Good afternoon, Chairman Santorum and Members of the Subcommittee. I am Alex Azar, Deputy Secretary of the Department of Health and Human Services (HHS or the Department). I am pleased to be here today with my colleague, Charles Conner from the U.S. Department of Agriculture (USDA), and with Mr. Dennis Wolff of the Pennsylvania Department of Agriculture. HHS appreciates the opportunity to discuss our food counterterrorism activities.

The events of September and October 2001 made it very clear that terrorism -indeed bioterrorism - is a serious threat to our Nation and the world. The Bush Administration and Congress responded forcefully to this threat by providing funding to strengthen our medical and public health capacities to protect our citizens from future attacks.

A great deal has been done in the past few years to enhance the safety and security of the food supply in the United States. Within HHS, the Food and Drug Administration (FDA) has worked with food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry to significantly strengthen the nation's food safety and security system across the entire distribution chain, from farm to table, to better protect our food supply against deliberate and accidental threats. This cooperation has resulted in greater awareness of vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and faster foodborne illness outbreak response capabilities. HHS's Centers for Disease Control and Prevention (CDC) maintains national surveillance for specific infections and for outbreaks of foodborne illnesses, supports states in investigating and controlling outbreaks, and maintains cross-communication with FDA and USDA.

Food safety and food defense continue to be top priorities for this Administration. A terrorist attack on the food supply could have both severe public health and economic consequences, while damaging the public's confidence in the food we eat. The changes in food safety and defense that we have been implementing in the last few years are the most fundamental enhancements in our food safety and defense activities in many years.

In my testimony today, I will first briefly describe HHS' overall role in counterterrorism activities. Then, I will discuss our collaborative activities with our food safety and defense partners. I will also describe some of FDA's counterterrorism activities to enhance protection of the food supply. Finally, I will briefly discuss some of our efforts with regard to avian influenza.

HHS' ROLE IN COUNTERTERRORISM ACTIVITIES

Under the President's National Response Plan, HHS leads federal public health efforts to ensure an integrated and focused national effort to anticipate and respond to emerging biological and other weapons threats. HHS is also the principal federal agency responsible for coordinating all Federal-level assets activated to support and augment the state and local medical and public health response to mass casualty events.

Principally through HHS's Centers for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA), funds have been provided to States and localities to upgrade infectious disease surveillance and investigation, enhance the readiness of

hospitals and the health care system to deal with large numbers of casualties, expand public health laboratory and communications capacities and improve connectivity between hospitals, and city, local and state health departments to enhance disease reporting.

CDC also operates HHS's Strategic National Stockpile (SNS), which contains large quantities of medicine and medical supplies to protect the American public if there is a public health emergency severe enough to cause local supplies to run out. Once Federal and local authorities agree that the SNS is needed, medicines will be delivered to any state in the U.S. within 12 hours. Consequently, each state is now required to develop plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible in the event of a deployment.

HHS's National Institutes of Health (NIH) is assigned the lead role in the development of medical countermeasures to biological attack, and in the conduct of research concerning potential agents of bioterrorism that directly affect human health. The National Institute of Allergy and Infectious Diseases (NIAID) is the NIH institute with primary responsibility for carrying out this assignment.

To further encourage the development of new medical countermeasures against chemical, biological, radiological and nuclear agents and to speed their delivery and use should there be an attack, President Bush, in his 2003 State of the Union address proposed and Congress subsequently enacted Project BioShield to assure developers of medical countermeasures that funds would be available to purchase these critical products for use to protect our citizens. Project Bioshield is operated out of the HHS Office of Public Health Emergency Preparedness, which also coordinates the HHS-wide emergency preparedness activities and serves as the principal point of contact at HHS for other Federal agencies and Departments.

FDA is the Federal agency that regulates everything we eat except for meat, poultry, and processed egg products, which are regulated by our partners at USDA. FDA's responsibility extends to live food animals and animal feed. FDA also is responsible for ensuring that human drugs, human biological products, medical devices, and radiological products as well as veterinary drugs are safe and effective and that cosmetics are safe. In addition, FDA is responsible for ensuring that the health consequences of foods and medicines are accurately and honestly represented to the public, so that they can be used as effectively as possible to protect and improve the public health.

FDA's primary mission is to protect the public health. Ensuring that FDA-regulated products are safe and secure is a vital part of that mission. While performing our mission, we play a central and a leadership role in the nation's defense against terrorism. First, terrorists could use an FDA-regulated product, such as food, as a vehicle to introduce biological, chemical, or radiological agents into the U.S. stream of commerce. Second, FDA-regulated products, such as human drugs, vaccines, tissues, blood, blood products, and medical devices, as well as veterinary drugs, will play a central role in preventing or responding to human and/or animal health concerns created by an act of terrorism. It is HHS's goal, with FDA working closely with other HHS agencies and other Federal agencies, and with state and local governments, industry, and the public, to reduce the likelihood that an FDA-regulated product could be used to poison or otherwise terrorize Americans. We also help ensure that the nation's public health

system is prepared to deter a potential threat and is ready to respond to an act of terrorism.

By way of background, although FDA has the lead responsibility within HHS for ensuring the safety of food products, the CDC has an important complementary public health role. As the lead Federal agency for conducting disease surveillance, CDC monitors the occurrence of illness in the U.S. attributable to the entire food supply. The disease surveillance systems coordinated by CDC provide an essential early-information network to detect dangers in the food supply and to reduce foodborne illness. In addition, these systems can be used to indicate new or changing patterns of foodborne illness. Because CDC detects and investigates outbreaks of foodborne illness through its networks, CDC is able to alert FDA and USDA about implicated food products associated with foodborne illness and works closely with the agencies to take protective public health action. In keeping with its agency mission, CDC also identifies, evaluates, and provides expert scientific opinion on the effectiveness of foodborne disease prevention strategies.

COLLABORATION WITH FOOD SAFETY AND FOOD DEFENSE PARTNERS

In its food safety and defense efforts, FDA has many partners - Federal, state and local agencies, academia, and industry. FDA is working closely with our Federal partners such as USDA, DHS, the Homeland Security Council at the White House, the Department of State, the Central Intelligence Agency (CIA), and the FBI to have the best information possible and to be prepared to act as needed. I also want to emphasize FDA's close working relationships with its sister public health agency, CDC, with Customs and Border Protection (CBP) in DHS, and with USDA's Food Safety and Inspection Service (FSIS), FDA's counterpart agency responsible for meat, poultry, and processed egg products. Some other Federal partners include USDA's Animal and Plant Health Inspection Service (APHIS), USDA's Foreign Agriculture Service, USDA's Agricultural Research Service, USDA's Food and Nutrition Service, Department of the Army Veterinary Services Activity, the Environmental Protection Agency (EPA), and the Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau.

FDA's activities in public health defense are coordinated through the HHS Secretary's Operations Center. This relationship facilitates communication among all HHS Operating Divisions, the Department, and other Federal agencies and departments, including DHS. FDA also has worked closely with the Interagency Food Working Group of the White House Homeland Security Council on three initiatives - development of a national network of food laboratories, identification of vulnerabilities and subsequent mitigations for commodities of concern, and the development of a national incident management system. In addition, FDA worked in partnership with the U.S. Environmental Protection Agency, USDA, DHS, and the Department of Defense to describe general Federal roles responsibilities for decontamination and disposal in response to animals, crop, and food incidents.

In addition, FDA's Office of Criminal Investigations (OCI) maintains professional relationships with domestic and foreign law enforcement agencies to receive and act on any information regarding the intentional contamination of FDA-regulated products. OCI has a

specialized staff with the clearances, capabilities, and backgrounds to analyze information from law enforcement and intelligence community agencies and to assist those agencies in conducting terrorism-related threat assessments involving FDA-regulated products. OCI serves as FDA's liaison with the intelligence community (CIA, FBI, Defense Intelligence Agency, National Counter-Terrorism Center, and others). In this liaison capacity, OCI maintains relationships and provides expert assistance on scientific, technical, or criminal issues to specialized units within those agencies. OCI field agents serve on selected Joint Terrorism Task Forces around the country and on other multi-agency counterterrorism task forces. OCI agents actively participate in daily briefings at the FBI-led National Joint Terrorism Task Force and at the Department of Homeland Security Information Analysis Infrastructure Protection. FDA also has an OCI agent assigned on a full-time basis to Interpol's office in Washington, D.C. OCI's coordination of the agency's criminal investigative matters, including those that relate to potential acts of terrorism, help to prevent, deter, detect, and interdict a terrorist attack on FDA-regulated products.

FDA is working closely with DHS and other Federal agencies to implement the President's Homeland Security Presidential Directives (HSPDs). The Secretary of DHS is responsible for coordinating the overall national effort to enhance the protection of the critical infrastructure and key resources of the nation, including food and agriculture defense. The President has issued HSPD-7,-8, and-9, which identify critical infrastructures, improve response planning, and establish a national policy to defend the agriculture and food systems against terrorist attacks, major disasters, and other emergencies. HSPD-9 calls for the development of a National Veterinary Stockpile (NVS). FDA and CDC participate in NVS Steering Committee activities.

The HHS and USDA Secretaries or their designees exercise key responsibilities as food sector-specific agencies. DHS serves as the coordinator of the Food and Agriculture Sector within the Government Coordination Council (GCC). The GCC is charged with coordinating agriculture and food security strategies and activities, policy, and communication across government and between the government and the sector. In addition, the Council plays a coordinating role with the public health and clinical issues resulting from a terrorist act involving the food supply.

Within the GCC, HHS and USDA serve as co-leads for the food sector, and USDA serves as the lead for the agriculture sector. The Food and Agriculture Sector is a public-private partnership that combines expertise from several Federal agencies (FDA, USDA, EPA, Department of Defense [DoD], Department of Commerce, Department of the Interior, and the Department of Justice) as well as that of state and local officials (representing agriculture, public health, and veterinary services), and the private sector (more than 100 trade associations and individual firms participate). As part of the HSPD-7 National Infrastructure Protection Plan (NIPP) development, FDA and USDA have drafted sector-specific plans, which will be revised after obtaining additional input from states and the private sector. Using these plans as components, DHS has formulated the Interim NIPP for all sectors. With the close working relationship of FDA and USDA and the other government and industry collaborators, the Food and Agriculture Sector activities to protect critical infrastructure have set the organizational and operational standard for other critical infrastructure sectors. DHS has applauded the Food and Agriculture Sector's organizational structure, consensus building, and the steps it has taken to

improve food defense.

FDA also is working closely with our state partners to enhance food defense. For example, during the fall of 2004, FDA issued the Food Security Surveillance Assignment to FDA field personnel and participating state authorities to conduct food defense-related inspections, reconciliation examinations, and collections and analyses of samples of food products that have an elevated risk for intentional contamination. The purpose of this assignment was to deter intentional contamination of food through heightened and targeted preventive activities and to identify and address any gaps in the system for responding to a period of increased food security risk. This assignment enhanced both FDA's and our state counterparts' preparedness for a future threat involving an FDA-regulated product. Since that time, FDA has issued and completed three additional assignments to further integrate our food defense activities into our food safety work.

In addition, FDA and CDC have been collaborating with a Council of Association Presidents to develop a nationwide food defense awareness training program. This Council, which consists of ten of the major state and local public health and regulatory professional associations, has an outreach capability to reach virtually all state and local public health officials. The training program will help raise food defense awareness at the local, state, and Federal levels.

Now, I would like to describe some of FDA's other counterterrorism activities.

IMPORTS

In Fiscal Year (FY) 2005, FDA had the challenge of reviewing and/or inspecting more than 8.6 million imported food line entries. In FY 2006, we expect 10 million imported food line entries. In recent years, FDA's presence has expanded at ports of entry, increased surveillance of imported foods, focused on high-risk domestic inspections, and enhanced our laboratory analysis capacity. To manage the ever-increasing volume of imported food shipments, FDA is working to utilize more risk-management strategies in the review of foods that are being imported or offered for import into the United States. Currently, working with information submitted either through CBP's electronic systems used for import entries or through FDA's new Internet-based Prior Notice System Interface, FDA screens shipments electronically before they arrive in the U.S. to determine if the shipment meets identified criteria for physical examination or sampling and analysis or warrants other review by FDA personnel. This electronic screening allows FDA to better determine how to deploy our limited physical inspection resources at the border on what appear to be higher-risk food shipments while allowing lower-risk shipments to be processed in accordance with traditional import procedures after the electronic screening.

IMPLEMENTATION OF THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002 (BIOTERRORISM ACT)

Subtitle A of Title III of the Bioterrorism Act provided the Secretary of Health and Human Services with new authorities to protect the nation's food supply against the threat of intentional contamination and other food-related emergencies. This legislation represents the most fundamental enhancement to our food safety authorities in many years. These additional

authorities improve our ability to act quickly in responding to a threatened or actual terrorist attack, as well as other food-related emergencies. Since this legislation was signed into law three years ago, FDA has been working hard to implement this law effectively and efficiently. Throughout this process, FDA has enjoyed close cooperation from our colleagues at CBP. I would now like to describe FDA's actions to implement several of the provisions in the Bioterrorism Act.

Registration of Food Facilities

Section 305 of the Bioterrorism Act requires registration of foreign and domestic food facilities that manufacture, process, pack, or hold food for consumption by humans or animals in the U.S. Thanks to this provision, FDA has, for the first time, a roster of foreign and domestic food facilities that provide food for American consumers. In the event of a potential or actual terrorist incident or an outbreak of foodborne illness, the registration information will help FDA to quickly identify, locate, and notify the facilities that may be affected.

On October 10, 2003, FDA and CBP jointly published an interim final rule to implement the registration requirement, which became effective on December 12, 2003, as required by the Bioterrorism Act. The registration interim final rule was effective immediately but provided an opportunity for public comment on specific issues. On October 3, 2005, FDA issued the Registration of Food Facilities Final Rule, which affirmed the requirements initially set forth in the interim final rule. As of December 2, 2005, approximately 271,000 facilities have registered with FDA. This includes about 116,000 domestic and about 155,000 foreign facilities.

Prior Notice of Imported Food Shipments

Section 307 of the Bioterrorism Act requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the U.S. This advance information enables FDA, working closely with CBP, to more effectively target inspections of food at the border at the time of arrival to ensure the safety and security of imported foods. On October 10, 2003, FDA and CBP jointly published an interim final rule to implement this provision. The interim final rule provided stakeholders an additional opportunity to comment on all provisions of the interim final rule for almost six months while the rule took effect on December 12, 2003, as required by the Bioterrorism Act. We are drafting a final rule that responds to the numerous timely comments we received and intend to publish the final rule as expeditiously as possible. Since December 2003, we have been receiving, reviewing, and responding to approximately 167,000 notifications each week about articles of food being imported or offered for import into the U.S.

With the prior notice requirement, specific information mandated by the Bioterrorism Act must be submitted to FDA before the imported food arrives in the U.S. This not only allows FDA's and CBP's electronic screening systems to review and screen the shipments for potential serious threats to health (intentional or otherwise) before food arrives in the U.S., but it also allows FDA staff to review prior notice submissions for those products flagged by the systems as presenting the most significant risk and determine whether the shipment should be held for further investigation.

In addition, FDA has been actively working with the analysts at CBP's National Targeting Center to utilize their Automated Targeting System as a supplementary tool to enhance the

Agency's ability to focus attention on those imported foods that may pose a serious threat to public health. This allows FDA to screen products against CBP databases containing sensitive criminal and terrorist-related information. Products identified as potentially "high risk" through FDA's and CBP's screening criteria are targeted and undergo a manual, comprehensive "import security review" by FDA's Prior Notice Center that operates 24 hours a day, 7 days a week, every day of the year. FDA uses defined risk factors to select the products for import security reviews, based on intelligence reports and information about the shipper and/or consignee that indicate a potential risk to the U.S. consumer and the domestic market. Prior Notice import security reviews complement the traditional import field examinations. In FY 2005, FDA conducted intensive prior notice import security reviews on 86,187 imported food shipments.

Administrative Detention

Section 303 of the Bioterrorism Act gives FDA authority to administratively detain any article of food for which the Agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. This authority was self-executing and provides an added measure to ensure the safety of the nation's food supply. Section 303 also requires FDA to provide by regulation procedures for instituting on an expedited basis certain enforcement actions against perishable foods subject to a detention order. On June 4, 2004, FDA published a final rule to implement this section. The rule also includes procedures for detaining an article of food, expedited procedures for detaining perishable foods, and the process for appealing a detention order.

Maintenance and Inspection of Records for Foods

Section 306 of the Bioterrorism Act authorizes FDA to have access to certain records when the Agency has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. It authorizes the Secretary to publish regulations to establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. On December 9, 2004, FDA published a final rule to implement this section. The recordkeeping regulation requires persons receiving or releasing food, including food ingredients, to identify the immediate previous sources of that food and the immediate subsequent recipients of that food; thus, this rule is often referred to as the "one up/one down" rule. The regulation enhances FDA's ability to track and contain foods that pose a threat of serious adverse health consequences or death to American consumers from accidental or deliberate contamination of food. Affected persons with 500 or more full-time equivalent employees had to be in compliance with the regulation on December 9, 2005. Smaller companies, which provide more than 80% of the food supply, have until June or December 2006 to be in compliance, depending on the number of employees they have. The Bioterrorism Act required FDA to consider the size of the business in developing the regulations. FDA exercised this discretion by giving smaller businesses more time to comply to enable them to learn from the experiences of their larger counterparts and thereby reduce costs.

Authority to Commission Other Federal Officials to Conduct Inspections

Section 314 of the Bioterrorism Act authorizes the Secretary to commission other Federal officers and employees to conduct examinations and investigations. Pursuant to this new authority, FDA and CBP have signed a Memorandum of Understanding to commission CBP

officers to conduct examinations and investigations pursuant to information obtained through the prior notice requirements. These examinations and investigations may be carried out on FDA's behalf at ports where FDA may not currently have staff or to augment FDA staff at ports that do have an FDA presence. This unprecedented FDA-CBP collaboration significantly strengthens our ability to secure the border while ensuring the movement of legitimate trade. In accordance with this authority, FDA has already commissioned 9,948 CBP officers. The Agency will continue to explore use of this authority with other agencies with whom we share jurisdiction over a facility as a tool to further improve efficiencies.

INDUSTRY GUIDANCE AND PREVENTIVE MEASURES

In 2003, FDA has issued guidance on the security measures the food industry may take to minimize the risk that food will be subject to tampering or other malicious, criminal, or terrorist actions. FDA issued such guidance, "Security Preventive Measures Guidance Documents," for food producers, processors, and transporters, for importers and filers, for retail food stores and food service establishments, and for cosmetic processors and transporters. In addition, we have issued specific security guidance for the milk industry. During domestic inspections and import examinations, FDA's field personnel, as well as our state counterparts, continue to hand out and discuss these guidance documents to firms that have not previously received them.

To help reduce the risk of an attack on the food supply, FDA and our partners at USDA have joined forces to provide a food security awareness training program entitled, "Protecting the Food Supply from Intentional Adulteration: An Introductory Training Session to Raise Awareness." The training is directed at individuals who play an important role in defending our nation's food from attack: Federal, state, local, and tribal food-industry regulators; school food authorities; and nutrition assistance program operators and administrators. Representatives from the food industry and individuals essential in responding to a food emergency due to an intentional attack ? such as law enforcement, public health, and homeland security officials ? also are encouraged to participate in the training program. The program is available to any interested individuals free of charge.

VULNERABILITY AND THREAT ASSESSMENTS

FDA has adopted a risk-based approach to address food defense and determine where to focus its resources. As part of our efforts to anticipate threats to the food supply, we have conducted extensive scientific vulnerability assessments of different categories of food, determining the most serious risks of intentional contamination with different biological or chemical agents during various stages of food production and distribution. FDA's initial assessment utilized an analytical framework called Operational Risk Management (ORM) that considers both the severity of the public health impact and the likelihood of such an event taking place. As part of this process, FDA has incorporated threat information received from the intelligence community.

To validate our findings, FDA contracted with the Institute of Food Technologists to conduct an in-depth review of ORM and provide a critique of its application to food security. This review validated FDA's vulnerability assessment and provided additional information on the public health consequences of a range of scenarios involving various products, agents, and processes.

FDA also contracted with Battelle Memorial Institute to conduct a "Food and Cosmetics, Chemical, Biological, and Radiological Threat Assessment." The assessment also affirmed the findings of FDA's ORM assessment. In addition, it provided another decision-making tool for performing risk assessments. Further, the Battelle assessment made a number of recommendations that addressed research needs, the need for enhanced laboratory capability and capacity, and the need for enhanced partnerships between Federal, state, and local governments to ensure food security. FDA is addressing each of these recommendations.

The ORM approach provided a high-level view of foods and agents that were of greater concern. Since the completion of the ORM, FDA has undertaken more in-depth vulnerability assessments of specific food commodities using a method called CARVER+Shock. This method uses processes adapted from techniques developed by DoD for use in assessing the vulnerabilities of military targets to asymmetric threats. Results of these updated assessments are being used to develop technology interventions and countermeasures, identify research needs, and provide guidance to the private sector.

In 2003, FDA began using the CARVER+Shock analytical tool to perform vulnerability assessments to identify what an individual or group, intent on doing damage to the food and agriculture sector, could potentially do based on the person's or group's capability, intent, and past history. The CARVER+Shock methodology was modified under Homeland Security Council leadership for use in the food and agriculture sector by FDA, USDA, and DoD with coordination by DHS, CIA, and FBI. FDA's approach has been to seek voluntary, mutually beneficial partnerships with various segments of the food industry. We have completed such cooperative assessments with segments of the regulated industry that involve bottled water, fluid dairy products, juice products, and infant formula. FDA also has collaborated with USDA to provide assistance to the USDA Food and Nutrition Service on the use of this analytical tool on specific commodities in the school lunch program.

In recent months, FDA has been part of a joint federal initiative along with USDA, DHS, and the FBI called the Strategic Partnership Program in Agroterrorism (SPPA). The SPPA initiative is again using the CARVER+Shock tool but, by seeking industry and state volunteers, is taking the tool to local venues. During these assessments, there are local industry, FBI, DHS, FDA, and USDA participants. These assessments not only identify vulnerabilities in other food commodities but also build local infrastructure around food defense issues. The SPPA program will run for two years and has a goal of completing 40-50 assessments during this period. The results from these assessments will be used to identify mitigation strategies and to focus research questions.

EMERGENCY PREPAREDNESS AND RESPONSE

FDA has established an Office of Crisis Management to coordinate the preparedness and emergency response activities within FDA and with our Federal, state, and local counterparts. Over the past few years, FDA has participated in and conducted multiple emergency response activities including exercises coordinated with other Federal and state agencies. For example, FDA and USDA's FSIS have focused on strengthening our working relationships through joint testing of several response plans in an exercise environment. FDA has participated in numerous exercises, including those sponsored by USDA/APHIS, that focus on the

occurrence of natural or intentional outbreaks in animals. We have conducted exercises to test our emergency response with respect to contamination of the food supply and animal feed. FDA also has reviewed food defense and rapid response and recovery procedures with industry groups and trade associations.

To enhance FDA's ability to manage, plan for, and respond to food emergencies, FDA has implemented the Emergency Operations Network Incident Management System (EON IMS), an electronic system for managing emergencies. It has three components: incident tracking and contact management, a collaboration and knowledge management tool for meetings and document management, and a Geographic Information System for mapping and impact assessment. The EON IMS is important in all emergencies and exercises requiring efficient receipt and dissemination of large volumes of information to our stakeholders, including the public and other Federal and state agencies. Once completed, this system will provide a web-based connection for all FDA offices and our partners, through which accurate real-time information about various incidents can be shared and discussed. It will be a component of a safety net that enhances our ability to prepare for a terrorist attack and respond should an attack occur. The development of this system conforms to HSPD-5, "Management of Domestic Incidents."

LABORATORY ENHANCEMENTS

An additional step in enhancing our response capability is to improve our laboratory capacity. A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for a broad array of biological, chemical, and radiological agents. To increase surge capacity, FDA has worked in close collaboration with USDA's FSIS to establish the Food Emergency Response Network (FERN) to include a substantial number of laboratories capable of analyzing foods for agents of concern. We are seeking to expand our capacity through agreements with other Federal and state laboratories. There are 123 laboratories representing all 50 states and Puerto Rico that have satisfactorily completed the FERN laboratory Qualification Checklist, which provides vital information to determine if a lab meets the criteria for participation in FERN and is eligible for Federal funding. In FY 2005, FDA was able to offer cooperative agreements to 8 State chemical laboratories which enhanced the current capability and capacity of the 10 FDA laboratories participating in FERN. Participation continues to grow. FERN will encompass a nationwide network of federal, state, and local laboratories working together to build the capacity to test the safety of thousands of food samples, thereby enhancing the nation's ability to swiftly respond to a terrorist attack.

We also are expanding federal, state, and local involvement in our eLEXNET system by increasing the number of laboratories around the country that participate in this electronic data system. eLEXNET is a seamless, integrated, web-based data exchange system for food testing information that allows multiple agencies engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. It enables health officials to assess risks and analyze trends, and it provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods. At present, there are 113 laboratories representing 50 states and the District of Columbia that are part of the eLEXNET

system with 95 actively submitting data. We are continuing to increase the number of participating laboratories and types of data being submitted into the system. Moreover, the governments of Canada, Mexico, and the United States agreed to establish a pilot to use eLEXNET to share food sample data among the three countries' laboratories. FDA has been working with Mexico and Canada to establish a secure network to facilitate the sharing of food-testing data between U.S., Mexican, and Canadian laboratories.

FDA also is collaborating with CDC, USDA, DHS, EPA and many other Federal agencies to create a Memorandum of Agreement for an Integrated Consortium of Laboratory Networks (ICLN). The ICLN will be an integrated system of laboratory networks, such as FERN, CDC's Laboratory Response Network (LRN), and USDA's National Animal Health Laboratory Network (NAHLN), to provide for early detection and effective consequence management of acts of terrorism and other events involving a variety of agents and more than one section or segment of the nation (i.e., humans, animals, plants, food, the environment). The LRN includes approximately 150 domestic and international laboratories. These laboratories are primarily responsible for testing human specimens and a subset of labs can test animal specimens. There are 39 laboratories in USDA's NAHLN that are primarily responsible for testing animal samples.

In addition, FDA collaborated with the U.S. Department of the Army to design and develop two mobile laboratories to be deployed at borders, ports, or other locations, to enhance our ability to provide timely and efficient microbiological and chemical analyses of imported food. FDA took possession of the completed mobile laboratories in April 2005. The Microbiological Mobile Laboratory Unit was utilized in October 2005 during an emergency deployment to assist the Department of Health and Hospitals Laboratories (DHHL) in Louisiana. The DHHL laboratories were unable to provide analytical support due to the damage caused by Hurricanes Katrina and Rita. FDA and the DHHL analysts worked together in the Mobile Laboratory to provide on-site analytical testing of water samples from shellfish-growing waters.

RESEARCH

To prioritize research needs and avoid duplication, FDA coordinates with its sister agencies within HHS, such as CDC, and with other Federal partners such as USDA, DHS, DoD, and the Department of Energy. Within FDA, we have embarked on an ambitious research agenda throughout the Agency to address potential terrorist threats. To increase focus on food defense, FDA is ensuring that significant resources are focused on priority food safety and defense issues. For example, research sponsored by FDA's Center for Food Safety and Applied Nutrition is aimed at developing the tools essential for testing a broad array of food products for a multiple number of biological and chemical agents. We are actively working with our partners in government, industry, and academia to develop such methods. FDA's work with AOAC International, an association of analytical chemists, on validating analytical methods for the detection of biological, chemical, and radiological agents in foods is considered the "gold standard" against which other validations programs are judged. Likewise, FDA's research on microbial genomics and analytical chemistry is widely recognized for its importance to other Federal agencies charged with forensic investigations of terrorism events.

Section 302(d) of the Bioterrorism Act directs FDA to provide for research on tests and

sampling methodologies designed to test food to detect adulteration rapidly, particularly methodologies that detect intentional adulteration and tests that are suitable for inspections of food at ports of entry to the United States. This section also requires the Agency to report annually to Congress on its progress. FDA has submitted its second annual report to Congress. It can be found on FDA's Bioterrorism Act webpage (http://www.fda.gov/oc/bioterrorism/bioact.html).

FDA began focusing its research program to address food defense concerns soon after the events of September 11, 2001. The report mentioned above describes more than 100 intramural and extramural research projects to develop tests and sampling methodologies for the detection of adulterated food. The Agency's research agenda is particularly focused on methods to detect high-priority biological agents (e.g., Clostridium botulinum neurotoxins) as well as chemical (e.g., ricin), and radiological threat agents that pose the greatest threats to the public and is focused on foods believed to be the most vulnerable or attractive to terrorists. Our researchers also are exploring food-testing protocols using the latest technologies, such as the optical affinity biosensor technology and the quadruple time of flight mass spectrometer, to improve timeliness and accuracy over existing techniques. Researchers are also gleaning information on test methods by using them in studies focused on interventions or shields for the food supply, studies focused on characterizing the behavior (growth, survival, stability) of agents in various food categories, and studies focused on decontaminating food processing facilities.

Among the Agency's research accomplishments are the development, adaptation, or validation of rapid and field-deployable methods to detect various agents in food and the establishment of testing protocols. FDA has shared these new data and technologies with Federal, state, and local entities to equip them to perform food safety testing. FDA has also shared research findings with industry in order to further protect the food supply from deliberate attack.

HHS AVIAN INFLUENZA EFFORTS

Finally, I would be remiss, Mr. Chairman if I did not mention efforts underway at HHS with regard to Avian Influenza. Recent events affecting public health including SARS, Monkeypox and Avian Influenza have highlighted the potential adverse health effects of human interaction with animals. Outbreaks of zoonotic disease are occurring with increasing frequency, from all corners of the world. It is difficult to predict when and where the next event will occur. It is apparent, however, that the public health and agriculture sectors must seek new partnerships and new ways to detect these microbial threats.

Department of Health and Human Services (HHS) Secretary Mike Leavitt has made influenza pandemic planning and preparedness a top priority. The FDA and other agencies within HHS are working together formally through the Influenza Preparedness Task Force that Secretary Leavitt has chartered to prepare the United States for this potential threat to the health of our nation. The Department is also working with other federal, state, local and international organizations to ensure close collaboration.

As you are aware, the potential for a human influenza pandemic is a current public health concern with an immense potential impact. Inter-pandemic (seasonal) influenza causes an average of 36,000 deaths each year in the United States, mostly among the elderly and nearly 200,000 hospitalizations. In contrast, scientists cannot predict the severity and impact of an

influenza pandemic, whether from the H5N1 virus currently circulating in Asia and Europe, or the emergence of another influenza virus of pandemic potential. However, modeling studies suggest that, in the absence of any control measures, a "medium-level" pandemic in which 15 percent to 35 percent of the U.S. population develops influenza could result in 89,000 to 207,000 deaths, between 314,000 and 734,000 hospitalizations, 18 to 42 million outpatient visits, and another 20 to 47 million sick people. The associated economic impact in our country alone could range between $71.3 and $166.5 billion. A more severe pandemic, as happened in 1918, could have a much greater impact.

There are several important points to note about an influenza pandemic:
? A pandemic could occur anytime during the year and could last much longer than typical seasonal influenza, with repeated waves of infection that could occur over one or two years.
? The capacity to intervene and prevent or control transmission of the virus once it gains the ability to be transmitted from person to person will be extremely limited.
? Right now, the H5N1 avian influenza strain that is circulating in Asia among birds is considered the leading candidate to cause the next pandemic. However, it is possible that another influenza virus, which could originate anywhere in the world, could cause the next pandemic. Although researchers believe some viruses are more likely than others to cause a pandemic, they cannot predict with certainty the risks from specific viruses. This uncertainty is one of the reasons why we need to maintain year-round laboratory surveillance of influenza viruses that affect humans.
? We often look to history in an effort to understand the impact that a new pandemic might have, and how to intervene most effectively. However, there have been many changes since the last pandemic in 1968, including changes in population and social structures, medical and technological advances, and a significant increase in international travel. Some of these changes have increased our ability to plan for and respond to pandemics, but other changes have made us more vulnerable.
? Because pandemic influenza viruses will emerge in part or wholly from among animal influenza viruses, such as birds, it is critical for human and animal health authorities to closely coordinate activities such as surveillance and to share relevant information as quickly and as transparently as possible.
In the United States, USDA and the Department of the Interior coordinate most work on avian influenza viruses among birds and other animals. HHS collaborates with USDA and the Department of the Interior in critical partnerships for domestic preparedness for a possible avian influenza outbreak in the United States. HHS relies on USDA for domestic and wild bird, backyard bird, live bird market and poultry products surveillance as a way to early detect threats to human health. Early detection will allow the US Government to have the most up-to-date and reliable information that will help to save human lives.

As you are aware, the President requested additional FY 2006 appropriations in support of his National Strategy on Pandemic Influenza. In seeking this funding, the goals are: to be able to produce a course of pandemic influenza vaccine for every American within six months of an outbreak; to provide enough antiviral drugs and other medical supplies to treat 25 percent of the U.S. population; and, to ensure a domestic and international public health capacity to respond to a pandemic influenza outbreak.

CONCLUSION

In conclusion, HHS is making significant progress in its ability to ensure the safety of the food supply. Due to the enhancements being made by FDA and other agencies and due to the close coordination between the Federal and State food safety, public health, law enforcement, and intelligence-gathering agencies, the United States' food safety and defense system is stronger than ever before. Although we are better prepared than ever before, we are continuously working to improve our ability to prevent, detect, and respond to terrorist threats.

Thank you for this opportunity to discuss our counterterrorism activities to protect the food supply. I would be pleased to respond to any questions.