REPORT 3 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (A-10)
Update on the Food and Drug Administration's (FDA) Efforts to Improve Food Safety
(Reference Committee E)

EXECUTIVE SUMMARY

Objective. This report responds to the final request of Resolution 520 (A-09) by providing background information on the 2007 Food Safety Plan and the 2009 President’s Food Safety Working Group, and describing the new 2010 initiative known as the “Transforming Food Safety Initiative,” which is intended to improve the safety of the country’s food supply.

Data Sources. The World Wide Web was searched, using the “Google” search engine, using the search term “food safety.” Highly relevant and trustworthy sources were examined to determine additional resources. The Web sites of the Food and Drug Administration (FDA), United States Department of Agriculture (USDA), and Centers for Disease Control and Prevention (CDC) also were searched using the term “food safety.”

Results. Foodborne illness, a preventable and underreported disease, continues to be a public health and economic challenge in the United States affecting both general and at-risk populations. On an annual basis, this disease is estimated to cause 76 million cases of illness, 325,000 hospitalizations, and 5,000 deaths. Recent changes in human demographics and food preferences, changes in food production and distribution systems, microbial adaptation, and lack of adequate public health resources and infrastructure have led to the emergence of both novel and traditional foodborne diseases. However, the domestic food supply chain is currently overseen by a mix of multiple federal, state, territorial, tribal, and local regulatory and public health agencies that often work independently under different legislative authorities and that are driven by different objectives and priorities. Accordingly, several new federal initiatives have been advanced to help keep the nation’s food supply safe from both unintentional and deliberate contamination.

Conclusion. Physicians have long recognized and acknowledged existing gaps and barriers to improving the food safety system in the United States. While the country’s food remains one of the safest in the world, these gaps have resulted in foodborne illness outbreaks and difficulty in gathering the data to investigate and coordinate the response to the outbreaks. Physicians play a critical role in the initial diagnosis of foodborne illnesses and are encouraged to remain up-to-date on the diagnosis and management of foodborne illnesses in order to recognize and report such cases when they present for evaluation.

To address current gaps in the food safety system, the President established the Food Safety Work Group (FSWG), which has proposed a national integrated food safety system with a public health-focused approach based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery. The resulting “Transforming Food Safety Initiative” operationalizes the recommendations of the FSWG and proposes a budgetary increase in the FY 2011 budget to fund these improvements to the food safety system. Staff will monitor the implementation of this initiative and provide appropriate feedback to Congress and the FDA as necessary.
Subject: Update on the Food and Drug Administration’s (FDA) Efforts to Improve Food Safety

Presented by: C. Alvin Head, MD, Chair

Referred to: Reference Committee E
(Brooks F. Bock, MD, Chair)

Resolution 520 (A-09), “Disease Transmission Via Foods: Public Health Disaster in Waiting” introduced by the American Association of Public Health Physicians and adopted at the American Medical Association’s (AMA) 2009 Annual Meeting, asked that our AMA publicly call for enhancement of the protocols, authority, oversight, and funding at the federal agencies that regulate the food industry and to monitor the success of such efforts. The resolution also directed that our AMA support transparency and tracking of foods from the point of origin to the point of sale, as well as timely coordination in the activities of federal regulatory agencies. See Policies H-440.858 and D-440.944 (AMA Policy Database).

Finally, the resolution asked for report back at the 2010 Annual Meeting on the progress that has been made on assuring a safer food supply for the American public. This report responds to the final request of Resolution 520 (A-09) by providing background information on the 2007 Food Safety Plan and the 2009 President’s Food Safety Working Group, and by describing the new 2010 initiative known as the “Transforming Food Safety Initiative,” which is intended to improve the safety of the country’s food supply.

DATA SOURCES

The World Wide Web was searched, using the “Google” search engine, using the search term “food safety.” Highly relevant and trustworthy sources were examined to determine additional resources. The Web sites of the Food and Drug Administration (FDA), United States Department of Agriculture (USDA), and Centers for Disease Control and Prevention (CDC) also were searched using the term “food safety.”

INTRODUCTION

Food safety is a core public health issue even though the United States’ food supply remains one of the safest in the world. Foodborne illness, a preventable and underreported disease, continues to be a public health and economic challenge in the United States affecting both general and at-risk populations. On an annual basis, this disease is estimated to cause 76 million cases of illness, 325,000 hospitalizations, and 5,000 deaths. The estimated economic burden attributable to foodborne illness has been placed between $10 and $83 billion in the United States. However, a 2010 study from the Pew Charitable Trusts and Georgetown University (which considered a total of 27 known pathogens) put the economic burden at $152 billion annually. After ingesting or eating contaminated food, the general population may experience symptoms and recover within a...
day or two. However, at-risk populations may experience more severe illness and have a greater risk of death. Such populations include older adults, young children, pregnant women and their unborn children, individuals with organ transplants, and those who are otherwise immunocompromised.

Recent changes in human demographics and food preferences, changes in food production and distribution systems, microbial adaptation, and lack of adequate public health resources and infrastructure have led to the emergence of both novel and traditional foodborne diseases. With increasing travel and trade opportunities, it is not surprising that a greater risk exists of contracting and spreading a foodborne illness locally, regionally, and globally. Food can be contaminated via many different vehicles and at multiple and different steps including: (1) at the source on the farm or in harvest water; (2) in processing or distribution facilities; (3) during transit; (4) on location at retail and food service establishments; and (5) in the home of the consumer. This far-reaching, complex, and increasingly globalized food supply chain, coupled with new pathogens and other contaminants, poses challenges that demand continued examination and renewal of the country’s food protection strategies and the development of more effective solutions to prevent contamination. Preliminary reports from the CDC suggest that a long-term decline in foodborne illness appears to be stalling and that “the lack of recent progress points to gaps in the current food safety system and [demonstrates] the need to continue to develop and evaluate food safety practices as food moves from the farm to the table.”

The FDA regulates all of the United States’ domestic and imported food, except for meat, poultry, and some egg products, which are regulated by the USDA. However, the domestic food supply chain is currently overseen by a mix of multiple federal, state, territorial, tribal, and local regulatory and public health agencies that often work independently under different legislative authorities and that are driven by different objectives and priorities. At the federal level, the FDA oversees more than 150,000 registered domestic food facilities, including food manufacturers and processors, food warehouses, and grain elevators. State and local regulatory authorities are responsible for the inspection and oversight of food establishments, including restaurants, grocery stores, cafeterias, and other outlets in health care facilities, schools, and correctional facilities. Specifically, states perform approximately 90% of all food safety inspections conducted at food manufacturing and distribution establishments. Finally, the CDC leads the federal effort in gathering data on foodborne illnesses, investigating illnesses and outbreaks, and monitoring the effectiveness of prevention and control efforts. The CDC also plays a key role in building state and local health department epidemiology practices, including laboratory and environmental health capacity to support foodborne disease surveillance and outbreak response.

Unfortunately, this diverse regulatory network does not adequately provide oversight of the entire food supply chain. Food establishments are not inspected according to uniform standards (food regulatory systems can and do operate under different standards); data are not captured on a national basis; and available data are not systematically examined for potential outbreak signals. Also, the national response to outbreaks remains uneven. Many stakeholders have pointed out that the FDA does not take full advantage of the existing inspection and surveillance capabilities of state, territorial, tribal, and local regulatory and public health partners. This is largely due to the fact that state standards and laws differ from those in the federal system. Significantly, these differences contribute to a lack of interoperability and the ability to share data among partners.
The 2007 Food Protection Plan

In May of 2007, then Secretary of the Department of Health and Human Services (DHHS) Michael Leavitt tasked the FDA to develop a comprehensive and integrated Food Protection Plan to keep the nation’s food supply safe from both unintentional and deliberate contamination. By acknowledging the new challenges and global changes affecting the food supply chain, the Plan focused on utilizing advances in science and technology to safeguard the nation’s food supply against unintentional and deliberate contamination. Thus, the Plan was centered on a comprehensive and integrated strategy of prevention, intervention, and response. It attempted to concentrate efforts on preventing problems using risk-based interventions and the generation of a rapid response should an outbreak be detected.

Accordingly, the first of the Plan’s foci was prevention. On this issue, the Plan stated that preventive measures had to be developed from the start of domestic and international food production processes. The plan advocated for: (1) increasing corporate responsibility to prevent food-borne illnesses; (2) identifying food vulnerabilities and assessing risks; and (3) expanding the understanding and use of effective mitigation measures. In creating this objective, the FDA specified that it would continue to work with industry, state, local, and foreign governments to develop the tools and science needed to identify vulnerabilities and determine the most effective approaches.

The second component of the 2007 Food Protection Plan was intervention. Intervention follows when prevention measures fail or are not properly implemented. The core concept of intervention is the use of targeted, risk-based strategies to provide a second layer of protection in both domestic and imported food products. To accomplish this, the second component focused on: (1) utilizing risk to guide food system inspections and sampling; (2) enhancing risk-based surveillance; and (3) improving the detection of food system “signals” that indicate contamination.

The final part of the Plan involved improving the existing FDA response to foodborne outbreaks of disease. Acknowledging that the response time between detection and containment of an outbreak is critical, the FDA proposed faster response activities and more effective communication to consumers; industry; and federal, state, and international partners in order to reduce the impact of foodborne diseases. To accomplish this goal, the FDA specified two objectives: (1) improving immediate response, and (2) improving risk communication to the public, industry and other stakeholders.

Inherent in the Plan was the recognition that the FDA needed more resources to accomplish its goals. Thus, the Plan’s one-year update in 2008 noted that the FDA continues to work with Congress to ensure that the Agency has adequate resources to protect the safety of the U.S. food supply. The FY 2008 Supplemental Appropriation signed into law by President Bush provided $150 million for the FDA including $72 million for Food Protection.

Additionally, the FDA has been seeking specific legislative changes that would empower the agency to fulfill its mission to protect the nation’s food system. These legislative requests include:

- allow the FDA to require preventive controls against intentional adulteration at points of high vulnerability in the food chain;
- authorize the FDA to issue additional preventive controls for certain high-risk foods;
require food facilities to renew their FDA registrations at least every two years and allow the FDA to modify the current food product categories for purposes of registration;

- authorize the FDA to accredit highly-qualified third parties to conduct voluntary food inspections;
- require a new reinspection fee from facilities that fail to meet current Good Manufacturing Practice (GMP) requirements;
- empower the FDA to require electronic import certificates for shipments of designated high-risk products from countries with which FDA has reached agreement on a certification program based on a level of safety sufficient to meet FDA standards;
- allow the FDA to charge export certification fees for food and animal feed to improve the ability of U.S. firms to export their products;
- authorize the FDA to refuse admission of imported food if FDA inspection access is delayed, limited or denied;
- empower the FDA to issue a mandatory recall of food products if voluntary recalls are not effective; and
- give the FDA enhanced access to food records during emergencies.

While not much success has been accomplished on these specific requests, legislation has been proposed that would empower the FDA to better protect the nation’s food supply. With the change in Administration in 2008, the Food Protection Plan of 2007 has not been further implemented. However, many elements of this plan have carried over into the current Administration’s efforts on food safety.

THE PRESIDENT’S FOOD SAFETY WORK GROUP

In his March 14, 2009 weekly address, the President acknowledged his concerns about the number of problems affecting food that makes its way to our kitchen tables. He highlighted many of the problems that impede improving food safety in the United States, including the fact that many of the laws and regulations governing food safety in the U.S. have not been updated and that the nation’s “system of inspection and enforcement is spread out so widely among so many people that it’s difficult for different parts of our government to share information, work together, and solve problems.” Furthermore, the FDA has not been provided with the financial and human resources to carry out the job that it is tasked to do. In order to address these problems, the President formed a new multi-agency Food Safety Working Group (FSWG) to advise him on how to upgrade the U.S. food safety system.

The FSWG is chaired by Health and Human Services Secretary Kathleen Sebelius and Secretary of Agriculture Tom Vilsack. The FSWG also includes agencies such as the Food Safety and Inspection Service, the CDC, the Department of Homeland Security, the Department of Commerce, the Department of State, the Environmental Protection Agency, and several White House offices. The FSWG is charged with recommending how to upgrade U.S. food safety laws for the 21st century, foster coordination of food safety efforts throughout the government, and ensure laws are being adequately enforced to keep the food pipeline safe.

On July 7, 2009, the FSWG issued its key findings on how to upgrade the food safety system for the 21st century. It recommended a public-health-focused approach to food safety based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.
Prioritizing Prevention

Often, the food safety system is reacting to problems rather than preventing harm. The FSWG recommended that food regulators shift towards prioritizing prevention and implementing measures designed to prevent problems before they occur. In order for this to succeed, rigorous standards for food safety need to be established and regulatory agencies must be given the authority and the tools necessary to ensure that the food industry meets these standards.

Strengthening Surveillance and Enforcement

There is a need for improved data collection and analysis in order to guide agencies in identifying which foods are at risk, which solutions work best (and therefore should be implemented), and who should be responsible. The FSWG recommended that the federal government prioritize crucial inspection and enforcement activity across the world; support safety efforts by states, localities and businesses at home; and utilize data to guide these efforts and evaluate their outcomes.

Improving Response and Recovery

No prevention system will be 100% effective and outbreaks of foodborne illness will occur. In that event, outbreaks must be identified quickly and controlled. The FSWG recommended that a food tracing system be established that will help shorten the time between outbreak detection, resolution, and recovery.

THE FDA RESPONSE

While numerous federal agencies are involved with food safety, the FDA as the primary agency responsible for establishing enforceable standards (and in response to direction from the FSWG), has begun setting new food safety standards and reviewing existing standards with regard to prevention strategies. In addition, the FDA has begun to work with the food industry to establish quantitative metrics for the primary factors affecting food safety by incorporating appropriate measures of success. Additionally, quality control for all regulatory issues that govern food safety will be measured. These metrics will improve the agency’s ability to verify that certain measures or practices are being carried out and are effective.

It is clear that any process to enforce and verify that the food safety system is functioning to prevent outbreaks will require a systematic, integrated approach to effective risk control and enforcement strategies. The FDA is planning to implement an inspection and enforcement program to ensure high rates of compliance with its food safety standards. In order to ensure that the system is national and fully integrated, the FDA has indicated that the plan will engage federal, state, territorial, tribal, and local regulatory and public health partners. The system will encompass inspections, laboratory testing, and response and will place priority on preventing foodborne illness in both human and animal food through the adoption and uniform application of model programs and other appropriate program standards. The FDA expects such an approach will result in: (1) better assessment of the potential risk at domestic food facilities along with more consistent and frequent inspections across the entire food supply chain; (2) improved food surveillance through integration of food facility inspection and testing information; and (3) enhanced rapid response capacity and efficiency.

Under this program, the FDA and federal, state, territorial, tribal, and local regulatory agencies will conduct food facility inspections under the same set of standards. Uniform national standards including inspection, investigation, and testing protocols and training and certification
requirements will be developed via collaboration between the FDA and its regulatory partners. Enforcement of existing standards will be improved and new program standards that are needed to adequately protect the entire food supply chain will be developed. These standards will be important so that a uniform foundation exists for designing and managing federal, state, territorial, tribal, and local food programs that reflects the best practices of a high quality regulatory program. The program standards will incorporate the critical elements of a regulatory program designed to protect the public from foodborne illness. Program audit criteria will be created and new performance metrics will be developed to ensure program objectives are met. Such an integrated system will result in more coordinated response efforts to multi-state outbreaks when they occur.

A successful national food safety system will have to build upon the work currently being done by FDA and its regulatory and public health partners by improving active communication, coordination, and support. It must be built with continuous input from FDA’s regulatory and public health partners and sustained through resources that will be provided to state and local regulatory and public health partners. These resources will be needed to build the state and local infrastructures along with establishing adequate legislative authorities to facilitate information sharing and communication among all partners, including the infrastructure for a national electronic information-sharing mechanism. These actions will result in a national food safety system that reduces foodborne illness, identifies sources of risk throughout the system, and facilitates early detection and response to outbreaks. A public health driven, collaborative, and leveraged approach to food safety activities and responsibilities will improve public sector resource utilization at a national level and provide additional capacity for ensuring a safe and secure food supply.

The Transforming Food Safety Initiative

The Transforming Food Safety Initiative operationalizes the national food safety system developed by the FDA and described above. This initiative provides the budgetary support so that the FDA can set standards for safety, expand laboratory capacity, pilot the use of track and trace technology, strengthen the import safety program, improve data collection and risk analysis, and begin to establish an integrated national food safety system with strengthened inspection and response capacity. In order to implement this initiative, the FDA has proposed a $318 million increase over its current food safety budget in the President’s FY 2011 budget, representing a 30% increase in funding.

As part of the Transforming Food Safety Initiative, the following activities are set to begin in 2010.

Prioritizing Prevention

1. Set new standards for food safety. FDA will develop guidances and binding regulations to set the foundation for a prevention-oriented food safety system. New standards will include preventive controls, recordkeeping, requirements for identifying food facilities, and program standards for inspections and collecting and analyzing samples. The FDA also will develop standards for enforcement, response, and recovery for use by the agency and its regulatory partners in an integrated national system for food safety.

2. Establish an integrated national food safety system focused on prevention. The FDA will conduct audits of regulatory and public health partners that will include reviews of inspection, investigation, sample collection and analysis, enforcement, response, recovery, and outreach activities. The audits will measure performance against FDA food safety program standards.
Through the integrated system, the FDA will substantially increase food inspections and
enhance feed surveillance.

3. Establish a modern import safety program. The FDA will develop standards for evaluating
food safety systems in foreign countries, continue third-party certification efforts, and develop
a registry of all importers. FDA also will expand and strengthen efforts to leverage
information and build capacity with our trading partners. When fully implemented, this
program will hold imported and domestic foods to a common high standard of safety.

Strengthening Surveillance and Enforcement

1. Enhance surveillance capabilities via the integrated national food safety system. The FDA will
add state liaisons to provide program guidance and direction. State liaisons will facilitate
timely communication with our regulatory and public health partners. The FDA also will
develop and implement a national work plan for inspecting food manufacturing and
distribution facilities and for collecting and analyzing compliance, surveillance, and
environmental samples.

2. Enhance surveillance capacity as part of a modern import safety program. The FDA will
gather data and evaluate food safety systems in foreign countries and collect and analyze 3,000
additional import samples annually.

3. Improve risk analysis and research for food and feed safety. The FDA will expand its capacity
to identify products at highest risk for contamination. This will allow the FDA to better target
and prioritize food safety efforts and sampling and inspection priorities. In addition, the FDA
will: improve data collection for risk analysis and detecting food safety signals; enhance the
reportable food registry to help consumers report problems with foods; and expand the
National Antimicrobial Resistance Monitoring System (NARMS) surveillance and monitoring
to test additional high priority commodities, such as seafood and animal feeds. In partnership
with the CDC and USDA, the agency will adapt the NARMS platform to monitor emerging
pathogens in food animals and retail foods of animal origin in the United States.

4. Expand laboratory capacity and capability. The FDA will expand laboratory capacity and
establish a new mobile laboratory for remote, on-site testing. The agency also will increase its
capacity to analyze and assess patterns in test results and develop and deploy rapid tests to
identify food and environmental contamination.

5. Increase inspection capacity through the integrated national food safety system. The FDA will
hire 94 new food safety inspectors. When fully trained, new inspectors will conduct an
additional 1,978 domestic food inspections, 228 domestic tissue residue inspections, and 159
additional foreign food inspections annually. The FDA also will increase the safety of food
and animal feeds by funding increased state sampling of feeds and feed ingredients. Finally,
the FDA will begin to improve the efficiency of inspections and inspection analysis by
establishing a system to electronically exchange data between the states and the agency.

6. Increase inspection capacity through a modern import safety program. As part of an import
safety program, the FDA will conduct audits of foreign regulatory bodies and begin developing
an updated inventory of foreign facilities to support the increase in foreign inspections.
Improving Response and Recovery

1. Pursue pilot studies with industry using track and trace technology. The track and trace studies will guide the FDA as it develops food product tracing regulations that provide for rapid tracing without overly burdening industry.

2. Expand laboratory capacity and capability to enhance response and recovery. This investment focuses on developing technology to improve response, recovery, and overall efficiency in food testing laboratories. By developing this technology, the FDA will be able to identify and confirm chemical contaminants in food samples without any prior knowledge of the type of compound present. The technology also will allow the FDA to more rapidly subtype and serotype priority pathogens. When fully deployed, this technology holds the promise of reducing the time to conduct these pathogen screening analyses to one or two days, compared with the current five to ten day timeframe.

Other Actions in Support of the Initiative

In order to support the efforts proposed above, the initiative also proposes information technology (IT) improvements. In particular, the FDA will invest in enterprise information technology and IT systems to establish, support, and maintain the systems necessary to collect Food Registration and Inspection User Fees. Additionally, the FDA has begun a multi-year effort to modernize its enterprise-wide IT infrastructure, which includes IT systems to improve food safety. The IT investment will ensure that the FDA can maintain an interoperable system to share regulatory data across their food programs and will support their ability to enhance nearly every aspect of food safety operations and regulatory activity.

In addition to enterprise IT investments, the “Transforming Food Safety Initiative” includes resources to ensure that the food program offices receive the support necessary to achieve the proposed public health outcomes. Support activities include finance and budgeting, human resource assistance, legal counsel, communications, ethics, headquarters coordination, and other related support functions.

THE IMPORTANCE OF REPORTING FOODBORNE ILLNESSES

Physicians play a critical role in the initial diagnosis of foodborne illnesses. Often, a physician is the first health care professional to see a case of foodborne illness that may turn out to be the sentinel case in the region, if not the country. For this reason, physicians are encouraged to remain up-to-date on the diagnosis and management of foodborne illnesses in order to recognize and report such cases when they present for evaluation. In fact, most foodborne illnesses are reportable diseases in the United States. The AMA has been leading the education of physicians on foodborne illnesses since 1998 when the first edition of “Diagnosis and Management of Foodborne Illnesses: A Primer for Physicians and Other Healthcare Professionals” was released. The most recent edition is available on the AMA Web site at: www.ama-assn.org/go/foodborne. An updated interactive Web edition is currently under development and will eventually be available on the same Web site.

CONCLUSIONS

Physicians have long recognized and acknowledged existing gaps and barriers to improving the food safety system in the United States. While the country’s food remains one of the safest in the world, these gaps have resulted in foodborne illness outbreaks and difficulty in gathering the data
to investigate and coordinate the response to the outbreaks. To address these problems, the
President established the FSWG, which in July 2009 proposed a national integrated food safety
system with a public health-focused approach to food safety based on three core principles:
prioritizing prevention, strengthening surveillance and enforcement, and improving response and
recovery. The resulting “Transforming Food Safety Initiative” operationalizes the
recommendations of the FSWG and proposes a budgetary increase in the FY 2011 budget to fund
these improvements to the food safety system.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted,
and that the remainder of this report be filed:

1. That our American Medical Association (AMA) support regulatory and legislative changes
that will empower the Food and Drug Administration (FDA) to implement its
“Transforming Food Safety Initiative” built upon the three core principles of: (1)
prioritizing prevention; (2) strengthening surveillance and enforcement; and (3) improving
response and recovery. (New HOD Policy)

2. That our AMA monitor the implementation of the “Transforming Food Safety Initiative,”
and provide feedback to the FDA as necessary. (Directive To Take Action)

3. That our AMA urge physicians to remain informed on the diagnosis and management of
foodborne illnesses and to report suspected cases of foodborne illnesses to their local
public health authority. (New HOD Policy)


Fiscal Note: Less than $500.
REFERENCES


estimates for Appropriations Committees.  

14. United States Food and Drug Administration. FDA requests $4.03 Billion to transform food 
safety system, invest in medical product safety, regulatory science.  