food contamination. In the case of a peanut butter processor, for example, the four steps might be implemented as follows:

1) Hazard identification would likely be focused on bacterial contamination,
2) The food safety plan would identify the need to a) roast the raw peanuts at sufficiently high temperature to ensure that any bacteria arriving from the farm is killed, then, b) keep the processing equipment clean so that the peanut butter is not exposed to bacteria while being processed and packaged. This would also include the need to guard against rodent and insect infestation, leaky roofs, and any other threat to equipment sanitation.
3) Documentation might include only temperature recording of the roaster while it is in operation and the recording of regular, thorough cleaning of the processing equipment; and, finally,
4) Performance Standards could be met by periodic sampling and testing of the final product, to confirm that it is free of bacteria.

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 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 universal HACCP-like processes.

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 goal for restoring the program to health. It would require additional funding of about $500 million, or about 2 cents a week for each American. 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, enact long overdue enforcement authorities for FDA, such as mandatory recall authority, annual registration for all food facilities, a revised administrative detention authority, accreditation of private laboratories, and a stronger traceback authority.

Fourth, direct the Secretary of Health and Human Services to develop an effective crisis management system that coordinates the response to foodborne disease outbreaks among CDC, FDA, and state and local government; cuts through the current bickering and turf battles among those entities; and effectively shortens the response time and resolution of future outbreak.

And, fifth, authorize and fund a food safety training academy that will provide uniform, science-based training for all food inspectors, at all levels of government and in the private sector.

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. 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. Meanwhile, as

report after report recommends dramatic change in our food safety oversight, the number of foodborne disease outbreaks have risen from about 100 per year fifteen years ago to 350 per year more recently. 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.

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