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TESTIMONY OF

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FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

OCTOBER 22, 2009

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning, Chairman Harkin and Members of the Committee. I am Dr. Margaret Hamburg, Commissioner of Food and Drugs at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to appear before you today to review current issues in food safety, especially pending food safety legislation that is of great interest to this Administration. I would first like to commend you, Mr. Chairman, for your leadership and your long-standing commitment to improving food safety. I also would like to commend many Members of this Committee and their staffs for their work on this important legislation, as well as Senator Durbin, the initial sponsor.

By way of background, FDA is the federal agency that is responsible for overseeing the safety of the food supply except for meat, poultry, and processed egg products, which are overseen by our partners at the U.S. Department of Agriculture (USDA). Ensuring that foods are safe and secure is a vital part of FDA's mission, and FDA is committed to ensuring that the U.S. food supply continues to be among the safest in the world.

Food safety is a core public health issue. Every year, millions of people in the United States suffer from foodborne illness, hundreds of thousands are hospitalized, and thousands die. Public health has been defined by the Institute of Medicine as "fulfilling society's interest in assuring the conditions in which people can be healthy." A precondition for health is having access to safe food.

Food can become contaminated at many different steps – on the farm, in processing or distribution facilities, during transit, at retail and food service establishments, and in the home. Over the years, we have made progress to prevent both intentional and unintentional contamination of food at each of these steps. However, changes in consumer dietary patterns, changes in industry practices, changes in the U.S. population demographics, evolving pathogens, and an increasingly globalized food supply chain pose challenges that are requiring us to adapt our current food protection strategies.

President Obama has made a personal commitment to improving food safety. In March 2009, President Obama stated that protecting the safety of our food and drugs is one of the most fundamental responsibilities our government has, and established the President's Food Safety Working Group. On July 7, the Working Group issued its key findings on how to upgrade the food safety system for the 21st century. The Working Group recommends a new public-health focused approach to food safety based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.

The Working Group noted the need to modernize the food safety statutes to provide key tools for FDA, the Food Safety and Inspection Service at USDA, and other components of the federal government to keep food safe. Some of the necessary legislative authorities highlighted in the findings include:

- enhanced ability to require sanitation and preventive controls at food facilities, based on a scientific hazard analysis;
- the ability to access basic food safety records at facilities;

- enhanced ability to use resources flexibly to target food at the highest risk and achieve the maximum gain for public health;
- enhanced ability to establish performance standards to measure the implementation of proper food safety procedures; and
- the ability to require mandatory recalls.

A food safety bill recently passed by the House of Representatives, H.R. 2749, the "Food Safety Enhancement Act of 2009," addresses all of the above authorities and includes many of the other key recommendations of the Working Group.

The comprehensive food safety bill under consideration in the Senate is S. 510, the "FDA Food Safety Modernization Act." Its sponsors include many Members of this Committee. It also includes many of the authorities identified as important by the Working Group, such as preventive controls and mandatory recall authority.

These bills illustrate that there is broad agreement on the general direction of food safety reform toward an improvement of risk-based preventive controls to reduce foodborne illness, a public health goal we all share. These legislative initiatives share the core principles identified by the Working Group: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.

A coalition of consumer groups is fighting for improvements in the food safety system so that more families do not have to suffer tragic consequences from foodborne disease. Major sectors in the food industry also support and are advocating for fundamental change.

But even with the President's support – even with the full efforts of HHS and USDA and other federal, state, local, tribal, and territorial food safety partners – and even with the backing of consumer groups and industry, our efforts will fall short unless Congress modernizes food safety laws to deal with the challenges of the 21st century.

FOOD SAFETY LEGISLATION

From FDA's perspective, there are three key questions to ask about food safety legislation:

- First, does the legislation refocus the system to place greater emphasis on prevention?
- Second, does the legislation provide FDA the legal tools necessary to match its existing and new food safety responsibilities?
- Third, does the legislation provide or anticipate resources for the Agency to match its responsibilities?

I will focus on S. 510 for a discussion of these questions. I will address each of these three questions in turn and highlight a few of the many important authorities in this bill.

Does the legislation support a new food safety system focused on prevention?

The legislation would indeed transform FDA's approach to food safety from a system that far too often responds to outbreaks rather than prevents them. It would do so by requiring and then holding companies accountable for understanding the risks to the food supply under their control and then implementing effective measures to prevent contamination.

FDA is eager to further the development of this modern system. Working with the Centers for Disease Control and Prevention and our partners at USDA, as well with industry, consumers, states, localities, and other key stakeholders, we are working to establish basic standards for preventive controls. This system will make our overall approach and philosophy to food safety more consistent across government.

Key provisions in the legislation relevant to this goal include section 103, which requires facilities to conduct hazard analyses and write and implement a preventive controls plan. Section 105 requires adherence to science-based safety standards for fresh produce to minimize the risk of serious adverse health consequences or death. These, and other provisions, are critical to modernizing our nation's food safety system.

Does the legislation provide FDA the legal tools necessary to match its existing and new responsibilities?

In the modernized food safety system envisioned by the legislation, FDA has the fundamental responsibility of overseeing and verifying the implementation of preventive measures by hundreds of thousands of companies. The Agency also retains the existing critical role of

protecting the public during an outbreak. FDA needs new legal authorities to be able to succeed in these roles and protect the public health.

The Senate bill, S. 510, represents a comprehensive and significant modernization of the food safety system and provides FDA with some essential legal tools. For example, section 301 (Foreign Supplier Verification Program) will provide FDA with important information about importers and require that they verify for each supplier that food is not adulterated and is in compliance with allergen labeling requirements, preventive control requirements, and safety standards for produce. These requirements are enforced by a prohibited act and refusal of entry. These new requirements will help reduce risks to consumers from potentially harmful products by requiring importers to take appropriate steps to protect product safety.

Section 207 provides important revisions to the existing standard for the administrative detention of foods. The current standard of "credible evidence or information" of "a threat of serious adverse health consequences or death to humans or animals" is too high given that a key purpose of the provision is to provide time to gather information regarding the product's potential to cause significant harm. As a result, the existing authority is often not useful in situations where it otherwise could help us prevent or minimize the harmful effects of an adulterated or misbranded food.

Other provisions of the bill, however, need to be strengthened by including effective enforcement mechanisms and other legal tools. For example, S. 510 does not provide FDA with explicit authority to access food records during routine inspections, one of the key authorities

identified by the Working Group. Routine records access is a critical component of a food safety regulatory framework and is one of the most significant gaps in FDA's existing authority. Although FDA has routine records access for certain other FDA-regulated products, and USDA has routine records access for USDA-regulated products, FDA does not have explicit authority for routine access to records for the vast majority of foods under its jurisdiction. This authority is essential to enable FDA to identify problems and require corrections before people become ill. Under current limited authority, FDA generally only has access to required records during an emergency situation involving serious threats to health or life. Routine records access also enables the Agency to verify during routine inspections that firms are maintaining the required records. An investigation this year by the HHS Office of Inspector General found significant lapses in compliance with recordkeeping requirements.

Another key legal tool that is not included in S. 510 involves information sharing. Enhancing FDA's information sharing authority is a critical element of an integrated federal/state system and is also essential for effective public health communications with FDA's international regulatory partners. The Working Group highlighted the need to improve information sharing during a foodborne illness outbreak to speed the epidemiological investigation and traceback of the source of the illnesses to protect consumers and help industry recover faster. FDA recommends that language be included similar to that in section 112(b) of H.R. 2749. Under that provision, FDA may provide federal agencies, state and local government agencies, foreign government agencies, and certain international organizations both confidential commercial and trade secret information relating to food with provisions to ensure its confidentiality, consistent with international obligations. FDA may also receive such information from such agencies and

organizations and maintain its confidentiality. When necessary to protect public health, FDA may also disclose to other persons confidential commercial information relating to food, provided those persons maintain the information's confidentiality. Such information sharing is critical for building an integrated food safety system partnership.

Section 103 of S. 510 outlines requirements for conducting a hazard analysis and implementing risk-based controls. This authority is an essential component of a modern food safety system. However, the effectiveness of this provision would be greatly strengthened if it deemed food that is in violation of this section as "adulterated," as in the House bill. As currently drafted, S. 510 addresses enforcement via the creation of a prohibited act. Creation of a prohibited act would support an injunction but would not provide a legal basis, for example, for a seizure, administrative detention (as amended by the legislation), or refusal of admission of imported food from a facility that is not in compliance with the requirements. We encourage this Committee to include an effective enforcement mechanism, as provided in the comparable section of H.R. 2749. That would make this section consistent with most other enforcement mechanisms in the Federal Food, Drug, and Cosmetic Act.

Similarly, section 105, which authorizes mandatory safety standards for fresh produce, addresses enforcement via the creation of a prohibited act. As explained above, this means that FDA may not seize or refuse admission of fresh produce because it is not in compliance with the requirements. Section 105 provides important authorities that will help prevent foodborne illnesses only if the standards are effectively implemented and enforced; therefore, it is essential to have effective tools for enforcing these requirements.

Section 204 (Enhanced Traceback and Recordkeeping) does not include any type of enforcement mechanism. To encourage compliance and to have consequences for lack of compliance with these important requirements, it is necessary to include an effective enforcement mechanism.

Does the legislation provide or anticipate resources for the Agency to match its new responsibilities?

An important element of S. 510 is that it provides FDA a mandate to achieve specified frequencies of inspection based on risk. Inspections are a critical element to ensuring high rates of compliance with the preventive control standards and other food safety performance standards that will help drive improvement in food safety and reduced rates of foodborne illness.

FDA supports the intent of section 201 to require a minimum inspection frequency based on risk. However, we are concerned that the bill does not provide a guaranteed consistent funding source to help FDA fulfill its new responsibilities. The Administration supports inclusion of a registration fee, as provided in the President's Budget for FY 2010, which could be used, in part, to fund this inspection mandate. We also suggest the inclusion of language that provides FDA flexibility to adjust the inspection frequencies. Further, we suggest adding language to authorize FDA to use accredited third parties, such as foreign regulatory agencies, to meet the inspection frequency for foreign facilities.

FDA supports the bill's inspection goals for domestic food facilities. However, food imports present a significant resource challenge. It is important that food imports meet the same

requirements as domestic products, and we are pleased that the bill provides FDA with new tools to help ensure they do, including the requirement that importers verify that their foreign suppliers are in compliance and the authorization to require certification of compliance for imported food under certain circumstances.

FDA plans to increase inspection of foreign food facilities, but we are concerned that the bill's foreign inspection mandate may not result in the best use of FDA's resources, in light of the approximately 230,000 registered foreign facilities (as of the beginning of this month) and the high cost of overseas inspections. We think we can achieve cost-effective oversight of imports by working with foreign governments, using the bill's new tools for import oversight, supporting a strong accredited third-party inspection program, and increasing targeted, risk-based foreign inspections, consistent with the United States' international trade obligations.

We are committed to working with Congress to ensure that FDA has sufficient resources, including fees, to carry out its inspection mandate. This will be essential to our success. We note that the current inspection mandate in the bill will far outstrip our current resources.

It is also of critical importance to provide resources to help build the capacity of our state and local food safety partners. FDA supports section 205(d) of S. 510, which reauthorizes appropriations for food safety capacity-building grants. Grants that could be extended over multiple years, if the state meets FDA performance standards, would be especially helpful by providing greater certainty and continuity for the grant recipients, thus encouraging their participation in the food safety program.

CONCLUSION

This is a historic moment for food safety in the United States – a moment for FDA and its sister agencies in the federal government to rise to the challenges of the 21st century. Success means fewer hospitalizations and deaths, fewer economically devastating recalls, and greater health for the American people.

The legislation is a major step in the right direction toward achieving the recommendations of the President's Food Safety Working Group. I look forward to working with you to address both the issues raised here today and any other matters of concern.

Thank you again for the opportunity to discuss FDA's perspective on pending food safety legislation and the Administration's interest in improving food safety. We understand that the Administration may have additional views on this legislation. I would be happy to answer any questions.