DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
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TESTIMONY OF

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FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

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INTRODUCTION

Good morning, Chairman Pallone and Members of the Subcommittee. 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 discuss the urgent need for reform of our nation's food safety system. I commend you and Chairman Waxman, and other Members of the Committee, and your staffs, for your leadership and hard work in developing this draft legislation.

This is my first testimony as FDA's Commissioner. And it is fitting that my first testimony focus on food safety.

I have devoted my career to advancing the public health. I served as the New York City Health Commissioner for six years in the 1990s, and then served as the Assistant Secretary for Planning and Evaluation at HHS. I have served on numerous committees related to public health as a member of the Institute of Medicine.

Food safety is a core public health issue. Every year, millions of our friends and neighbors 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.

It is a tremendous honor to have been chosen by President Obama to lead this great Agency. I am aware of the President's personal commitment to improving food safety and of the progress being made by his Food Safety Working Group. The President has backed up his commitment with resources, proposing historic increases in funding for FDA's food safety efforts (see appendix).

I am also aware of the support of Secretary Kathleen Sebelius and HHS, and of Secretary Tom Vilsack and the U.S. Department of Agriculture (USDA), for progress on food safety.

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. I am impressed that 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.

That's why this hearing is so important.

FOOD SAFETY LEGISLATION

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

- First, does the legislation support a new system focused 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?

To comment on the discussion draft, let me address each of these three questions in turn. I will highlight a few of the many important new authorities in this bill.

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

The draft legislation would indeed transform our nation's approach to food safety from responding to outbreaks to preventing 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 industry, consumers, states, localities, and other key partners, we will establish basic standards for preventive controls. We will then join with states and localities to create an integrated national system of inspection, verification, and enforcement.

Key relevant provisions in the legislation include section 102, which requires facilities to conduct hazard analyses and implement preventive controls. It also requires companies to have a comprehensive food safety plan. Section 104 requires adherence to science-based safety standards issued by the Secretary for fresh produce and certain other raw agricultural commodities to prevent contamination. Section 112 improves FDA's ability to share key information on food safety between levels of government. 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 a new food safety system, 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. This legislation would provide these critical tools.

The draft legislation recognizes the importance of modernizing FDA's efforts to protect the safety of the food supply. Sections 102, 103, and 104 provide that the failure to comply with preventive controls, the food safety plan requirement, performance standards, or safety standards for produce would deem the food adulterated. An adulterated food is subject to seizure, condemnation, and forfeiture, and also may be refused admission when offered for import into the United States. Section 132 makes the Agency's administrative detention authority more useful by expanding the circumstances under which the Agency can detain a food, thereby

preventing its movement or distribution while the Agency takes appropriate regulatory action. Section 134 increases the criminal penalties for certain "knowing" violations, including distributing violative food, and section 135 provides the Agency with civil penalties when a person violates the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act). Together, these authorities underscore the responsibilities of firms to only market safe food and give the Agency essential tools to enforce these requirements to protect American consumers.

The draft bill also recognizes the importance of providing FDA with improved access to information. Section 101 requires facilities to register annually, deems products of non-registered facilities misbranded and consequently prohibits their sale, and allows FDA to modify the food categories that firms provide during registration. These measures will help ensure that the Agency has accurate information about who is making food for American consumers.

Section 201 will provide FDA with important information about commercial importers and require that they comply with good importer practices as a condition of maintaining the registration. This section also prohibits importing a product without being properly registered, and deems a product misbranded if it is imported by an unregistered broker or importer.

The requirements in this section of the bill represent significant enhancements to FDA's authorities with respect to imported products. At present, importers and brokers are not required to register with FDA. These changes will reduce risks to consumers from potentially harmful products by requiring importers to take appropriate steps to protect product safety, and by

allowing FDA to take action against importers who do not implement appropriate measures to ensure the safety of the products they import.

Section 106 provides FDA with explicit authority to access food records during routine inspections, thereby addressing one of the most significant gaps in FDA's existing authority. The authority provided in this provision is essential to enable FDA to identify problems and require corrections before people become ill. It also enables the Agency to verify during routine inspections that firms are maintaining proper records.

Although FDA has routine records access for certain other FDA-regulated products, and USDA has similar authority for the food products it regulates, FDA does not have explicit authority for the vast majority of foods under its jurisdiction. This provision provides FDA with access to critical information to identify problems before an emergency occurs. Under current limited authority, FDA generally only has access to required records during an emergency situation involving serious threats to health or life. Records access and recordkeeping by all persons in the distribution chain are the key mechanisms of providing regulators with information on plant operations, product safety, and product distribution. Such information is necessary to verify compliance and to identify problems.

The requirement in section 107 to implement a product tracing system for food will also provide FDA with enhanced information that will help the Agency trace foods more quickly during an outbreak. The current requirement to keep records for the immediate previous source and immediate subsequent recipient (one up / one back) requires the Agency to go to each point in

the distribution chain during an outbreak to trace the source and distribution of the contaminated product, which is not a sufficiently expedient process when trying to prevent more people from becoming ill. The ability to trace the path of any food, including tomatoes, other fresh produce, and peanut butter, back through every point in the supply chain or forward through the supply chain, is crucial for limiting foodborne illness in an outbreak, for preventing future outbreaks, and for reducing the impact on the segments of the industry whose products were not associated with the illnesses.

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

The draft legislation makes an important investment in the resources needed for major progress. After all, FDA must have the resources necessary to meet its responsibilities. Otherwise, the public will not benefit from the promise of a modern food safety system, and the Agency will fail to meet the expectations of the President, Congress, and the public.

The bill authorizes three fees that are also requested in the President's FY 2010 budget. For example, section 101 provides for a registration fee. This fee is of critical importance to enable the Agency to increase its inspection coverage of the approximately 378,000 registered facilities and to enhance its other food safety activities. Section 108 provides for a reinspection fee for a food facility that commits a violation that requires additional inspections by FDA. This will help cover the costs of reinspecting FDA-regulated facilities that fail to meet current Good Manufacturing Practices (cGMPs) or other FDA requirements. Section 144 authorizes the Secretary to charge and collect a fee for the issuance of export certificates for food and animal

feed which would facilitate trade. This fee will help cover the cost of this program, which is necessary for firms to do business with countries that require such certificates.

Section 105 proposes a rigorous inspection schedule for food facilities, ranging from at least every six to 18 months for high-risk processing facilities, every 18 months to three years for low-risk processing facilities and food labelers and packers, to every three to four years for warehouses. These requirements start 18 months after enactment. To meet these requirements, section 105 allows the Agency to use inspections conducted by inspectors from recognized State, local, other Federal, and foreign government officials.

FDA would like to raise three issues about section 105.

First, the amount of resources required to achieve these inspection goals would far exceed even the historic increases in the President's FY 2010 budget. It would be difficult, if not impossible, for FDA to hire and train thousands of additional staff so quickly—even while relying on inspections by state, local, and other federal and foreign government officials. As a result, FDA would support modification of these provisions to take into account the operational challenges involved, such as by changing these inspection frequencies.

Second, as we develop a new food safety system, FDA will have better information to guide the Agency's approach to inspection and oversight. We will understand where we must inspect more frequently because of the high risk of certain foods, facilities, and processes. We will also understand where we can protect public health without conducting inspections as frequently. As

a result, FDA would support flexibility to modify the inspection requirements based on the best available data on risk.

Third, section 105 could do more to provide flexibility to FDA in meeting the inspection challenge. The draft legislation allows the Agency to rely on inspections by other Federal agencies as well as by state, local, and foreign governments. An additional promising mechanism for international inspections is certification by accredited third parties. FDA would like the flexibility to explore the use of such an accreditation system and audit the performance of accredited third parties. With strong standards and robust oversight by FDA, this approach could help address the oversight challenge posed by the more than 200,000 registered foreign facilities exporting to the United States.

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 challenge of the 21st century. Success means fewer hospitalizations and deaths, fewer devastating recalls, and greater health for the American people. As Secretary Sebelius recently noted at the Food Safety Working Group listening session, "with the leadership and commitment by our President and so many Members of Congress, and this renewed partnership across HHS, USDA, and our sister Federal agencies, I know that this is the time when we will finally make real progress and strengthen our nation's food safety system."

The draft legislation is a major step in the right direction, and I look forward to working with you to address both the issues raised here today and any other matters of concern. I commend the Committee for its determination and leadership on this legislation. On behalf of the hundreds of dedicated staff devoted to food safety at FDA, I look forward to assisting with the legislative process.

I will be happy to answer any questions.

Appendix to FDA Testimony

Food Safety Highlights of the President's FY 2010 Budget

FDA will conduct a broad range of food safety activities with the new FY 2010 resources. For example, during FY 2010:

- FDA will hire 678 additional full-time equivalent staff to expand programs and activities that protect America's food supply.

- FDA will fund the cost-of-living pay adjustment for FDA professionals who conduct food product program activities.

- FDA will increase domestic and foreign risk-based inspections, conduct more audits of controls designed to prevent contamination, establish three additional high volume laboratories, and conduct more food safety intervention, sampling, and surveillance through our Office of Regulatory Affairs. The FY 2010 budget increase will allow FDA to hire more than 220 additional investigators. When fully trained and deployed, the new investigators will enable FDA to conduct the following additional field activities, based on the FY 2010 increases in budget authority and user fees proposed in this initiative:

  -4,000 additional domestic food safety inspections
  -100 additional foreign food and feed inspections
  -20,000 additional import food and feed field exams
  -3,000 additional samples for analysis in FDA laboratories.

- FDA will begin to implement a new strategic framework for an integrated national food safety system. Under this framework, FDA will build and expand existing programs and relationships with its regulatory partners: our federal, state, local, tribal, and territorial partners. This will allow FDA to increase information sharing and improve the quantity and quality of food safety data that FDA receives from its food safety partners.

- FDA will work with all stakeholders to better ensure that food protection is built into the complete life cycle, from food production to food consumption.

- FDA will improve its understanding of food and feed vulnerabilities and risks. This will include improving FDA's ability to use baseline data to measure the impact of food safety efforts and to track the status of foodborne illnesses in the United States. Achieving a better understanding of vulnerabilities and risks will allow FDA to adjust food and feed safety priorities and ensure that food programs achieve the best health benefit for the American public.

- FDA will improve its ability to detect signals of contamination and also improve its ability to collect and analyze adverse events for food and feed.

- FDA will respond more quickly to foodborne outbreaks and will improve its ability to quickly trace contamination to its source.

- FDA will improve risk communication during a food safety event so that the public can respond promptly to FDA alerts and protect themselves from harm.

- FDA will increase the capacity of the Food Emergency Response Network by establishing three new laboratories for chemical analysis.

- FDA will further develop an integrated genomic data base for *Salmonella* and conduct research to reduce knowledge gaps.

- FDA will charge fees to cover the cost of reinspecting FDA-regulated facilities that fail to meet current Good Manufacturing Practices or other FDA requirements.

- FDA will charge fees to cover the cost of issuing export certificates for food and feed.

- FDA will upgrade and integrate information technology systems, including systems that we use to screen, sample, detain, and take enforcement actions against imported food and feed products that violate FDA safety standards.