

Keeping America's Food Safe:

A BLUEPRINT FOR FIXING THE FOOD SAFETY SYSTEM AT THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Robert Wood Johnson Foundation

MARCH 2009

PREVENTING EPIDEMICS.
PROTECTING PEOPLE.

TRUST FOR AMERICA'S HEALTH
IS A NON-PROFIT, NON-PARTISAN
ORGANIZATION DEDICATED TO
SAVING LIVES AND MAKING
DISEASE PREVENTION A
NATIONAL PRIORITY.

The Robert Wood Johnson Foundation focuses on the pressing health and health care issues facing our country. As the nation's largest philanthropy devoted exclusively to improving the health and health care of all Americans, the Foundation works with a diverse group of organizations and individuals to identify solutions and achieve comprehensive, meaningful and timely change. For more than 35 years the Foundation has brought experience, commitment, and a rigorous, balanced approach to the problems that affect the health and health care of those it serves. Helping Americans lead healthier lives and get the care they need—the Foundation expects to make a difference in our lifetime. For more information, visit www.rwjf.org.

TFAH BOARD OF DIRECTORS

Lowell Weicker, Jr.

President
*Former 3-term U.S. Senator and
Governor of Connecticut*

Cynthia M. Harris, PhD, DABT

Vice President
*Director and Associate Professor
Institute of Public Health, Florida
A&M University*

Patricia Baumann, MS, JD

Treasurer
*President and CEO
Bauman Foundation*

Gail Christopher, DN

*Vice President for Health
WK Kellogg Foundation*

John W. Everets

David Fleming, MD

*Director of Public Health
Seattle King County, Washington*

Arthur Garson, Jr., MD, MPH

*Executive Vice President and Provost and
the Robert C. Taylor Professor of Health
Science and Public Policy
University of Virginia*

Robert T. Harris, MD

*Former Chief Medical Officer and Senior
Vice President for Healthcare
BlueCross BlueShield of North Carolina*

Alonzo Plough, MA, MPH, PhD

*Director, Emergency Preparedness and Re-
sponse Program
Los Angeles County Department of
Public Health*

Theodore Spencer

*Project Manager
Natural Resources Defense Council*

REPORT AUTHORS

Jeffrey Levi, PhD.

*Executive Director
Trust for America's Health
and
Associate Professor in the Department
of Health Policy
The George Washington University
School of Public Health and Health
Services*

Laura M. Segal, MA

*Director of Public Affairs
Trust for America's Health*

Serena Vinter, MHS

*Senior Research Associate
Trust for America's Health*

REPORT CONSULTANT

Michael R. Taylor, JD

*Research Professor of Health Policy
School of Public Health
The George Washington University
Former Deputy Commissioner for Policy
U.S. Food and Drug Administration
Former Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture*

ACKNOWLEDGEMENTS

This report is supported by a grant from the Robert Wood Johnson Foundation. The opinions expressed in this report are those of the authors and do not necessarily reflect the views of the foundation.

Introduction

“ TO SAY THAT FOOD SAFETY IN THIS COUNTRY IS A PATCHWORK SYSTEM IS GIVING IT TOO MUCH CREDIT. FOOD SAFETY IN AMERICA HAS BECOME A HIT-OR-MISS GAMBLE, AND THAT IS TRULY FRIGHTENING. IT’S TIME TO FIND THE GAPS IN THE SYSTEM AND REMEDY THEM. ”

-- SEN. TOM HARKIN (D-IA), CHAIRMAN OF THE SENATE COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY¹

“ WHETHER PRODUCED DOMESTICALLY OR IMPORTED, AMERICANS MUST BE ABLE TO TRUST THAT THE FOOD SOLD IN THEIR GROCERY STORES AND RESTAURANTS IS SAFE. IT IS CRITICAL TO ENSURE THAT THE FOOD AND DRUG ADMINISTRATION HAS THE TOOLS IT NEEDS TO PROPERLY MONITOR AND INSPECT THE FOOD THAT IS CONSUMED IN THIS COUNTRY. ”

-- SEN. SAXBY CHAMBLISS (R-GA), RANKING REPUBLICAN ON THE SENATE AGRICULTURE COMMITTEE²

The U.S. food safety system is in crisis. The recent *Salmonella* contamination of peanut butter products and jalapeño and Serrano peppers, *E. coli* outbreaks in spinach and lettuce, and reports about cattle slaughter practices and the safety of farm-raised fish in China have all heightened anxieties about the vulnerability of the nation’s food supply.^{3,4}

Approximately 76 million Americans – one in four – are sickened by foodborne disease each year. Of these, an estimated 325,000 are hospitalized and 5,000 die.⁵ According to the World Health Organization (WHO), foodborne illnesses include “...diseases, usually either infectious or toxic in nature, caused by agents that enter the body through the ingestion of food.”⁶

Foodborne diseases caused by major pathogens alone are estimated to cost up to \$44 billion annually in medical costs and lost productivity.^{7,8} Major outbreaks can also contribute to significant economic losses in the agriculture and food retail industries, which account for approximately 13 percent of the U.S. gross domestic product (GDP)

and are the largest industries and employers in the United States.⁹ Americans spend more than \$1 trillion on food annually.

A November 2008 public opinion poll conducted by the Consumer Reports National Research Center found that 83 percent of Americans are very concerned or concerned about food safety, particularly the contamination of food with harmful pathogens, and 81 percent of Americans are very concerned or concerned about the safety of imported foods.¹⁰

Studies from the National Academy of Sciences (NAS), the Institute of Medicine (IOM), the U.S. Government Accountability Office (GAO), and the U.S. Food and Drug Administration (FDA) Science Board, which serves as an advi-

sory committee to FDA, have all raised serious concerns about the system that is responsible for keeping the country's food safe.^{11, 12, 13, 14}

These reports describe how the current system is fractionalized and focuses on antiquated threats instead of taking a strategic approach to protecting the nation's food

supply through state-of-the-art technologies, practices, and policies.

Yet despite all these challenges, experts estimate that most foodborne illnesses could be prevented if the right measures were taken to improve the U.S. food safety system.

Top concerns that experts have identified include:

■ Outdated Laws and Policies

- ▲ Current laws and policies are disproportionately focused on monitoring the end of production, instead of trying to detect and prevent problems throughout the entire production process.
- ▲ No federal agency has statutory authority or a practical mandate to forge an integrated strategy that puts the research, regulatory, and educational tools of government to work in a coherent way to minimize risks.
- ▲ The U.S. food safety system has not been fundamentally modernized since its inception over 100 years ago. Current food safety policies are largely based on early 20th-century laws written to deal with concerns that rarely pose significant threats today because of changes in farming and processing practices and technologies.¹⁵
- ▲ FDA has limited legal tools for enforcing prevention-oriented food safety standards (detecting and preventing outbreaks throughout the entire production process).

■ Inadequate Federal Leadership, Coordination, and Resources

- ▲ No federal agency has ultimate authority or responsibility. No one person in the federal government has the oversight and is held accountable for carrying out comprehensive, preventive strategies for reducing foodborne illnesses.
- ▲ Without clear leadership or authority, there is no systemic ability to set risk-based priorities and deploy resources.

- ▲ Food safety agencies are underfunded and understaffed for dealing with the range and scope of modern food safety threats.
- ▲ There is limited federal, state, and local coordination and only voluntary uniform standards.

Many food safety advocates believe the long-term goal should be to consolidate and align all federal food safety functions into a single agency to increase effectiveness, responsibility, and accountability. Currently, according to a 2007 GAO report, “the federal oversight of food safety is fragmented, with 15 agencies collectively administering at least 30 laws related to food safety.”¹⁶ The GAO has called for a “fundamental re-examination of the federal food safety system.”¹⁷

However, most experts recognize that changing the entire system would likely be “extremely difficult, time-consuming, and highly controversial” since the major functions span across three different agencies – the U.S. Department of Health and Human Services (HHS), the U.S. Department of Agriculture (USDA), and the U.S. Environmental Protection Agency (EPA). All of these agencies have different authorities, responsibilities, and cultures.¹⁸

There are a number of advocates who proposed more immediate potential solutions by focusing on strategically reorganizing the existing system. One way to do this is to start by addressing the food safety functions within HHS first. This report examines the existing programs at HHS and examines ways to strategically restructure the agencies at HHS to better protect the nation's food supply.

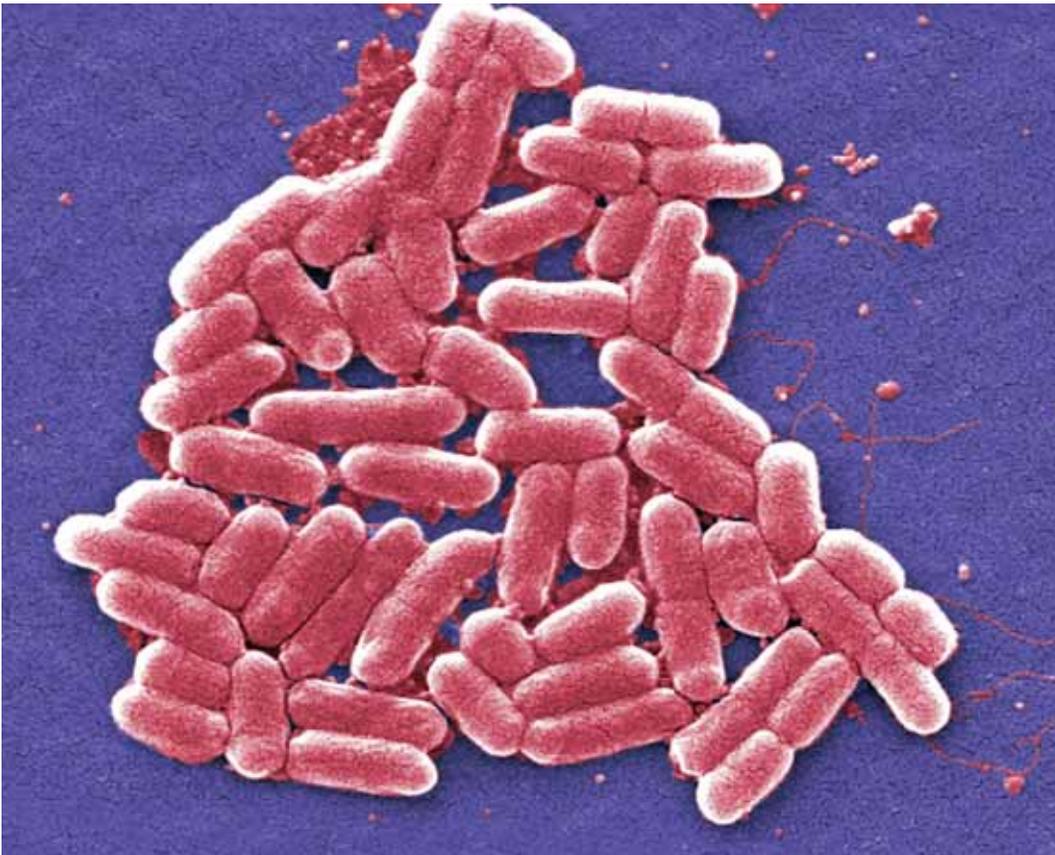
I. FOOD SAFETY PROGRAMS AT HHS: THE CURRENT STRUCTURE

Agencies within HHS are responsible for a significant majority of the federal food safety functions. The FDA regulates numerous aspects of the food system, including millions of food producers, processors, transporters, storage facilities, and grocery stores and restaurants. It regulates 80 percent of the nation's food supply, including \$417 billion

worth of domestic food and \$49 billion in imported food annually.¹⁹ Experts estimate the vast majority of known foodborne illness outbreaks are associated with products regulated by FDA. The U.S. Centers for Disease Control and Prevention (CDC), also part of HHS, is responsible for detecting and tracking foodborne disease outbreaks.

MAJOR FOOD SAFETY RESPONSIBILITIES AT HHS

- FDA includes three major food safety divisions, including:
 - ▲ The **Center for Food Safety and Applied Nutrition (CFSAN)**, which has the responsibility for overseeing the safety of all domestic and imported foods with the exceptions of meat, poultry, and frozen, dried, and liquid eggs, which are under the authority of USDA's Food Safety and Inspection Service (FSIS).
 - ▲ The **Center for Veterinary Medicine (CVM)**, which makes food safety policy for animal drug and antibiotic residues, animal feed, pet foods, and cloned and genetically engineered animals.
 - ▲ The **Office of Regulatory Affairs (ORA)**, which is the field organization for FDA that conducts food inspections, oversees imported food, manages food testing laboratories, develops enforcement cases, and manages the majority of FDA's food safety resources.
- At CDC, the **Office of Food Safety** is responsible for surveillance and identification of foodborne illness outbreaks.



RECENT FOODBORNE DISEASE OUTBREAKS IN PRODUCTS REGULATED BY FDA

- August and September 2006: *E. coli* in bagged spinach sickens 199 people in 26 states, killing three.²⁰ Growers in California, where the majority of U.S. spinach and lettuce is grown, estimate losses to be as high as \$200 million.²¹
- September 2006: Tomatoes contaminated with *Salmonella* cause 183 cases of illness in 21 states.²²
- November and December 2006: Spring onions contaminated with *E. coli* served at Taco Bell restaurants in the northeast United States sicken 71 people.²³
- February 2007: *Salmonella* in Peter Pan peanut butter causes 425 illnesses in 44 states.²⁴ ConAgra estimated that its recall of Peter Pan and Great Value peanut butter cost \$50 to \$60 million.²⁵
- February and March 2007: FDA receives more than 17,000 consumer complaints about tainted pet food, including the deaths of 1,950 cats and 2,200 dogs. Melamine-contaminated pet food imported from China is to blame for the deaths and illnesses among pets; 60 million packages of nearly 100 brands of pet food are recalled.²⁶
- June 2007: Veggie Booty snacks contaminated with *Salmonella* sicken 65 people in 20 states.²⁷
- January 2008: A produce handler at a grocery store in Buffalo, N.Y., is diagnosed with hepatitis A. As a precaution, county health officials issue a warning to anyone who may have purchased and consumed certain kinds of produce from the store in the prior three-week period. Health officials vaccinate more than 8,300 people over a five-day period at a cost of some \$500,000.²⁸
- April 2008: Imported cantaloupes from Honduras contaminated with *Salmonella* sicken 60 people in 16 states and Canada; at least 16 are hospitalized.²⁹
- June 2008: *Salmonella* found in jalapeño and Serrano peppers sickens 1,442 people in 43 states, the District of Columbia, and Canada. At least 286 persons are hospitalized, and the infection may have contributed to two deaths.³⁰ Prior to the identification of peppers as the vehicle of the outbreak, food safety officials had warned Americans to avoid raw red round, red Roma, and red plum tomatoes, leading tomato growers to post losses upwards of \$100 million in sales during the investigation.³¹
- September 2008: Melamine-contaminated infant formula and related dairy products produced in China are found in countries across the globe. FDA issues an advisory that warns members of Asian communities in the United States that infant formula manufactured in China and imported illegally into the United States could pose a risk to infants.³²
- January 2009: Peanut butter and peanut butter products contaminated with *Salmonella* sicken more than 690 people in 46 states. More than one-fifth of those infected are hospitalized and the infection may have contributed to nine deaths.³³ FDA recalls more than 2,700 peanut butter products from store shelves across the country.

2 CURRENT HHS FOOD SAFETY FUNCTIONS DO NOT MEET TODAY'S THREATS

“ WHEN WE LOOK AT RECENT HEADLINES, IT IS HARD NOT TO SEE A FOOD SAFETY SYSTEM IN CRISIS, A DYSFUNCTIONAL FEDERAL AGENCY AND THE FDA UNABLE TO PERFORM ITS MISSION AND TO PROTECT THE AMERICAN PEOPLE. ”

-- REP. ROSA DELAURO (D-CT), CHAIRWOMAN OF THE HOUSE APPROPRIATIONS SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FDA, AND RELATED AGENCIES³⁴

Key problems with the food safety functions at HHS include:

■ **Inadequate leadership, prioritization, and coordination.** FDA commissioners and staff are responsible for regulating food, drugs, and medical devices. *There is no single official at FDA whose full-time job is food safety and who has line authority over all elements of FDA's food safety program.*

▲ Top FDA managers usually focus on drugs and medical devices. They often only get involved in food safety during crises, such as major disease outbreaks.

▲ The main FDA offices that have a focus on food safety – CFSAN, CVM, and ORA – are managed separately and have their own priorities. The directors of these three offices report to the FDA commissioner, although responsibility for coordinating FDA's strategy for improving food safety rests with an associate commissioner for foods who has no line management or budget authority over CFSAN, CVM, or ORA.

▲ Detection and surveillance functions are housed at CDC and are not well-coordinated with FDA's regulatory functions; there is little connection between monitoring threats and outbreaks and how food is regulated and inspected.

■ **Inadequate staffing and resources.** A 2008 report by the FDA Science Board's Subcommittee on Science and Technology found that continual underfunding of FDA has forced the agency to severely curtail food inspections (a 78 percent reduc-

tion over 35 years) at a time when the number of food producers has grown exponentially at home and abroad.

▲ According to the subcommittee, the continual underfunding of food safety activities has exposed Americans to increasing risk from both imported and domestically produced foods. The subcommittee has urged Congress to increase the food safety funding base by \$755 million over five years (2009-2013), including \$350 million to strengthen food import safety and \$100 million to strengthen federal food safety oversight of nutritional supplements and animal feed.³⁵

▲ Between 2003 and 2007, the main food safety function at FDA lost 20 percent of its science staff and 600 inspectors.³⁶ According to GAO, the turnover rate in FDA science staff is twice that of other government agencies.³⁷ FDA's food program received \$542 million in FY 2009; the total FDA budget for FY 2009 was estimated at \$2.399 billion. More than half of the total food-related dollars and staff time at FDA is managed by the regulatory affairs staff, without line accountability to the directors of CFSAN and CVM, whose programs the field resources are intended to support.

■ **Inadequate hazard detection throughout the production process.** The system has too few inspection points and resources. The inspections that are conducted concentrate primarily on products after they have already been produced. FDA does not have a good system in place for regulating prod-

ucts through the entire production process. Food can become contaminated at multiple points during production.

■ **Inadequate modernization.** Current statutes that provide the foundation for FDA's food safety functions date back to 1906 and 1938. FDA's laws were drafted to respond to problems prevalent in an early 20th-century agricultural and food system. These laws empower FDA to act primarily only after food safety problems occur, rather than to act to prevent them. The technology and practices for producing food is changing rapidly. The food inspection and regulation procedures are out of date and have not kept pace with scientific advancements, such as biotechnology and high-tech packaging, or with changes in consumer culture, such as an increased interest in ready-to-eat meals and increased frequency in eating out at restaurants. FDA is permitted to inspect pro-

cessing plants and warehouses and remove harmful or potentially harmful food from the market through court enforcement action, and to block imports if it detects potential problems, but it is not structured or funded to ensure prevention is built in throughout the entire production process.

■ **Inadequate inspection of imports.** Only one percent of imported foods are inspected. According to USDA's Economic Research Service, approximately 15 percent of the nation's food supply is imported,³⁸ including approximately 60 percent of the fresh fruits and vegetables and 75 percent of the seafood Americans consume.^{39, 40}

■ **Inadequate standards.** There is limited coordination of food safety programs among federal, state, and local agencies, and states and localities are not required to meet uniform national standards for food inspections.

INADEQUATE COORDINATION WITH STATE AND LOCAL FOOD AGENCIES

The food safety system is a network of national, state, and local agencies. The current decentralized governmental food safety system means state and local governments currently have jurisdiction for food safety issues in their communities beyond those that are directly regulated and monitored by federal agencies. In lieu of official required national standards, two voluntary efforts have been developed to try to create more uniform standards and practices as well as enhancing the efficiency and effectiveness of the nation's food safety system: the FDA's Food Code and a Voluntary National Retail Food Regulatory Program.

3. THE BENEFITS OF ALIGNING FOOD SAFETY FUNCTIONS AT HHS

Bringing the food safety functions at HHS together under one agency would provide HHS with an organizational structure and operational capacity to implement a science- and risk-based food safety program that is effective in preventing foodborne illness. This would improve the HHS food safety program in a number of ways, including:

■ **Identifying and responding to threats and outbreaks quickly and efficiently.** To better protect the food supply, officials need data and analysis of outbreaks and the causes of foodborne illnesses, as well as in-

formation about chemical and microbiological contaminants. A unified food safety agency at HHS would result in an integrated, systems approach that coordinates the functions at CDC, FDA, and private research organizations to help prevent, detect, and contain threats.

■ **Setting and enforcing science-based, prevention-oriented food safety standards.** The food industry takes many measures to ensure that the food it produces is safe, but the government has the responsibility for establishing and regulating the standard of care

the industry must meet in preventing food safety problems and minimizing potential exposure to particular hazards. A unified food safety agency within HHS could have the stature and ability to set sound standards and deploy its inspection and enforcement resources strategically and flexibly to achieve a high level of compliance and maximum public health protection.

■ **Responding effectively to food safety crises.** When multi-state outbreaks of food-borne illness occur or major food contamination problems are discovered, a separate, unified food agency at HHS could provide clear, strong leadership, and bring together the CDC and FDA, and work with USDA, EPA, state and local agencies, and foreign governments. Having a single food safety leader within HHS would result in clear lines of responsibility and authority within government and clear and coherent communication with the public.

■ **Provide food safety leadership nationally and internationally.** A unified agency at HHS could serve as a national and international food safety leader. It could take responsibility for improving the integration of the federal-state-local food safety

system, promoting the industry's adoption of food safety best practices, and enhancing food safety standards and practices among foreign governments and foreign suppliers of food to the U.S. market.

In addition to strengthening the HHS food safety program, this new structure also would benefit FDA's medical products side. FDA's three medical product centers oversee a very large medical products industry in the United States. This industry is also globalizing rapidly and harnessing new technologies, thus presenting new opportunities and new challenges for the health system and patients alike. As with the food program, the medical product programs should have full-time leadership at a level that can both drive needed internal change on such issues as drug safety and post-market oversight of medical products, and represent FDA effectively in the coming health care reform debate.

Furthermore, Congress is currently considering a tobacco regulation bill that would place a major new regulatory program within FDA. If this change occurs, placing FDA's food program under separate management would allow for more focus on food safety responsibilities and issues.

“THE TRAGEDIES ARE PREVENTABLE IF WE HAVE THE WILL TO FIX THE SYSTEM. AND TO TRULY FIX THE SYSTEMIC PROBLEMS IN OUR FOOD SAFETY SYSTEM, WE MUST FUNDAMENTALLY RESTRUCTURE THE FOOD SAFETY BUREAUCRACY AT THE FDA.”

-- REP. ROSA DELAURO⁴¹

“AMERICANS SPEND MORE THAN \$1 TRILLION ON FOOD EACH YEAR -- WHEN FAMILIES GO TO THE LOCAL RESTAURANT OR TO THE GROCERY STORE, OR WHEN CHILDREN GO TO SCHOOL, THEY SHOULDN'T HAVE TO WORRY ABOUT WHETHER OR NOT THEY WILL BECOME ILL FROM THE FOOD THEY EAT. RECENT OUTBREAKS OF FOOD-BORNE ILLNESS AND NATIONWIDE RECALLS OF CONTAMINATED FOOD FROM BOTH DOMESTIC AND FOREIGN SOURCES HIGHLIGHT THE NEED FOR CONGRESS TO ACT TO MODERNIZE AND STRENGTHEN OUR NATION'S FOOD SAFETY LAWS.”

-- SEN. JUDD GREGG (R-NH)⁴²

4. BACKGROUND ON REFORM EFFORTS

“ THE NEAR UNANIMITY ABOUT THE AGENCY’S WEAKNESSES -- AMONG CONGRESSIONAL DEMOCRATS AND REPUBLICANS, INDUSTRY AND CONSUMER GROUPS, AND AUTHORITATIVE INDEPENDENT ANALYSTS -- IS STRIKING. BUT HAND WRINGING IS NOT ENOUGH. THE FDA DESPERATELY NEEDS AN INFUSION OF MONEY AND TALENT. ”⁴³

-- THE NEW YORK TIMES, EDITORIAL, FEB. 3, 2008

“ WE NEED A SINGLE AGENCY THAT’S WORKING IN A MODERN FRAMEWORK. WE DON’T HAVE THAT TODAY. ”⁴⁴

-- U.S. AGRICULTURE SECRETARY TOM VILSACK

“ CONGRESS MUST IMPROVE FDA AND BRING IT INTO THE 21ST CENTURY SO THAT AMERICANS CAN MAKE SAFE AND HEALTHY FOOD CHOICES AT GROCERY STORES, MARKETS, AND RESTAURANTS. ”⁴⁵

-- SEN. RICHARD BURR (R-NC)

Over the years, Congress and other government watchdogs, including GAO and FDA itself, have issued calls for reform. Back in 1977,

Legislative Proposals

In the 110th Congress, more than 80 pieces of legislation related to food safety were introduced and dozens of Congressional hearings were held on the topic of food safety. A number of bills have already been introduced in the 111th Congress.

For instance, the Food Safety Modernization Act, introduced by Rep. Rosa DeLauro (D-CT), would both modernize the food safety law under which the current FDA program operates and create within HHS a new Food Safety Administration (FSA) to implement the law. FSA would include all food-related functions and resources now housed within FDA. The proposed FSA would report directly to the HHS secretary. This bill focuses on enhancing and improving food safety functions within HHS.

The FDA Food Safety Modernization Act, sponsored by Sen. Richard Durbin (D-IL), Sen. Judd Gregg (R-NH), Sen. Richard Burr (R-NC), Sen. Edward Kennedy (D-MA), and Sen.

the U.S. Senate Committee on Governmental Affairs recommended combining the food safety inspection services of HHS and USDA.⁴⁶

Saxby Chambliss (R-GA) would require more preventive controls and performance standards, and give the HHS secretary additional authority to regulate food, including suspending the registration of a food facility and the power to request voluntary recalls of contaminated or suspect food products. Currently, FDA only has the power to work with the food industry to voluntary recall contaminated or suspect food products. The proposed FDA Globalization Act, sponsored by Rep. John Dingell (D-MI), includes language that would impose user fees for food facilities based on costs to defray implementation of the bill, and incorporate hazard analysis into a facility’s food plan. This bill also would set safety standards for produce; mandate the traceability of foods; provide FDA with access to records; and give the agency mandatory recall authority.

Another bipartisan proposal is the Safe FEAST Act (Safe Food Enforcement, Assessment, Stan-

dards and Targeting Act), introduced by Rep. Jim Costa (D-CA) and Rep. Adam Putnam (R-FL). This bill requires food facilities to take steps regarding hazard evaluation and implementation of risk-based preventive controls and re-

Internal Attempts at Reform

FDA and FDA's Science Board, an advisory board to the agency, have both released recommendations for ways to improve food safety activities within FDA. In November 2007, FDA released its own plan to strengthen and update its food safety system. FDA's "Food Protection Plan" stresses the need to realign roles and responsibilities within the agency and for legislative action.⁴⁷ The 10 recommended legislative changes include authorizing the agency to require food facilities to renew their FDA registrations every two years, which the agency argues will allow for superior prevention, and empowering the agency to issue mandatory recalls of contaminated products when voluntary recalls fall short. GAO has called the Food Protection Plan an important step forward in articulating a framework for improving food safety. However, GAO criticized FDA for failing to outline what the "...overall resource need is for implementing the plan, which could be significant."⁴⁸

Also in November 2007, the FDA Science Board issued a report, "FDA Science and Mis-

quires the HHS secretary to establish minimum standards for implementation of those requirements. It includes mandatory recall authority. U.S. importers must also ensure compliance of foreign facilities with U.S. safety standards.

sion at Risk," warning that the agency does not have the capacity to ensure the nation's food safety. The report underscored many reasons for the crisis at FDA, including a dramatic increase in and diversification of food safety responsibilities; increasing complexity due to globalization and lack of cross-sector coordination; increased scientific demands as technology and science change; and, finally, inadequate resources. The report recommended that FDA leverage other resource programs to handle some of the increased scientific demands and make agency-wide changes in staffing and science administration. A follow-up report presented to Congress estimated that in order to implement these recommendations and improve FDA's food safety oversight, the agency would need to increase its budget by an additional \$755 million by fiscal year 2013, phased in over five years.⁴⁹ In 2008, Congress provided an additional \$150 million to FDA in emergency supplemental funding, of which \$72.9 million was to improve food safety functions.

External Calls for Reform

A number of independent organizations, including GAO, IOM, and NAS, have all issued reports and recommendations for improving food safety oversight within FDA. GAO has issued a series of reports on federal food safety programs over the past decade. In 1998, GAO highlighted the limitations in FDA's authority and the agency's need to more effectively target its limited resources. "A decade later, the story remains the same and has only taken on a greater sense of urgency due to changing demographics and consumption patterns that, according to FDA, have put more of the U.S. population at risk of contracting foodborne illness."⁵⁰ According to GAO, it has made a total of 34 food safety related recommendations to FDA since

2004; however, as of May 2008, FDA had implemented only seven of these recommendations.⁵¹

Most recently, in December 2008, IOM issued "HHS in the 21st Century: Charting a New Course for a Healthier America," which called the problems with the U.S. food safety system "...a public health issue that HHS cannot address adequately within its current structure," and added that some reorganization "...would be both logical and advantageous, despite the difficulties."⁵² The IOM report recommended unifying the food safety responsibilities of FDA and FSIS under one agency housed within HHS, which it deemed "...the most appropriate locus for comprehensive regulation."⁵³

FIGURE 2: Proposed Food Safety Administration (FSA) Organizational Chart



A MODERNIZED FOOD SAFETY AGENCY

A streamlined, coordinated FSA would result in:

- **An Integrated and Accountable Senior Leadership.** The FSA administrator would bear ultimate responsibility for the management and success of the food safety program, but the management structure should include an FSA Leadership Council that places the headquarters and field operating units on an equal footing and unites them as members of the agency's senior leadership. FSA would be a deliberative body responsible for strategic planning, setting agency-wide priorities, and resource allocation.
- **An Integrated Public Health and Science Function.** The proposed structure would consolidate in one unit the scientific divisions of CFSAN and CVM to form an integrated, farm-to-table scientific capacity. This would include a new epidemiology unit staffed with professional epidemiologists who would

support FSA's priority-setting and prevention initiatives and build an active partnership with CDC to develop human illness data and perform the analyses needed for prevention.

- **An Integrated Compliance and Enforcement Program.** The proposed structure consolidates the compliance and enforcement elements of CFSAN, CVM and related ORA units and resources into a single operating unit. This unit would work in collaboration with the Leadership Council to design and implement data collection, inspection, and enforcement programs to achieve compliance with prevention-oriented food safety standards. This change would enable the field force to function as an integral, flexible component of the public health prevention program and would strengthen enforcement by streamlining the case review process.

POTENTIAL STRUCTURE FOR A UNIFIED FOOD SAFETY ADMINISTRATION AT HHS

Centers and offices at FDA that would move to the new FSA include:

- **Center for Food Safety and Applied Nutrition (CFSAN)**, the headquarters unit that makes most food safety policy for FDA, houses most of the relevant scientific capacity (except food testing capacity), and manages pre-market oversight of food and color additives, infant formula, and nutrient claims.
- **Center for Veterinary Medicine (CVM)**, the headquarters unit that makes food safety policy for animal drug and antibiotic residues, animal feeds, pet foods, and cloned and genetically engineered animals.
- **Office of Regulatory Affairs (ORA)**, the field organization for FDA that conducts food inspections, oversees imported food, manages food testing laboratories, develops enforcement cases, and manages the majority of FDA's food safety resources.
- **National Center for Toxicological Research (NCTR)**, a research unit in FDA that develops methods for detecting, assessing, managing, and preventing contamination and other threats to the food supply.

The new FSA could also have offices set up to handle certain food-related functions and resources currently handled by the Office of the FDA Commissioner. These staff resources include:

- **Office of Food Protection**, a relatively new unit that serves as liaison to HHS on food protection issues, and is charged with developing and implementing the FDA Food Protection Plan, an agency-wide strategy for domestic and imported food protection.

- **Office of Policy**, which develops and coordinates the review and analysis of broad agency policy, ensures consistency in the development and content of policy, and ensures that regulations and other agency documents published in the Federal Register meet applicable requirements.
- **Office of Chief Counsel**, a legal office that handles both civil and criminal cases involving the agency, provides legal advice and policy guidance for agency programs, and participates in rulemaking proceedings, legislative matters, policy deliberations, and international negotiations on agency-related matters.
- **Office of Operations**, an administrative management office that includes information technology (IT) functions as well as a crisis staff.
- **Office of International and Special Programs**, a staff office that coordinates FDA's international activities.
- **Office of Scientific and Medical Programs**, a staff office that includes oversight of scientific capacity-building and liaison with the scientific community.
- **Office of Legislation**, an office that drafts congressional testimony, responds to congressional inquiries, and assists in the development of agency-related legislation.
- **Office of Public Affairs**, a communications office that interfaces with the media on FSA-related issues.



SOME MAJOR CHALLENGES TO RESTRUCTURING

- **Structure of the Field Program.** One of the most challenging set of design issues concerns the FSA field program. This includes unifying the compliance and enforcement policy processes that now exist in separate FDA headquarters and field units, and determining how FSA field units should interact with the field units of the medical products agency. There is a strong case that each of the food and medical products agencies should have a dedicated, specialized inspection force, but there may be opportunities for shared services with respect to offices and laboratories, as well as the sharing of staff to meet surge capacity needs in emergencies.
- **Achieving Headquarters Efficiencies.** FDA currently achieves administrative efficiencies through the centralization at the agency or HHS level of many of the support services that CFSAN, CVM, and ORA need to operate, including financial management and payroll, procurement, facilities management, and human resources. Shared service mechanisms would be needed to maintain these efficiencies. Information technology (IT), on the other hand, is an “overhead” function that is so integral to managing a risk-based, prevention-oriented food safety program that FSA would need an in-house IT leadership capacity (a chief information officer) to be part of the FSA management team and work with the FSA Leadership Council to help build the needed information systems. This would not necessarily preclude having the procurement and other support services associated with IT systems being provided on the shared services basis outlined above.
- **The FSA Relationship with CDC.** CDC has traditionally maintained food safety epidemiology functions independently. The proposed structure does not recommend shifting CDC’s functions to FDA, but instead envisions an active partnership with CDC through FSA’s Public Health and Science Unit. To work, such a partnership requires a funding mechanism through which FSA and CDC could enter into “reimbursable agreements” under which CDC would receive FSA funds to provide the specific data and analysis FSA needs to do its job. This would put more resources into the badly underfunded food safety program at CDC, and it would create a contractual, client-service provider relationship in which FSA’s information needs and CDC’s accountability for meeting them would be clear.
- ▲ **Implementation Planning.** A careful implementation plan and process is essential to minimizing the cost and disruption entailed in any major reorganization and to ensure the long-term success of FSA. Many lessons have been learned from past efforts at organizational change in both the public and private sectors.⁵⁴ To successfully transition to a new food safety agency in HHS, it is particularly important to:
 - ▲ **Fully engage employees and stakeholders** to benefit from diverse perspectives and expertise and to build buy-in for the new agency and its structure.
 - ▲ **Invest in staff training and development** to build on the significant human capital at FDA and expand opportunities for employees in the new structure.
 - ▲ **Ensure maintenance of effort and program effectiveness** to make certain that food safety protection is maintained.
 - ▲ **Anticipate and budget for transition costs** to ensure that the costs needed for a successful transition are fully understood and provided for.

6. A STAGED PATHWAY TO COMPREHENSIVE FOOD SAFETY REFORM

Solving the structural problems in the HHS food safety program is an important element of food safety reform, but TFAH believes it

should be understood as part of a comprehensive food safety reform strategy that can be pursued in stages.

Immediate Steps

1. Increase Funding for HHS Food Safety Programs and Align Resources with the Highest-Risk Threats

Funding for FDA's food program must grow substantially to meet today's threats. This would mean at least doubling the funding in real terms over the next five years. FDA is responsible for overseeing the biggest threats to the country's food safety, but the agency lacks the resources needed to carry out its programs and adequately protect the nation from foodborne disease threats. Funding for CDC's food safety epidemiology program should also be increased significantly. Government funding should be strategically allocated to food safety research, regulation, and education to maximize reduction in foodborne disease. Resources for inspections should be distributed and used in the manner most likely to contribute to disease reduction.

2. Modernize the Mandate and Legal Authority of the HHS Secretary to Prevent Illness

Congress should give the HHS secretary a statutory mandate and broadened legal tools to prevent foodborne illness by enforcing the duty of food companies to implement modern preventive controls and meet government-established food safety performance standards. A new food safety law should also strengthen oversight of food imports and provide needed new authorities to: (1) access company food safety records; (2) suspend the registration of a food facility; (3) order a cessation of distribution or recall of food; (4) enact user fees for food facilities based on costs to help strengthen food safety functions; (5) set performance standards, including safety standards for produce; and (6) mandate the traceability of food.

3. Create a Deputy Commissioner with Line Authority over All Food Safety Programs

Pending legislative establishment of a new Food Safety Administration, the HHS secretary has ample authority to place the existing components of FDA's food safety program under the line management authority of a single official and should do so immediately. This would address an important part of the structural problem at FDA, which is that no official whose full-time job is food safety has line management authority over the entire program's operating units. It would also create a focal point for planning and implementing the modernization of the HHS food safety program contemplated by pending reform legislation and makes an identifiable official accountable for the overall success of the reform effort. On an interim basis, the existing structures of CFSAN and CVM could be maintained, which would minimize disruption and costs as the longer-term management solution embodied in the proposed FSA is developed and implemented.

4. Improve Coordination Among Federal, State, and Local Food Agencies.

While the states play a critical food safety role, particularly at the retail level, the federal-state relationship is not well defined or financed. States should be encouraged and incentivized to adopt and comply with the uniform standards and practices of the FDA's Food Code and the National Retail Food Regulatory Program.

Medium-Term Steps

5. Strategically Realign and Elevate Food Safety Functions at HHS

Currently, FDA's senior management focus is split between regulating medical products (drugs and devices) and food, with its food functions typically taking a backseat in terms of resources and management attention. Congress should pass legislation mandating that FDA's food functions be brought together under unified leadership at a newly created Food Safety Administration (FSA) within HHS, with a single official, reporting to the

secretary, focusing full-time on, and being responsible and accountable for, providing food safety leadership nationally and internationally and effectively implementing a modern, prevention-oriented food safety system.

FSA would include the functions and resources now housed within CFSAN and CVM, as well as the food-related functions and resources of ORA's field program and the FDA Office of the Commissioner.

Long-Term Steps

6. Modernize Meat and Poultry Inspection Laws

While this report focuses on changes at HHS, over time, Congress should also address USDA's FSIS and modernize meat and poultry inspection laws. FSIS currently operates under an antiquated inspection mandate and with weak powers to carry out a modern, prevention-oriented, farm-to-table food safety program. The result is the wasteful use of resources and a program that is less effective than it could be in preventing foodborne illness.

7. Set a Long-Term Goal to Integrate Federal Food Safety Agencies

As a long-term goal, Congress should consider consolidating all federal food safety

functions into a single agency. This would mean aligning the functions currently at HHS, USDA, and EPA. This would allow the government to evaluate and allocate where to best focus resources and attention so they are in line with modern threats. With the charge to address the food supply as a whole, this agency could set priorities and deploy resources in a manner most likely to reduce foodborne illness and be fairly held accountable for the results. The single food safety agency should oversee regulation and inspection, but also must also have research and surveillance functions as part of its mandate. It should also be required to report on accomplishments, progress, and problems.

APPENDIX A:

Restructuring Food Safety at HHS:

DESIGN AND IMPLEMENTATION

BY MICHAEL R. TAYLOR, J.D.; STEPHANIE D. DAVID, J.D.

(Mr. Taylor is Research Professor of Health Policy in the School of Public Health at The George Washington University (GW). Ms. David is a Senior Research Assistant in the Department of Health Policy at the GW School of Public Health and Health Services.

*Prepared for a project on “Restructuring Food Safety at the Department of Health and Human Services” Funded by the Robert Wood Johnson Foundation
March 10, 2009*

INTRODUCTION

This paper is part of a project funded by the Robert Wood Johnson Foundation to examine options for improving the leadership and management structure for food safety at the Department of Health and Human Services (HHS).⁵⁵ The project is being pursued as Congress considers much-needed food safety legislative reforms to shift from today’s largely reactive approach to one based on risk-based prevention throughout the food system. The broad goal of the project is to ensure that the organizations within HHS that will be charged with implementing the reforms are designed for success.

A companion paper produced for the project cited leadership and management problems arising from the current structure of the Food and Drug Administration (FDA) and FDA’s interaction with the Centers for Disease Control and Prevention (CDC).⁵⁶ As explained more fully in the companion paper, FDA’s food safety activities are spread across three separately-managed operating units – the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the Office of Regulatory Affairs (ORA) – as well as a research center, the National Center for Toxicological Research (NCTR). These organizations work at relatively low levels in the

HHS hierarchy, and no official whose fulltime job is food safety has line management authority over them and thus meaningful accountability for their overall success.

The consequences of this fragmented structure and leadership gap are evident in the failures of prevention and response seen in recent nationwide outbreaks of illness associated with fresh produce and peanut butter. While the HHS/FDA food safety program is certainly hampered by obsolete statutes and inadequate resources, stronger statutes and more resources will yield minimal benefit if HHS is not equipped organizationally to make good use of them.

To address these structural problems, the companion paper calls for unifying and elevating within HHS FDA’s food safety policy, inspection and enforcement activities and better integrating them with CDC’s critical epidemiological functions to create an effective HHS program to improve food safety. Taking that direction as its starting point, this paper takes the next step by outlining how a restructured food safety program at HHS might be designed and by identifying issues that need to be addressed in both the design and implementation of a new structure.

This paper is grounded not only in the belief that some restructuring of the food safety program at HHS is needed, but that consolidating FDA's food safety functions in a new Food Safety Administration within HHS, as proposed in pending legislation,⁵⁷ would provide the most complete solution to the leadership and management problems posed by the current structure. It is critical to recognize, however, that organizational change on this scale is a major undertaking and requires careful consideration of both the destination – the design of a new structure – and how to get there, including a well-planned transition and implementation.

In light of this, the authors convened a group of experts,⁵⁸ consisting primarily of former FDA and CDC officials, to provide input on the design of a Food Safety Administration and help identify issues that must be addressed in the transition to a new structure. This paper benefits greatly from the information and perspectives they provided, though the authors alone are responsible for its content.

It is crystal clear from discussions with the expert group that there is more than one way to design a new food safety agency within

HHS. Getting to at least a right answer and implementing it successfully will require careful deliberation by Congress and the executive branch. This brief paper can at best stimulate and inform, not substitute for, those deliberations, which must be inclusive and transparent. While Congress and senior political officials in the executive branch will set the broad direction of restructuring to improve the HHS food safety program, many stakeholders will have views, and only the people working in the program can make a new structure work.

The first sections of this paper suggest the key leadership attributes of an effective food safety organizational structure at HHS and the program improvements that the new structure should be designed to achieve. The paper then proposes a structure that would have these attributes and be equipped to achieve the needed program improvements; it also notes alternative design approaches. The final section of the paper identifies a number of procedural and substantive issues that must be addressed to achieve the benefits of restructuring while minimizing program disruption and cost.

Leadership Attributes of an Effective Food Safety Structure at HHS

To be successful in both addressing immediate problems and implementing reform, the HHS food safety leadership and management structure should have these attributes:

■ **Clearly-defined management responsibility, authority and accountability** – One official with full-time responsibility for food safety needs to be in charge and accountable for the success of the overall HHS food safety program and for leading the transformation to an effective, prevention-oriented food safety system.

■ **Authority and mandate to deploy all available resources strategically to prevent foodborne illness** – HHS needs to deploy its resources and work collaboratively to leverage state and local resources in a planned and integrated way to address food safety problems systemically and preventively, rather than piecemeal and reactively.

■ **Stature within the government system as the basis for national and international leadership on food safety** – To provide leadership and drive progress on food safety externally, the HHS food safety program needs to have visibility and standing within government.

Specific Program Improvement Capacities of an Effective Structure

Food safety reform is being driven by the widely recognized need to achieve specific improvements in the HHS food safety program. Any new structure for food safety at HHS should be analyzed in relation to its capacity to implement a science- and risk-based food safety program that is effective in preventing foodborne illness, which includes achieving:

- More systematic and integrated food safety data collection, research and analysis by FDA and CDC to inform food safety prevention efforts, set priorities and evaluate progress;
- More effective joint response by FDA and CDC to multi-state foodborne illness outbreaks to detect outbreaks earlier, contain outbreaks sooner, and draw lessons for future prevention;
- Better deployment of FDA's field force and enforcement tools as integral components of a prevention-oriented food safety strategy;
- Improved risk-based priority setting and use of scarce resources to improve food safety;
- More timely and effective implementation of new regulatory initiatives, such as the promulgation of produce safety standards integrated with an effective inspection and compliance plan;
- Improved federal leadership to build a true and effective food safety partnership among federal, state and local agencies; and
- Design and implementation of a modern, preventive approach to ensuring the safety of food imports.

Basic Configuration of a Food Safety Administration

On February 4, 2009, Rep. Rosa DeLauro introduced the Food Safety Modernization Act of 2009 (H.R.875), which would both modernize the food safety law under which the FDA program operates and create within HHS a new Food Safety Administration (FSA) to implement the law. The FSA would include all the functions and resources now housed within CFSAN, CVM, and NCTR, including not only food safety functions but also nutrition, food labeling, animal drug regulation and all other functions of these units. The FSA would also include the food-related functions and resources of ORA's field program and the Office of the FDA Commissioner (see box below). The proposed FSA would report directly to the Secretary of HHS.

In essence, this bill would separate FDA's food functions from its medical product functions and create two agencies operating on the same plane within HHS. Under the bill, the Food and Drug Administration would be renamed the Federal Drug and Device Administration and continue to be referred to as FDA. While creating separate agencies, the

bill calls for FDA and the FSA to share facilities and other resources as appropriate for the sake of efficiency and effectiveness.

On its face, such a Food Safety Administration would have at least some of the leadership and management attributes required for success. The Administrator of Food Safety would have responsibility and accountability for the success of all HHS food safety activities, including better integrating the activities of CDC and the FSA. The Administrator would be charged specifically with deploying the Department's food safety resources to achieve the greatest possible benefit in preventing foodborne illness and with better integrating federal, state and local food safety activities. By providing a single, elevated focal point for food safety leadership and accountability within HHS, the FSA would have the standing to work effectively within the federal government – in dealings with the Office of Management and Budget and other agencies – and to provide leadership on food safety nationally and internationally.

FDA OFFICES WITH FOOD-RELATED RESPONSIBILITIES

PROGRAM LEVEL CENTERS AND OFFICES

Center for Food Safety and Applied Nutrition (CFSAN) – the headquarters unit that makes most food safety policy for FDA, houses most of the relevant scientific capacity (except food testing capacity), and manages pre-market oversight of food and color additives, infant formula, and nutrient claims.

- **Center for Veterinary Medicine (CVM)** – the headquarters unit that makes food safety policy for animal drug and antibiotic residues, animal feeds, pet foods, and cloned and genetically engineered animals.
- **Office of Regulatory Affairs (ORA)** – the field organization for FDA that conducts food inspections, oversees imported food, manages food testing laboratories, develops enforcement cases, and manages the majority of FDA's food safety resources.
- **National Center for Toxicological Research (NCTR)** – a research unit in FDA that develops methods for detecting, assessing, managing, and preventing contamination and other threats to the food supply.

STAFF OFFICES (Within the Office of the Commissioner)

- **Office of Food Protection** – a relatively new unit that serves as liaison to the Department of Health and Human Services on food protection issues, and is charged with developing and implementing the FDA Food Protection Plan, an agency-wide strategy for domestic and import food protection.
- **Office of Policy** – a policy unit that develops and coordinates the review and analysis of broad agency policy, ensures consistency in the development and content of agency policy, and ensures that regulations and other agency documents published in the Federal Register meet applicable requirements.
- **Office of Chief Counsel** – a legal office that handles both civil and criminal cases involving the agency, provides legal advice and policy guidance for agency programs, and participates in rulemaking proceedings, legislative matters, policy deliberations, and international negotiations on agency-related matters.
- **Office of Operations** – an administrative management office that includes IT functions and budget, as well as a crisis management staff.
- **Office of International and Special Programs** – a staff office that coordinates FDA's international activities.
- **Office of Scientific and Medical Programs** – a staff office that includes oversight of scientific capacity building and liaison with the scientific community.
- **Office of Legislation** – a legislative office that drafts congressional testimony, responds to congressional inquiries and assists in the development of agency-related legislation.
- **Office of Public Affairs** – a communications office that interfaces with the media and press on FDA-related issues.

Whether the FSA would fulfill its leadership potential, however, would depend on how the new agency is structured and managed. It would be possible to place the food safety elements of FDA under a single, new management umbrella and still not achieve the leadership goals or be capable of achieving the specific program improvements outlined above. That will depend not only on how the

elements of the new agency are put together on paper but on whether they overcome the fragmentation in the current structure and operate instead as an integrated unit.

The following schematic provides an overview of the FSA's key functions and how they could be structured organizationally to exercise food safety leadership and achieve the desired program improvements.



The key objective of the proposed structure is to break down the organizational barriers to effective collaboration that hamper FDA in its current structure and form instead a functionally seamless organization that is able to implement a common, coherent food safety strategy.

For this reason, Figure 1 is not in the form of a conventional, hierarchical organizational

chart but rather is intended to convey the idea of all elements of the FSA working as an organic whole to design and implement a food safety strategy.

The following brief synopsis of roles to be played by the various elements of the FSA will emphasize the management features that are key to fulfilling the “one program, one strategy” aspiration underlying the proposed FSA.

Senior Leadership

The senior leadership structure of the FSA must lodge full management responsibility and authority for food safety in a single accountable official, namely the FSA Administrator, who would report to the Secretary of HHS. In addition, however, the FSA leadership structure should include a chief operating officer and mechanisms for engaging other senior managers as members of an integrated, collaborative leadership team.

- **Administrator** – provides executive leadership to the FSA in its implementation of the food safety laws and strategies to prevent foodborne illness; serves as the food safety leader within HHS, with ultimate accountability for the success of the FSA and the HHS food safety program.
- **Deputy Administrator** – serves on behalf of the Administrator as the chief operating officer of the FSA with primary responsibility for internal management of the agency and oversight of staff offices.
- **Leadership Council** – chaired by the Administrator and comprised of the heads of all FSA operating units (both headquarters and field);⁵⁹ functions as a deliberative

Operating Units

- **Public Health and Science** – consolidates in one unit the scientific divisions of CFSAN⁶¹ and CVM,⁶² as well as possibly NCTR, to form an integrated, farm-to-table scientific capacity for data collection and analysis and development of an integrated food safety research program; includes the CFSAN and CVM research laboratories; would include a new epidemiology unit that would support FSA's priority setting and prevention initiatives with respect to foodborne illness and build an active partnership with CDC to develop human illness data and perform analyses needed for prevention; also interacts with USDA agencies, including Food Safety and Inspection Service, the Animal and Plant Health Inspection Service and the Agricultural Research Service on matters of common scientific concern, such as the on-farm etiology of foodborne hazards.

body responsible for strategic planning and agency-wide priority setting and resource allocation; the Council places headquarters and field units on an equal footing in setting the FSA's direction and provides a focal point for developing integrated solutions to major food safety challenges, such as implementing preventive controls domestically and ensuring that food imports are produced under the same preventive control standards applicable to domestic products; the staff offices in the office of the Administrator provide staff support to the members of the Leadership Council and their operating units.

- **Outbreak Response Center** – serves as the focal point for integrating all aspects of the FSA and HHS response to foodborne illness outbreaks and other food safety and food defense emergencies, including interface with CDC, USDA, and state and local health officials, traceback and other investigatory work, recalls and public communications; staffing includes one or more designated representatives of the FSA operating units and staff offices that play a role in outbreak response.⁶⁰
- **Food Safety Prevention and Standards** – responsible, working in collaboration with Public Health and Science, for food safety priority setting, policymaking and standard setting and for planning strategies and targeted initiatives to prevent foodborne illness; houses the FSA's expertise on food systems and the food industry and the intervention tools that are available to prevent or minimize foodborne hazards; draws primarily from the CFSAN and CVM offices involved in sector-specific food safety regulation.⁶³
- **Pre-Market Review** – responsible for managing the animal drug and medicated feed programs; the food additive, animal feed additive, and color additive programs; the GRAS and biotech pre-market notification programs; and the color certification program; comprised of the elements of

CFSAN and CVM currently responsible for these programs.⁶⁴

- **Nutrition and Labeling** – responsible for all nutrition and labeling policy and regulatory activities, including regulation of nutrition labeling and claims, infant formula, and dietary supplements, and the promulgation of food standards; consists essentially of the current CFSAN Office of Nutrition, Labeling and Dietary Supplements.
- **Compliance Policy and Enforcement** – consolidates the compliance and enforcement elements of CFSAN, CVM and related ORA resources into a single operating unit; responsible, working in collaboration with the Leadership Council and all other operating units, for developing and implementing field-based data collection, inspection, and enforcement programs and taking enforcement actions to achieve compliance with food safety standards and to deter and penalize violations; collaborates with Public Health and Science and Food Safety Prevention and Standards to establish risk-based criteria for responding to inspection findings and ensure that the compliance and en-

forcement program supports achievement of the FSA’s public health prevention goals.

- **Inspection and Investigations** – manages, in close collaboration with Compliance Policy and Enforcement and the Leadership Council, the FSA’s inspection and investigations program for both domestic and imported foods and collaborates with Compliance Policy and Enforcement and Chief Counsel in taking enforcement action; works on behalf of the Leadership Council to build state and local food safety capacity and collaboration that leverages state and local resources to ensure compliance with food safety standards; performs food-related functions now performed by ORA’s field inspection and federal-state relations staffs and the Office of Criminal Investigations.
- **Field Laboratories** – analyzes food and feed for chemical and microbial contaminants and performs other laboratory work to meet the data needs of FSA’s operating units; comprised of food-related facilities and resources drawn from FDA’s current field lab system but restructured to meet the needs of the FSA (a challenge discussed further below).

Staff Offices

The staff offices provide critical services in support of the FSA’s senior leadership and all operating units.

- **Infrastructure, Management and Budget** – ensures that the FSA has the human and physical resources it needs to be successful, develops and manages implementation of FSA’s budget, oversees human resources and other administrative management activities within the FSA, and interacts with other elements of HHS on management issues; the Chief Information Officer is housed here with responsibility for IT initiatives agency wide.
- **Policy, Planning and Program Evaluation** – provides policy analysis and program planning and evaluation services to operating units; includes a staff responsible for ensuring integrity and accountability in the FSA’s

implementation of its program, through its own analysis and investigations and collaboration with the HHS Inspector General.

- **Chief Counsel** – provides legal services to the FSA senior leadership and all FSA operating units; in the current structure, the FDA chief counsel is housed administratively in the HHS Office of General Counsel, as presumably the FSA chief counsel would be.
- **Communications and Stakeholder Outreach** – manages internal and external communications via the internet and other communication tools and by maintaining the FSA’s relationship with the press; conducts active outreach to consumer, industry, professional, and scientific/academic stakeholders to ensure two-way communication on issues of interest to FSA and its stakeholders.

■ **Legislative Affairs** – manages the FSA’s relationship with Congress on legislative and oversight matters.

■ **International Affairs** – serves as the focal point for coordinating FSA’s policy, standard

setting, and technical assistance relations with foreign governments and international organizations; and supports the operational units in carrying out the international activities inherent in their missions.

Key Features

The key feature of the structure outlined above is that it creates a single agency with unified management to replace the three major, separately-managed organizations now working on food safety within FDA. The structure de-emphasizes traditional bureaucratic lines between sub-components of the agency and emphasizes that all elements of the agency are connected to and set up to collaborate with all other elements, as indicated in the schematic presented earlier.

This “one agency” design is key to achieving each of the program improvements outlined earlier in the paper – improvements that have been impeded by the current structure. The lodging of overall accountability for the program’s success in a single administrator and the establishment of the Leadership Council are the key management tools for ensuring that all elements of the FSA operate as a sin-

gle agency with “one program/one strategy” when it comes to protecting food safety.

A further feature of the proposed structure is that it would make a single official accountable for optimal allocation of all available food-related resources. As indicated in the table below, FDA’s food-related resources in 2008 totaled about \$696 million and about 3,400 staff years. These resources are distributed primarily across CFSAN and CVM and their corresponding field programs managed by ORA. In addition, FDA attributes \$33.5 in Office of the Commissioner (OC) program funding to food safety, including resources for the Office of Food Protection in the Office of the Commissioner (OC/OFP), as well as crisis management, international activities, and other staff costs. NCTR’s budget is devoted substantially, though by no means exclusively, to food-related research and testing.⁶⁵

FDA FOOD-RELATED RESOURCES -- FY 2008 Budget					
Dollars in Millions					
	CFSAN	CVM	NCTR	OC	Total Resources
Center	\$172.0	\$71.3	\$44.0	\$33.5	\$320.8
FTE	780	376	190	—	1,346
Field	\$337.8	\$37.3	—	—	\$375.1
FTE	1,853	219	—	—	2,072
Total Budget	\$509.8	\$108.6	\$44.0	\$33.5	\$695.9
Total FTE	2,633	595	190	—	3,418

Source: FDA Congressional Budget Justification FY 2009

Well over half of the total food-related dollars and staff time at FDA is managed by ORA, without line accountability to the directors of CFSAN and CVM, whose programs the field resources are intended to support. The new structure would lodge management

of these resources with a single Administrator and a unified agency leadership structure, which would be responsible for their optimal allocation across the entire food program, within limits imposed by Congress.⁶⁶

A Caveat

The FSA organizational schematic presented on p. 20 and the discussion that follows do not substitute for a formal and complete organizational chart for a new Food Safety Administration. They are offered instead to illustrate the functions that should be included in the FSA and how they should interact. Nor, by any means, do they provide the last word. A number of design and management issues deserve discussion, as outlined below, and there are al-

ternative ways the FSA could be organized, for the long run or on an interim basis. Moreover, each operating unit and staff office requires an internal management structure that will enable it to operate efficiently and in an integrated way with other units, in keeping with the objectives of the overall FSA structure.

To stimulate discussion, key structural issues are noted in the next section.

Design and Management Issues

Several significant design and management issues arose during the development of the structural approach outlined in this paper – issues that merit further discussion. These include:

1. *Whether, as an alternative to creating the new structure for the FSA outlined above, the FSA should be formed simply by placing the current CFSAN, CVM and ORA structures under an Administrator for Food Safety.*

Comment: Putting the existing components of FDA's food safety program under the line management authority of a single official would address an important part of the structural problem at FDA, namely the fact that no official whose fulltime job is food safety has line management authority over all of the program's operating units. Lodging such authority with a single official would create a focal point for planning and implementing an integrated, preventive program and make an identifiable official accountable for its overall success. Maintaining the existing structures of CFSAN and CVM would also minimize the disruption and costs associated with a more comprehensive reorganization.

The principal reasons for considering a more complete reorganization are, first, to overcome the history of organizational fragmentation and lack of a common food safety culture within FDA, and, second, to equip the new FSA to implement a fully integrated, farm- to-table food safety strategy, based on the principle of prevention. Implementing such a strategy requires all of the food safety operating units to work together in new ways.

In particular, it requires the work of FDA's field force to be fully integrated with the work of the scientific, standard-setting, and policy units in headquarters in a collective effort to set and enforce food safety standards. This necessitates some structural change.

Merging at least some elements of CFSAN and CVM should also bring some performance and efficiency improvements. For example, merging the current scientific divisions of these two centers, along with NCTR, within a single Office of Public Health and Science could increase critical mass and promote synergy in such key disciplines as chemistry, microbiology and toxicology, foster more interaction between program and research scientists, and promote a farm-to-table orientation in the deployment of scientific resources.

2. *How to structure the FSA's field program – compliance policy, inspection, and laboratories – and its relationship with FDA's field program for drugs and medical devices.*

Comment: One of the most significant features of the proposed structure is the merger of the separate compliance offices in CFSAN, CVM and ORA into a single Compliance Policy and Enforcement office that is field-based but an integral part of the FSA's senior leadership. This seems essential for two reasons: first, to overcome the fragmentation in the current FDA structure that can slow enforcement decision making and, second, to enable the flexible, risk-based deployment of

resources and targeting of actions needed to implement a prevention-oriented food safety strategy. It is, however, a major change from current practice that will generate much discussion within the current organization.

The relationship between the food safety and medical products inspection forces is one of the most challenging design and transition issues raised by the creation of a Food Safety Administration. The proposed structure is premised in part on the assumption that, as food safety systems and problems become more sophisticated, the food safety inspection force needs to become more specialized, which is part of what justifies creating a separate food-oriented inspection force.

Many FDA inspectors already specialize in conducting drug and medical device inspections, and some specialize in inspecting certain food facilities. Many FDA inspectors are currently called upon, however, to conduct both food and medical product inspections, to varying degrees. This no doubt provides FDA field managers with desirable flexibility in deploying scarce inspection resources, especially in response to emergencies. On the other hand, current calls for substantially increasing FDA's resources for food inspection may permit changes in staffing levels and geographic distribution that would diminish the importance of this flexibility advantage; and it might be desirable and feasible for separate food and medical product inspection programs to establish agreements under which staff and other resources could be shared in emergencies.

In any event, the creation of separate inspection programs will require careful analysis of how both can make optimal use of their resources, followed by a well-planned transition. This analysis should include how to manage the necessary criminal investigation function, which is currently performed by the Office of Criminal Investigations in FDA's Office of Regulatory Affairs.

Similar issues arise with respect to FDA's 13 field laboratories. While there is considerable specialization in some FDA laboratories,

with some devoted largely to drug testing and others mostly analyzing food samples,⁶⁷ most FDA labs perform at least some analysis in both areas. Sharing of lab facilities and staff between food and medical product programs should remain a possibility.

Regardless of any higher level organizational change within FDA, however, the issue of how to make optimal use of FDA's field lab capacity – and how to upgrade it to support a more prevention-oriented food safety strategy – will have to be addressed. Increasingly specialized analytical capacity and higher volume microbial testing of food samples are likely needed to support a more prevention-oriented strategy and enforce stricter accountability for meeting food safety standards. These needs will have to be considered in planning the transition to a new food safety agency and deciding how field labs should be structured.

Consideration should also be given to whether the current structure of FDA regional and field offices would be optimal for the FSA from a management and efficiency standpoint. This would include revisiting the need for regional offices as a management layer between the frontline inspection and compliance force and the headquarters units, in light of the goal of more tightly integrating headquarters and field operations.

3. How the relationship between CDC and the FSA should be structured.

Comment: Integrating the food safety efforts of CDC and FSA is essential for the future success of the HHS food safety program. Scientists at CDC play a critical role in investigating and responding to multi-state outbreaks of foodborne illness, along with state and local health officials and federal food safety regulators at FDA and USDA. CDC and FDA were widely criticized, however, for their seemingly disjointed response to the 2008 Salmonella Saintpaul outbreak. There is a clear need to improve collaboration between CDC and FDA in the management of multi-state outbreaks.

Beyond outbreak response, CDC is the federal government focal point for foodborne illness surveillance and reporting and thus has an even larger role to play in a modernized, prevention-oriented food safety system by generating the data and analysis on foodborne illness needed to set public health priorities and plan prevention strategies. Currently, however, CDC lacks the resources, clear mandate and institutional incentives to play this broader role. The result is that food safety regulators at FDA lack the data they need to mount risk-based prevention strategies and targeted interventions to reduce foodborne illness. In any restructuring of food safety at HHS, this problem must be solved.

It could be argued that, to address these problems, the elements of CDC that work on foodborne illness should be transferred to a new Food Safety Administration. This would ensure clear accountability on the part of a single official, the FSA administrator, for the management of multi-state illness outbreaks that fall within FDA's current jurisdiction. It would also be the most direct way to build closer working relationships and clear accountability between CDC's food safety epidemiologists and FSA's food safety regulators for purposes of generating the epidemiological data and analysis required for prevention.

There are, however, some important barriers and disadvantages to transferring the food safety elements of CDC to a new FSA. The most significant barrier is that these elements are embedded in eight different CDC offices and programs that address the epidemiological and environmental health aspects of many problems, of which food safety is only one.⁶⁸ CDC scientists are also tied into networks of state and local health officials who work on food safety along with other public health problems at the same time. Extracting CDC's food safety activities from their current institutional framework and moving them to the FSA would disrupt important working relationships within CDC and with the states.

Another argument against organizationally consolidating the CDC's food safety activities with the FSA is that, in the current configura-

tion, CDC can function as an independent source of data on rates of foodborne illness and thus provide an independent measure of progress on food safety for both FSA and the USDA food safety program for meat and poultry. In fact, the Secretary of HHS should charge CDC with regularly updating its now ten-year-old estimates of the number of illnesses, hospitalizations and deaths associated with foodborne pathogens. Such independent, periodic estimates are important both as a benchmark for society's progress in reducing foodborne illness and an indicator of where intensified efforts are needed.

Notwithstanding the advantages of leaving the CDC food safety functions organizationally separate, as in the proposed structure, significant change is needed in the relationship between CDC and food safety policymakers and regulators, both to improve outbreak investigation and response and meet the data needs of the FSA. The head of the FSA should be charged with overseeing, in close collaboration with CDC, the HHS role in investigation and response to major illness outbreaks. Most outbreaks do not involve an active HHS role because they are local in nature and are handled by state and local officials, with CDC providing back up when requested. Under the proposed FSA structure, the epidemiological interaction with state and local agencies in these local cases, as well as in larger national outbreaks, would remain with CDC. Mechanisms should be developed, however, to facilitate close collaboration between CDC and FSA in all phases of major outbreaks, including an FSA role in product tracing and food testing to assist with the epidemiology, and to provide a single focal point for HHS leadership and accountability in managing multi-state outbreaks. Overall, there should be a seamless, real time flow of information between CDC and the FSA during any outbreak investigation involving FSA-regulated products.

In addition to improving outbreak response, mechanisms are required to ensure that CDC has both capacity and accountability to provide FSA the epidemiological data and analysis FSA needs to prevent illness. In July 2008,

then-Senator Barack Obama introduced the Food-borne Illness Surveillance and Response Act of 2008 (S.3358, 110th Cong.), which would address this issue by giving CDC a clear mandate to generate the needed data and by establishing “partnership” mechanisms for defining data needs. Consistent with this approach, the proposed FSA structure envisions that the FSA’s Public Health and Science (PHS) unit would include professional epidemiologists who would be the FSA focal point for building an active partnership with CDC and for defining and meeting FSA’s epidemiological data needs.

For such a partnership to go beyond words, a funding mechanism would be required to ensure that CDC has both resources and accountability for generating the needed data and analysis. One such mechanism would be for FSA to have a mandate and resources to enter into contracts (“reimbursable agreements”) with CDC under which CDC would receive FSA funds to provide the specific data and analysis FSA needs to do its job. This would put more resources into the badly underfunded food safety program at CDC; and it would create a contractual, client-service provider relationship in which FSA’s information needs and CDC’s accountability for meeting them would be clear.

An effective partnership between the CDC units working on food safety epidemiology and the FSA units working on food safety regulation is an essential element of a risk-based, prevention-oriented food safety system at HHS. Building that partnership should thus be one of the Department’s highest food safety reform priorities. Given the history of the CDC-FDA relationship, active commitment to the partnership by the Secretary of HHS will be required, especially if the CDC functions remain organizationally separate from FSA.

4. Whether NCTR should be incorporated in the FSA in whole or in part.

Comment: FDA’s National Center for Toxicological Research is a world class toxicology research facility, located in Jefferson, Arkansas. NCTR performs advanced toxico-

logical methods research, as well as research related to the safety of specific chemical and microbiological agents and hazards and possible risk-reduction interventions. Although NCTR performs work of interest to all of FDA’s program areas, significant work relates directly to food safety and nutrition. NCTR is, however, under-utilized as a scientific resource by FDA’s operating units. To enhance the contribution of NCTR to the food safety mission, the proposed FSA structure outlined above incorporates NCTR into the FSA’s Public Health and Science unit. This would substantially bolster the ability of the FSA to generate the scientific tools and data it needs to do its job by giving it direct line management and budget authority over a first-rate research facility.

A legitimate argument against this approach is that much of NCTR’s work is genuinely cross-cutting in its application, especially its toxicological methods research, and significant work relates directly to FDA’s drug regulatory mission. It makes no sense, however, to split NCTR between the FSA and the medical products agency. Its scientific divisions are, for good reason, organized by discipline, not product category. Separating them would be highly disruptive and diminish the overall scientific capacity that now exists.

More worthy of consideration is the possibility of configuring NCTR more as a contract research facility, with a substantial share of its budget coming via reimbursable agreements with FSA and the medical products agency. It could be housed administratively within either agency, or even elsewhere within HHS, such as with the National Toxicology Program at the National Institute of Environmental Health Sciences. As in the proposed relationship between FSA and CDC, however, clarity of program-related research needs and NCTR accountability for meeting them would be achieved through the contract mechanism. In any event, NCTR is an important scientific asset whose productivity for the food safety program needs to be considered and enhanced in any reorganization.

5. Where to house FDA's cosmetics and dietary supplement programs.

FDA's cosmetic and dietary supplement regulatory programs do not fit comfortably in a structure that is divided between medical product and food regulation. Cosmetic regulation is currently housed in CFSAN, but the scientific and safety issues it raises are more akin to those addressed by the dermatology division of FDA's Center for Drug Evaluation and Research; and one of the recurring issues in cosmetic regulation is whether marketing claims and intended uses for some cosmetic products render them legally drugs. Likewise, dietary supplements are categorized legally as foods and housed in CFSAN, but the supplement category includes not only vitamins, minerals and other clearly nutritional substances but also herbal products and others that are marketed and sought after for their drug-like effects. In fact, the issue of whether supplement claims cross the line to become, legally, drug claims is a recurring issue.

There are thus legitimate arguments on both sides of the issue of whether these programs should be in the FSA or the medical products agency. The issue is of great interest to the regulated industries and other stakeholders and thus requires careful consideration.

6. How to achieve efficiency in administrative and staff support functions.

Comment: FDA currently achieves administrative efficiencies through the centralization at the agency or HHS level of many of the support services that CFSAN, CVM, ORA and NCTR, as well as the medical products components of FDA, need to operate. These include services related to financial management and payroll, procurement, facilities management, human resources, equal employment opportunity (EEO), and information technology. In some cases, such as financial and facilities management, the provision of services is split between FDA agency-level offices and HHS. In any event, mechanisms need to be established to maintain these efficiencies.

As a general rule, for administrative services being provided by FDA-level offices, the FDA offices providing them should remain intact and could be attached administratively either to the FSA or the medical products agency. They could continue to function as shared services units for both agencies, with costs allocated accordingly and performance measures in place to ensure that the FSA's administrative needs are met at an agreed upon level of timeliness and quality. In the case of services centralized at the HHS level, such as most human resources work (hiring and promotion), this arrangement would continue, and thus the creation of the FSA would not affect the efficiency with which these services are currently provided.

With regard to information technology (IT), the FSA would need an in-house IT leadership capacity (a Chief Information Officer) to be part of the FSA management team and work with the FSA Leadership Council to help build the information systems needed to manage a risk-based, prevention-oriented food safety program. This would not preclude having the procurement and other support services associated with IT systems being provided on the shared services basis outlined above. A key IT need is to modernize the tools and systems needed to oversee imports, and some efficiencies might be obtainable in that arena by sharing data systems and services with the medical products agency.

While EEO services are now provided at the FDA agency level, the FSA should have its own EEO capacity so that the Administrator can be held accountable for the FSA's EEO performance. The FSA would also require its own administrative law judge to carry out hearing functions required by law.

Beyond administrative and management services, certain staff functions are essential to the functioning of a government agency, especially one that is required to deal extensively with Congress, the media, stakeholders, and the general public. These include, as reflected in the earlier schematic, Legislative Affairs and Communications and Stake-

holder Outreach. These services are provided by relatively small staffs that ideally have specialized program knowledge to back up the other skills needed for this work. There are minimal economies of scale in such functions, in contrast to functions like payroll and procurement, and thus minimal cost in dividing the existing FDA staffs in

Implementation Issues

A good design for a Food Safety Administration remains words on a page until successfully implemented. And the challenge of implementing the transformative restructuring proposed here should not be underestimated. Many lessons have been learned, however, from past efforts at organizational change in both the public and private sectors.⁶⁹ These lessons, many of which amount to simple common sense, should be applied here. The central message is this: planning the implementation of a good organizational design requires just as much care, analysis and attention as the design itself.

Among other things, an implementation plan for a new Food Safety Administration in HHS should address the following needs:

1. An active process to engage employees and learn from their experience – Restructuring is done to improve agency performance for the public good. More than anyone else, however, agency employees know what works and what does not work, and the goals of restructuring will not be met without the buy in and sustained effort of employees. It is thus critical that agency employees be systematically engaged through a transparent process in the design and implementation of any restructuring.

2. Maximizing opportunities for employees in the new organization – For most employees, the strongest incentive for buy in on the restructuring of their agency is the prospect that it will significantly improve the agency's performance. Employee support will also be influenced by the perceived opportunities for professional growth and enhanced personal productivity. Thus, careful attention needs to be given to such core personnel issues as preserving grades and advancement opportunities.

these areas between the FSA and the medical products agency. To the extent shared services can yield efficiencies, however, they should be considered.

Likewise, the FSA leadership needs its own legal, policy, and management support to be successful.

3. Working closely with employee unions – The majority of FDA employees are represented by unions and work under collective bargaining agreements that ensure the employees' right to bargain over changes in working conditions.⁷⁰ Collective bargaining can be a constructive process if well managed on both sides, but it takes time and needs to be considered as part of the process of designing and implementing a new structure.

4. Dialogue with government partners and public stakeholders – Many other organizations and individuals, inside and outside government, will have an interest in and be affected by the creation of a Food Safety Administration. These include other government agencies involved in food safety (such as USDA, EPA and state and local agencies), congressional members and staff, consumer and public health groups, and the food industry. These groups should be consulted through transparent processes during the planning and implementation phases of restructuring.

5. Division of personnel and facilities with the medical products program – Under the proposed structure, some headquarters staff offices will be divided, with some personnel going to the FSA and some to the medical products agency. A process will be required that assures a fair allocation of personnel slots and that appropriately qualified people occupy those slots in both agencies. A process will also be required to allocate and/or replace facilities and equipment currently assigned to these staff offices. As noted earlier, the transition of field personnel and resources to separate food and medical product inspection and compliance programs presents an even larger challenge and will also require a well-planned

process. The allocation of personnel slots in the Senior Executive Service and Senior Biomedical Research Service is another critical transition issue. Sufficient numbers of these positions is critical to recruiting and retaining the senior managers and scientific leaders that will be essential to the success of the FSA.

6. Staff training and development – The new structure and integrated operational approach of the FSA will change the way people work throughout the agency, as will the new inspection and compliance strategies required to make the FSA’s field force an integral part of a prevention-oriented food safety strategy. An investment in staff training will thus be required during the transition to prepare for new ways of working, and ongoing investment in staff training and development will be required to implement an increasingly science- and risk-based program. Staff training and development should be a built-in feature of all operating components, but the Leadership Council should consider how best to manage the upfront transition training, as well as on going staff training and development.

7. Delegations of authority – The legal authority to implement the Federal Food, Drug and Cosmetic Act (FDCA) is vested in the Secretary of HHS, who has delegated most of that authority to the FDA Commissioner, who has in turn delegated most of the food-related authorities to CFSAN, CVM and ORA. These delegations will have to be reviewed and revised as appropriate to ensure that the FSA has full legal authority to implement the FDCA, taking into account assignments of authority responsibility in the law establishing the FSA.

Conclusion

As this paper makes clear, the transition to a new structure for food safety at HHS will require an investment of time and effort. It is an investment, however, in the long-term success of the HHS food safety program that will pay dividends for many years to come. And the cost of not acting is great. A fragmented, disempowered food safety program makes

8. Maintenance of effort and effectiveness during the transition – Any transition to a new structure has the potential to distract employees from the agency’s mission. This potential should be carefully assessed in planning the transition to a new FSA and steps taken to minimize disruption, such as prioritizing critical functions that cannot be allowed to lapse and phasing in personnel and facility transitions in a carefully paced and predictable manner.

9. Cost of the transition – The transition to a new agency will incur costs. These would include staff time required for planning and implementing the new agency and the transition to it, possible one-time added facility and equipment costs, and possibly employee relocation costs. These should be estimated in advance and budgeted for so that resource issues do not prevent an on-time implementation of the transition.

10. Interim structure – As discussed in the companion paper, the Secretary of HHS has broad authority to change reporting relationships and establish new leadership positions within HHS. The Secretary could thus act administratively to vest in a single FDA official line management authority over all FDA food safety activities, as well as authority and accountability for better integrating FDA and CDC food safety activities. Whether done administratively prior to the enactment of legislation creating the FSA or as part of a legislatively-mandated process, such an interim structure might be advisable to provide a focal point for leadership in planning and implementing the transition to the FSA, as well as making immediate progress on pressing food safety issues facing FDA and the Department.

poor use of taxpayer dollars, and it imposes substantial economic and personal costs on people who experience preventable food-borne illness. We should begin now the carefully planned transition to a food safety agency that can do the job expected and deserved by America’s consumers.

Endnotes

- 1 Harkin, T. Remarks during Senate Agriculture Committee hearing on a deadly salmonella outbreak linked to a Georgia peanut plant that has sickened more than 550 people and killed at least eight. Washington, D.C., February 5, 2009.
- 2 Chambliss, S. "Sen. Chambliss Cosponsors Measure to Boost Food Safety Oversight." Press Release, March 3, 2009. http://216.40.253.202/~usscanf/index.php?option=com_content&task=view&id=1849&Itemid=71 (accessed March 16, 2009).
- 3 U.S. Food and Drug Administration. "FDA Detains Imports of Farm-Raised Chinese Seafood Products Have Repeatedly Contained Potentially Harmful Residues." News Release, June 28, 2007. <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01660.html> (accessed February 19, 2009).
- 4 Risling, G. "Huge Beef Recall Stems from Calif. Plant." *The Associated Press*, February 18, 2008. http://www.usatoday.com/money/economy/2008-02-17-4234314486_x.htm (accessed February 19, 2009).
- 5 Mead, P.S., L. Slutsker, V. Dietz, et al. "Food-Related Illness and Death in the United States." *Emerging Infectious Diseases* 5, no. 5 (1999): 607-625.
- 6 World Health Organization. "Food Safety and Foodborne Illness." WHO, March 2007. <http://www.who.int/mediacentre/factsheets/fs237/en/> (accessed February 11, 2008).
- 7 World Health Organization. "Food Safety and Foodborne Illness." WHO, March 2007. <http://www.who.int/mediacentre/factsheets/fs237/en/> (accessed February 11, 2008).
- 8 Williamson, S.H. "Five Ways to Compute the Relative Value of a U.S. Dollar Amount, 1790 – 2006." MeasuringWorth.Com, 2007. <http://www.measuringworth.com/calculators/uscompare/result.php> (accessed February 11, 2008). Medical costs and lost productivity due to foodborne illnesses were estimated to cost \$35 billion annually in 1997. TFAH adjusted this figure for inflation for 2007, the most recent year for which comparisons can be made. TFAH used the Consumer Price Index calculation, which is the inflation measure cited by the U.S. Department of Labor, Bureau of Labor Statistics. <http://data.bls.gov/cgi-bin/cpicalc.pl> (accessed February 11, 2008).
- 9 Smith DeWaal, C. and D.W. Plunkett. *Building a Modern Food Safety System: For FDA Regulated Foods*. Washington, D.C.: Center for Science in the Public Interest, 2007, p. 3.
- 10 Consumer Reports National Research Center. *Food-Labeling Poll 2008: Final Tables*. Yonkers, NY: Consumers Union, 2008, p. 8. <http://www.greenerchoices.org/pdf/foodpoll2008.pdf> (accessed January 26, 2009).
- 11 National Academy of Sciences. *Addressing Foodborne Threats to Health: Policies, Practices, and Global Coordination, Workshop Summary*. Washington, D.C.: National Academy Press, 2006.
- 12 Committee to Ensure Safe Food from Production to Consumption, Institute of Medicine and National Research Council. *Ensuring Safe Food: From Production to Consumption*. Washington, D.C.: National Academy Press, 1998.
- 13 Government Accountability Office. *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*. Washington, D.C.: U.S. Government Accountability Office, 2004.
- 14 Subcommittee on Science and Technology, Science Board, U.S. Food and Drug Administration. *FDA Science and Mission at Risk: Estimated Resources Required for Implementation*. Washington, D.C.: U.S. Department of Health and Human Services, 2008.
- 15 Robinson, R.A. *Food Safety and Security, Fundamental Changes Needed to Ensure Safe Food*. Washington, D.C.: U.S. General Accounting Office, October 2001.
- 16 Ibid.
- 17 Walker, D.M. *Federal Oversight of Food Safety, High-Risk Designation Can Bring Needed Attention to Fragmented System, Testimony before the Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies, Committee on Appropriations, House of Representatives*. Washington, D.C.: U.S. Government Accountability Office, 2007. <http://www.gao.gov/new.items/d07449t.pdf> (accessed November 5, 2007).
- 18 The Institute of Medicine. *HHS in the 21st Century: Charting a New Course for a Healthier America*. Washington, D.C.: National Academy Press, 2008, p. 75.
- 19 U.S. Government Accountability Office. *Federal Oversight of Food Safety: FDA Has Provided Few Details on the Resources and Strategies Needed to Implement its Food Protection Plan*. Washington, D.C.: U.S. Government Printing Office, 2008.
- 20 U.S. Centers for Disease Control and Prevention. "Update on Multi-State Outbreak of E. coli O157:H7 Infections From Fresh Spinach, October 6, 2006." <http://www.cdc.gov/ecoli/2006/september/updates/100606.htm> (accessed January 27, 2009).
- 21 Park, M.Y. "E. Coli Outbreak Hurts Spinach Farming Industry, Restaurants." *Fox News*, September 22, 2006. <http://www.foxnews.com/story/0,2933,215257,00.html> (accessed January 27, 2009).
- 22 U.S. Centers for Disease Control and Prevention. "Salmonellosis – Outbreak Investigation, October 2006." http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis_2006/110306_outbreak_notice.htm (accessed January 27, 2009).
- 23 U.S. Centers for Disease Control and Prevention. "Multi-state Outbreak of E-coli 0157 Infections, November-December 2006." <http://www2a.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00255> (accessed January 27, 2009).
- 24 U.S. Centers for Disease Control and Prevention. "Salmonellosis – Outbreak Investigation, February 2007." http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis_2007/outbreak_notice.htm?s_cid=ccu022607_food1_r_e (accessed January 27, 2009).
- 25 Hoffman, S.A. "Mending Our Food Safety Net." Resources no. 177 (Summer 2007), p. 12.

- 26 CNN. "Mix of Chemicals May Be Key to Pet-food Deaths." CNN.com. <http://www.cnn.com/2007/US/05/01/recall.riddle/index.html> (accessed January 27, 2009).
- 27 U.S. Centers for Disease Control and Prevention. "Salmonella Wandsworth Outbreak Investigation, June – July 2007." <http://www.cdc.gov/salmonella/wandsworth.htm> (accessed January 27, 2009).
- 28 WGRZ. "Cost Estimate for Hepatitis A Clinics: \$500,000." WGRZ.com http://www.wgrz.com/news/news_article.aspx?storyid=55337&provider=gnews (accessed January 27, 2009).
- 29 U.S. Centers for Disease Control and Prevention. "Investigation Update: Outbreak of Salmonella Litchfield Infections, 2008." <http://www.cdc.gov/salmonella/litchfield/> (accessed January 27, 2009).
- 30 U.S. Centers for Disease Control and Prevention. "Investigation of Outbreak of Infections Caused by Salmonella Saintpaul." <http://www.cdc.gov/salmonella/saintpaul/> (accessed January 27, 2009).
- 31 Associated Press. "Growers Tally Loss to Salmonella Scare. Tomato Damage \$100 Million." *The Washington Times*, July 20, 2008. <http://www.washington-times.com/news/2008/jul/20/growers-tally-loss-to-salmonella-scare/> (accessed January 27, 2009).
- 32 U.S. Food and Drug Administration. "Melamine Contamination in China. Updated January 5, 2009." <http://www.fda.gov/oc/opacom/hot-topics/melamine.html> (accessed January 27, 2009).
- 33 U.S. Centers for Disease Control and Prevention. "Investigation Update: Outbreak of Salmonella Typhimurium Infections, 2008-2009." <http://www.cdc.gov/salmonella/typhimurium/> (accessed January 27, 2009).
- 34 DeLauro, R. Remarks at ceremony introducing legislation that would split off oversight of the food industry from the Food and Drug Administration by creating a new Food Safety Administration. Washington, D.C., February 4, 2009.
- 35 Subcommittee on Science and Technology, Science Board, U.S. Food and Drug Administration. *FDA Science and Mission at Risk: Estimated Resources Required for Implementation*. Washington, D.C.: U.S. Department of Health and Human Services, 2008.
- 36 Information provided to TFAH in private communication from Bill Hubbard, former Associate Commissioner for Policy and Planning, Food and Drug Administration, and Advisor for a Stronger FDA, March 19, 2008.
- 37 U.S. Government Accountability Office. *Food and Drug Administration – Effect of User Fees on Drug Approval Times, Withdrawals, and Other Agency Activities*. Washington, D.C.: U.S. Government Accountability Office, 2002.
- 38 U.S. Food and Drug Administration. *Food Protection Plan: An Integrated Strategy for Protecting the Nation's Food Supply*. Washington, D.C.: U.S. Department of Health and Human Services, 2007. <http://www.fda.gov/oc/initiatives/advance/food/plan.pdf> (accessed February 7, 2008).
- 39 Ibid.
- 40 Subcommittee on Science and Technology, Science Board, U.S. Food and Drug Administration. *FDA Science and Mission at Risk*. Washington, D.C.: FDA Science Board, November 2007, p. 21.
- 41 DeLauro, R. Remarks at ceremony introducing legislation that would split off oversight of the food industry from the Food and Drug Administration by creating a new Food Safety Administration. Washington, D.C., February 4, 2009.
- 42 Office of U.S. Senator Dick Durbin. "Durbin, Gregg, Bipartisan Group of Senators, Introduce Comprehensive Bill to Reform FDA's Food Safety Systems." News Release, March 3, 2009. <http://durbin.senate.gov/showRelease.cfm?releaseId=308982> (accessed March 18, 2009).
- 43 *New York Times*. "The F.D.A. in Crisis: It Needs More Money and Talent." February 3, 2008.
- 44 Bjerga, A. "Vilsack Says Single Food-Inspection Agency Needed." *Bloomberg News*, February 6, 2009.
- 45 The Institute of Medicine. *HHS in the 21st Century: Charting a New Course for a Healthier America*. Washington, D.C.: National Academy Press, 2008, p. 76.
- 46 Office of U.S. Senator Dick Durbin. "Durbin, Gregg, Bipartisan Group of Senators, Introduce Comprehensive Bill to Reform FDA's Food Safety Systems." News Release, March 3, 2009. <http://durbin.senate.gov/showRelease.cfm?releaseId=308982> (accessed March 18, 2009).
- 47 U.S. Food and Drug Administration. *Food Protection Plan: An Integrated Strategy for Protecting the Nation's Food Supply*. Washington, D.C.: U.S. Department of Health and Human Services, 2007.
- 48 U.S. Government Accountability Office. *Federal Oversight of Food Safety: FDA Has Provided Few Details on the Resources and Strategies Needed to Implement its Food Protection Plan*. Washington, D.C.: U.S. Government Printing Office, 2008.
- 49 Subcommittee on Science and Technology, Science Board, U.S. Food and Drug Administration. *FDA Science and Mission at Risk: Estimated Resources Required for Implementation*. Washington, D.C.: U.S. Department of Health and Human Services, 2008.
- 50 U.S. Government Accountability Office. *Federal Oversight of Food Safety: FDA Has Provided Few Details on the Resources and Strategies Needed to Implement its Food Protection Plan*. Washington, D.C.: U.S. Government Printing Office, 2008, p. 1-2.
- 51 U.S. Government Accountability Office. *Federal Oversight of Food Safety: FDA Has Provided Few Details on the Resources and Strategies Needed to Implement its Food Protection Plan*. Washington, D.C.: U.S. Government Printing Office, 2008, p. 10.
- 52 The Institute of Medicine. *HHS in the 21st Century: Charting a New Course for a Healthier America*. Washington, D.C.: National Academy Press, 2008, p. 75.
- 53 The Institute of Medicine. *HHS in the 21st Century: Charting a New Course for a Healthier America*. Washington, D.C.: National Academy Press, 2008, p. 79.
- 54 See, for example, GAO, *Results-Oriented Cultures – Implementation Steps to Assist Mergers and Organizational Transformations* (GAO-03-669, 2003 July).

- 55 The project is based in the Department of Health Policy at the George Washington University School of Public Health and Health Services and is being undertaken in collaboration with Trust for America's Health. For further information on this paper or the project, contact Mr. Taylor at mike.taylor@gwumc.edu or 202-994-4234 or Ms. David at Stephanie.david@gwumc.edu or 202-994-4249.
- 56 Taylor, M. and David, S. *Unifying and Elevating Food Safety Leadership at HHS – The Need for Organizational Change to Improve Food Safety* (January 2009) (available on request from the authors).
- 57 “Food Safety Modernization Act of 2009” (H.R. 875, 111th Cong. 1st Sess.), introduced by Rep. Rosa DeLauro on February 4, 2009.
- 58 Robert Brackett, former Director of FDA’s Center for Food Safety and Applied Nutrition; Gail Cassell, Member, FDA Science Board; Margaret Glavin, former FDA Associate Commissioner for Regulatory Affairs; William Hubbard, former FDA Associate Commissioner for Policy and Planning; Jim Hughes, professor, Rollins School of Public Health, Emory University and former director of CDC’s Center for Infectious Disease; Tim Jones, State Epidemiologist of Tennessee; Jeff Levi, Executive Director, Trust for America’s Health; Bob MacLeod, former FDA Director of Budget Execution; Glenn Morris, director of the Emerging Pathogens Institute, University of Florida and former CDC EIS officer and FoodNet site principal investigator; Jim O’Hara, former FDA Associate Commissioner for Public Affairs and HHS Deputy Assistant Secretary for Health; and Bob Sauer, former FDA Director of Personnel.
- 59 FSA operating units include Public Health and Science, Food Safety Prevention & Standards, Pre-Market Review, Nutrition & Labeling, Inspection & Investigations, Field Laboratories, and Compliance Policy and Enforcement.
- 60 These include Public Health and Science, Food Safety Prevention & Standards, Inspection & Investigations, Field Laboratories, Compliance Policy and Enforcement, Chief Counsel, Stakeholder Outreach, and Communications.
- 61 CFSAN has seven science divisions housed in three different offices. The Office of Regulatory Science includes the Divisions of Analytical Chemistry, Microbiology, and Bioanalytical Chemistry. The Office of Applied Research and Safety Assessment includes the Divisions of Molecular Biology, Mvirulence Assessment, and Toxicology. The Office of Regulations, Policy and Social Sciences includes the Division of Social Sciences.
- 62 CVM has three science divisions, all housed in the Office of Research, including the Divisions of Residue Chemistry, Animal Research, and Animal and Food Microbiology.
- 63 This includes from CFSAN the Office of Food Safety and elements of the Offices of Food Defense, Communication and Emergency Response; Cosmetics and Colors; and Regulations Policy and Social Sciences; and, from CVM, elements of the Office of Surveillance and Compliance.
- 64 This includes from CFSAN the Office of Food Additive Safety and elements of the Office of Cosmetics and Colors; and from CVM the Offices of New Animal Drug Evaluation and Minor Use & Minor Species Animal Drug Development and elements of the Office of Surveillance and Compliance.
- 65 It is difficult to determine the share of NCTR resources that is “food related.” NCTR does significant work that relates to medical products, and much of its research cuts across FDA product categories. The over-reporting of food-related resources in the table is more than offset by the fact that the table does not include rent and other facilities costs related to the food programs in CFSAN, CVM and ORA. A fair share of these resources would have to be allocated to the FSA.
- 66 A significant portion of the CVM budget, for example, is tied to pre-market review of animal drugs under user fee legislation and thus cannot be reallocated to address foodborne illness or other public health concerns.
- 67 For example, FDA’s San Juan, Philadelphia and Detroit labs focus on drug testing, while labs in San Francisco, Denver and Kansas City labs do more food-related work.
- 68 While CDC has created a Food Safety Office to coordinate its food safety activities, the scientists who do most of the food safety work are assigned to eight different CDC offices and programs, including the Division of Adolescent and School Health, the Division of Bacterial and Mycotic Diseases, the Division of Parasitic Diseases, the Division of Viral and Rickettsial Diseases, the Epidemiology Program Office, NCEH Environmental Health Services, Public Health Practice Program Office, and Travelers Health.
- 69 See, for example, GAO, *Results-Oriented Cultures – Implementation Steps to Assist Mergers and Organizational Transformations* (GAO-03-669, 2003 July).
- 70 Most unionized FDA employees are members of the National Treasury Employees Union or the American Federation of Government Employees.



1730 M Street, NW, Suite 900
Washington, DC 20036
(t) 202-223-9870
(f) 202-223-9871