Testimony of:
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Good afternoon, Chairman Stupak, Ranking Member Burgess, and other distinguished Members of the Subcommittee. I am Jodi Nudelman, Regional Inspector General for Evaluation and Inspections of the U.S. Department of Health & Human Services (HHS) Office of Inspector General (OIG). I appreciate the opportunity to appear before you to discuss our oversight work as well as the vital role that the Food and Drug Administration (FDA) plays in protecting the Nation's food supply.

Recent high-profile outbreaks of foodborne illness have underscored the importance of food facility inspections. My testimony today will focus on my office's recent review of FDA's inspection program.[1] In short, our report identifies significant weaknesses in FDA's inspections of domestic food facilities. We found that many food facilities went 5 or more years without an FDA inspection. We also found that there was a large decline in the number of food facility inspections conducted by FDA over a 5-year period, as well as a decline in the number of violations identified by FDA inspectors. Further, when violations were identified, FDA did not routinely take swift and effective action to ensure that these violations were remedied.

Our recent report is a part of a larger body of OIG work that demonstrates that more needs to be done to ensure the safety of the Nation's food supply. In a report on food traceability, we found that only 5 of 40 selected products could be traced through each stage of the food supply chain.[2] In addition, more than half of the facilities that handled these food products failed to meet FDA recordkeeping requirements. In another report, we found that 5 percent of selected facilities failed to register their facilities with FDA as required. Of those facilities that did register, almost half failed to provide accurate information in FDA's registry.[3] Finally, we completed a report that found that FDA did not always follow its procedures when overseeing certain pet food recalls and noted that FDA does not have the statutory authority to mandate recalls.[4]

OIG'S MISSION IS TO PROTECT HHS PROGRAMS AND BENEFICIARIES

OIG is an independent, nonpartisan agency committed to protecting the integrity of the more than 300 programs administered by HHS as well as the health and welfare of the people served by them. OIG fights fraud, waste, and abuse through a nationwide network of investigations, audits, and evaluations, as well as enforcement and compliance activities.

OIG's work results in recoveries of misspent or stolen funds and in recommendations for program savings and improvements to program efficiency and effectiveness. In FY 2009, OIG investigations

[1] OIG, *FDA Inspections of Domestic Food Facilities*, OEI-02-08-00080, April 2010.

[2] OIG, *Traceability in the Food Supply Chain*, OEI-02-06-00210, March 2009.

[3] The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires certain food facilities to register with FDA. The purpose of registration is to provide FDA with reliable information that enables FDA to quickly locate facilities during outbreaks of foodborne illness. See OIG, *FDA's Food Facility Registry*, OEI-02-08-00060, December 2009.

[4] OIG, *Review of the Food and Drug Administration's Monitoring of Pet Food Recalls*, A-01-07-01503, August 2009.

resulted in $4 billion in settlements and court-ordered fines, penalties, and restitution. OIG audits resulted in almost $500 million in expected recoveries. OIG also produced equally important but less quantifiable gains in deterrence and prevention of fraud, waste, and abuse and in improved program operations. Additionally, OIG has raised awareness of critical issues among policymakers, Government agencies, and other relevant stakeholders. Moving forward, OIG is committed to building on our successes and continuing to protect the integrity of Government programs and their beneficiaries.

FOOD FACILITY INSPECTIONS ARE AN IMPORTANT TOOL TO ENSURE FOOD SAFETY

Each year, more than 300,000 Americans are hospitalized and 5,000 die after consuming contaminated foods and beverages.[5] FDA is responsible for safeguarding the Nation's food supply by ensuring that food is free of disease-causing organisms, chemicals, or other harmful substances.[6] Recent outbreaks, such as the salmonella outbreak caused by insanitary conditions at a peanut-processing plant in 2009—as well as others that resulted in large recalls of spinach, peppers, and alfalfa sprouts—have raised questions about FDA's inspections process and its ability to protect the Nation's food supply.

FDA inspects food facilities to ensure food safety. During an FDA inspection, an inspector may identify potential violations of the Food, Drug, and Cosmetic Act or other applicable laws and regulations. Based on the outcome of the inspection, FDA assigns the facility one of three classifications: official action indicated (OAI), voluntary action indicated, or no action indicated.

According to FDA guidance, when inspectors uncover violations that are significant enough to warrant OAI classification, FDA should consider taking some type of regulatory action. This regulatory action generally consists of either an advisory action or an enforcement action. Advisory actions usually allow an opportunity for the facility to voluntarily correct the violations found during the inspection, whereas enforcement actions are usually initiated in court and the facility is compelled to correct the violations found during the inspection.

Once an FDA inspection finds violations at a facility, FDA uses several methods of determining whether a facility has subsequently corrected the violations. FDA may review evidence of corrective actions provided by a food facility or FDA may reinspect a facility to verify that corrections were made.

OIG ASSESSED THE FREQUENCY AND RESULTS OF FDA'S FOOD FACILITY INSPECTIONS

Our study assessed the extent to which FDA conducted inspections and identified violations in domestic food facilities.[7] It also assessed the extent to which FDA took regulatory action against food facilities with violations and ensured that these violations were corrected.

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[5] Paul S. Mead et al., "Food-Related Illness and Death in the United States," *Emerging Infectious Diseases*, vol. 5, 1999, pp. 607–625. Available online at http://www.cdc.gov/ncidod/eid/Vol5no5/mead.htm. Accessed on December 14, 2009.

[6] FDA is responsible for ensuring the safety of almost all food products sold in the United States, with the exception of meat, poultry, and some egg products, which are regulated by the U.S. Department of Agriculture.

[7] This study includes inspections of domestic food facilities conducted by FDA or by States under contract with FDA.

We based our study on three sources of data: (1) FDA's data on food facility inspections, (2) FDA's documentation of facility violations and followup activities, and (3) structured interviews with FDA staff.

To determine the extent to which FDA conducts inspections, we analyzed FDA's data on all domestic food facility inspections for fiscal years (FY) 2004 through 2008. To determine the extent to which FDA took action against food facilities with violations and ensured that those violations were corrected, we requested from FDA all documentation related to OAI classifications received by facilities in FY 2007. We chose FY 2007 because it was the most recent timeframe that would also allow FDA sufficient time to initiate any actions and to complete any activities designed to ensure that violations were corrected.

MOST FOOD FACILITIES WENT UNINSPECTED FOR AT LEAST 5 YEARS

Our study found that 56 percent of food facilities that were subject to FDA inspection went 5 or more years without an FDA inspection. If FDA does not routinely inspect food facilities, it is unable to ensure that these facilities are complying with applicable laws and regulations and that the food handled by these facilities is safe. Except in a few instances, there are currently no specific guidelines that govern the frequency with which inspections should occur.

Our study also found that the number of food facility inspections has declined, even as the number of food facilities has increased. In FY 2004, FDA inspected more than 17,000 facilities; in FY 2008, this number dropped to fewer than 15,000. During the same period, the number of food facilities subject to FDA inspection increased from about 59,000 to almost 68,000 facilities. We also identified a decline in the number of high-risk facilities inspected by FDA.[8]

FDA officials attributed the decline in inspections primarily to a significant decrease in staffing levels that resulted from funding cuts. These officials noted that between 2003 and 2008, FDA lost almost a quarter of the staff that performs food facility inspections. They also noted that many of those losses came from the ranks of FDA's most experienced employees.

THE FREQUENCY OF VIOLATIONS IDENTIFIED BY FDA INSPECTIONS DECLINED, AND MOST FACILITIES WITH VIOLATIONS WERE REPEAT OFFENDERS

Facilities receive OAI classifications when inspectors determine that the violations found are significant enough to potentially warrant regulatory action. Facilities most commonly received OAI classifications for unsafe food manufacturing and handling practices and insanitary conditions in the facilities, such as improper handling of food or evidence of rodent infestations.

From FY 2004 to FY 2008, the percentage of inspected facilities that received OAI classifications dropped from nearly 4 percent to less than 2 percent. Further, over this 5-year period, the number of facilities with OAI classifications declined from 614 facilities to 283 facilities.

[8] Each year, FDA designates certain facilities as high risk. This designation helps FDA determine which facilities should be given a higher priority for inspection. Generally, these facilities handle types of food that have a greater potential to cause harm.

Our study also found that nearly three-quarters of the facilities that received OAI classifications in FY 2008 had a history of violations. Even more worrisome, half of the facilities that received OAI classifications had been cited for exactly the same violations in prior inspections. In one notable example, FDA found that a facility had the same unsafe manufacturing practices and insanitary conditions as it did during the previous four inspections. After each inspection, the facility promised to make corrections; however, each subsequent inspection revealed that nothing had changed.

We also found that a small number of facilities refused to grant FDA officials access to records during an inspection. These records included descriptions of sanitation practices within each facility, lists of customers that received the facility's products, and descriptions of consumer complaints. FDA does not currently have the statutory authority to require food facilities to provide access to these records.[9]

FDA DID NOT TAKE REGULATORY ACTION AGAINST MANY FACILTIES WITH VIOLATIONS

According to FDA guidance, when a facility receives an OAI classification, FDA should consider taking some type of regulatory action. This regulatory action generally consists of either advisory action or enforcement action. In FY 2007, FDA took advisory actions against 44 percent of the 446 facilities that initially received an OAI classification, whereas FDA initiated enforcement actions against 2 percent of these facilities.[10]

FDA lowered the classifications of 29 percent of the facilities that initially received OAI classifications. The most common reason for lowering a classification was that other FDA officials did not concur with the inspector's initial classification. The second most common reason for lowering a classification was that the facility either took or promised to take corrective actions. Although FDA guidelines allow inspection classifications to be lowered, FDA district offices appeared to be inconsistent when lowering classifications. For example, some district offices did not lower their OAI classifications after a facility promised to take corrective action, whereas other district offices did this more commonly.

For 25 percent of facilities initially receiving OAI classifications, FDA neither took any regulatory action against the facilities nor lowered the classifications. In just over half of these cases, FDA officials noted that they did not take regulatory action because of their interpretation of FDA's program guidance. For example, FDA guidelines suggest that multiple warning letters should not be issued for the same violations. Several officials reported that they did not issue a warning letter because FDA had previously issued a warning letter to the facility.

FDA OFTEN DID NOT TAKE SWIFT AND EFFECTIVE ACTION TO ENSURE THAT VIOLATIONS WERE REMEDIED

FDA often failed to follow up with facilities to ensure that violations were corrected. In FY 2007, 280 facilities received OAI classifications that were not lowered by FDA. FDA did not reinspect 36

[9] FDA has access to certain records held by infant formula facilities as well as certain records needed to trace an article of food through the food supply chain. The limited circumstances under which FDA can access these records are described in 21 U.S.C. §§ 374 and 350.

[10] The advisory actions taken by FDA consisted of warning letters, untitled letters, and regulatory meetings. The enforcement actions taken by FDA consisted of seizures and injunctions.

percent of these facilities within a year of the inspection or review evidence to ensure that the violations were corrected.

For the remaining facilities, FDA took additional steps to ensure that the violations had been corrected. Specifically, FDA reinspected 35 percent of the facilities within a year of the initial inspection. For an additional 30 percent of facilities, FDA reported that it reviewed some type of evidence from the facilities demonstrating that they had corrected the violations.[11] Examples of this evidence included photographs documenting corrections made in the facility, revised food labels documenting changes made to correct labeling violations, and a description of how employees were counseled.

OIG RECOMMENDS SEVERAL ACTIONS TO STRENGTHEN FDA'S DOMESTIC INSPECTIONS PROGRAM

Based on these findings, we made six recommendations to FDA to improve its domestic inspections program. Specifically, we recommended that FDA:

- increase the frequency of food facility inspections, with particular emphasis on high-risk facilities;
- provide additional guidance about when it is appropriate to lower OAI classifications;
- take appropriate actions against facilities with OAI classifications, particularly those that have a history of violations;
- ensure that violations are corrected for all facilities that receive OAI classifications;
- seek statutory authority to allow FDA access to facilities' records during the inspection process; and
- consider seeking statutory authority to impose civil penalties through administrative proceedings.

IN CONCLUSION, MORE NEEDS TO BE DONE TO PROTECT THE SAFETY OF THE NATION'S FOOD SUPPLY

Our report identified significant weaknesses in FDA's inspections program. If FDA does not routinely inspect food facilities, it is unable to ensure that these facilities are complying with applicable laws and regulations and that the food handled by these facilities is safe. In addition, FDA must take swift and effective action to ensure that all violations are remedied. Taken together, the findings of this report demonstrate that more needs to be done to protect public health and to ensure that FDA has the necessary tools to prevent outbreaks of foodborne illness.

OIG recognizes the importance of ensuring the safety of the food supply and will continue our work in this area. We are currently conducting a review that assesses FDA's oversight of inspections conducted by State inspectors under contract. In addition, we are conducting an audit of selected

[11] Note that these percentages do not sum to 100 percent because of rounding.

food recalls to determine whether FDA's oversight was adequate to ensure that the recalls were complete, accurate, and timely.

This concludes my testimony. I welcome your questions.