



## **Structural Change at HHS to Improve Food Safety: A Transition Opportunity**

### **Summary**

The nation's food safety system is in crisis. A 2008 report by Trust for America's Health (TFAH) identified major gaps in the nation's food safety system, including obsolete laws, misallocation of resources, and inconsistencies among major food safety agencies. Revitalizing that system, and driving the changes in government and industry food safety practices that are needed to restore public confidence, will require sustained leadership from the Department of Health and Human Services (HHS). HHS is, however, structurally ill-equipped to provide that leadership. The Food and Drug Administration (FDA) is fragmented internally and plagued by chronically weak leadership on food safety: no FDA official whose full time job is food safety has line authority over all elements of FDA's food safety program. And the essential interaction between FDA and the Centers for Disease Control and Prevention (CDC) is not working.

The incoming Secretary should make food safety reform a high priority, and he should set a new direction from the outset by (1) establishing an empowered and accountable focal point for leadership within HHS, and (2) launching a comprehensive HHS food safety reform effort, including collaboration with Congress to modernize the food safety laws and establish within HHS a Food Safety Administration.

*To that end, TFAH urges the Obama Administration to administratively create a new position of FDA deputy commissioner for foods and senior advisor to the Secretary for food safety, a position jointly held by one person and directly accountable to the Secretary to assure integration of food safety policy and leadership within HHS. Creation of such a position would serve as an interim step prior to legislatively creating a separate Food Safety Administration with enhanced regulatory authority. It would immediately strengthen leadership on food safety within HHS on pressing matters such as produce safety and import oversight and provide a focal point for broader food safety reform efforts involving Congress, the Department of Agriculture and other elements of the administration.*

### **The Food Safety Reform Context**

#### **The Call for Reform**

The recent nationwide outbreaks of illness associated with lettuce, spinach, tomatoes and peppers, coupled with chemically-tainted fish, dairy products and pet food from China, simply underscore what experts have been saying for a long time: the government's food safety program has not kept up with dramatic change in the U.S. and global food system and is doing a poor job of preventing and responding to food safety problems.

Current food safety polices are largely based on early twentieth century laws written to deal with concerns that rarely pose significant threats today because of changes in farming and processing practices and technologies. Only one percent of imported food is inspected, while 60 percent of

produce and 75 percent of seafood consumed in the United States is imported. The federal investment in food safety has been inconsistent and misaligned; 85 percent of known food-based outbreaks fall under FDA jurisdiction, yet FDA's food safety functions receive about \$400 million less than those at USDA, with little investment in technology or research. These gaps amid highly-publicized food outbreaks have led to an erosion of consumer confidence in the federal system. A 2007 public opinion poll conducted by TFAH found that 67% of Americans are worried about food safety.

Since 1998, the National Academy of Sciences (NAS) and the Government Accountability Office (GAO) have been calling for a legislative and organizational overhaul of the food safety system, including both HHS and the Department of Agriculture (USDA), to modernize obsolete laws, overcome organizational fragmentation, and make better use of science and regulatory resources to prevent foodborne illness.

In January 2007, GAO declared the federal government's food safety program at "high risk" of failure because needed reforms have not been implemented, and, in November 2008, GAO included food safety among the 13 topics most in need of "urgent action" by the new Congress and administration.

### **Recent Legislative Reform Efforts: The Focus on HHS and FDA**

Sen. Richard Durbin and Rep. Rosa DeLauro have long supported the comprehensive food safety reform called for by NAS and GAO, including merger of the food safety programs currently lodged at the FDA and USDA into a single agency operating under a modernized, risk-based law that focuses on the public health goal of preventing foodborne illness. Sen. Durbin and Rep. DeLauro have introduced a series of companion bills to achieve this reform. Sen. Harkin has also supported food safety reform and a single food safety agency.

In the 110<sup>th</sup> Congress, Sen. Durbin, Rep. DeLauro and other congressional leaders focused their food safety reform efforts primarily on HHS and FDA, which regulates the safety of 80% of the nation's food supply, including virtually all food imports, and is widely regarded to be in the most immediate need of strengthening to be effective on food safety.

To modernize FDA's legislative mandate and authority, Sen. Durbin introduced in July 2008 a bi-partisan reform bill (S. 3385, co-sponsored by Sens. Harkin, Gregg, Dodd, Burr, and Alexander). A bi-partisan bill was also introduced in the House (H.R. 5904, introduced by Reps. Costa, Putnam, Cardoza, Nunes and Farr). Though differing in important respects, these bills both call for a potentially transformative shift in FDA's food safety program from a largely reactive approach to prevention of foodborne illness as the core purpose.

### **HHS Restructuring on the Agenda**

In July 2008, then-Senator Barack Obama introduced a groundbreaking bill (S. 3358) that addresses two of the structural problems that plague the HHS food safety program. The bill would improve how CDC interacts with FDA and other regulatory agencies and directs HHS to lead an effort to build state and local food safety capacity and better integrate state and local efforts into the national food safety system.

On September 26, 2008, Rep. DeLauro introduced a comprehensive FDA food safety reform bill (H.R. 7143) that would restructure food safety at HHS by creating a Food Safety Administration reporting directly to the Secretary and having responsibility for all HHS food safety activities.

## **The Need for Restructuring and Its Benefits**

### **The Food Safety Leadership and Management Problem at HHS**

To be successful in driving food safety reform, HHS needs a leadership and management structure that has:

- Clearly-defined management responsibility, authority and accountability;
- Capacity to deploy all HHS resources strategically in support of a coherent plan to improve food safety;
- Visibility and standing within the government; and
- Capacity for national and international leadership on food safety.

The current organizational structure for food safety at HHS is lacking on every one of these functional attributes required for success. No one is effectively in charge. Control of resources is scattered among several separately-managed organizations within and outside of FDA. The food safety program and its leadership are submerged within HHS and lack standing within the executive branch. And, as a result, there is no real focal point for HHS leadership on food safety, nationally or internationally.

The primary structural problem in the HHS food safety program lies within FDA. FDA performs its food safety regulatory functions through three separately-managed organizational units, including two headquarters units and a large field organization:

- *Center for Food Safety and Applied Nutrition (CFSA)* – the headquarters unit that makes most food safety policy for FDA, houses most of the relevant scientific capacity (except food testing capacity), and manages approval programs for food and color additives and infant formula.
- *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.

The directors of these units report to the FDA commissioner. Responsibility for coordinating implementation of FDA’s strategy for improving food safety currently rests, however, with an Associate Commissioner for Foods, who is housed in the office of FDA’s Deputy Commissioner for Operations. The Associate Commissioner for Foods, often referred to as FDA’s “food czar,” has no line management or budget authority over CFSA, CVM or ORA.

Under this leadership and management structure, there is no single official at FDA whose full time job is food safety *and* who has line and budget authority over all elements of FDA's food safety program. The FDA commissioner has the authority on paper, but the commissioner also has direct reporting relationships with the heads of the three major headquarters units responsible for regulating medical products (drugs, biologics and medical devices). The career officials who run CFSAN, CVM and ORA are able to manage activities within their own units, but none of them is empowered to mount agency-wide initiatives, coordinate activities between units, or exert food safety leadership in dealings with CDC, USDA, the food industry, foreign governments, or other key elements of the food safety system outside FDA.

The negative impact of this fragmented leadership structure on FDA's food safety program has been compounded historically by the fact that most commissioners come from a medical background and tend to focus on the medical products side of FDA's program, except in times of food safety crisis. The FDA leadership focus on medical products is understandable and will continue to be important, with the pressing need to change the FDA culture on drug safety, oversee critical medical innovation, and represent FDA in health reform. As a practical matter, however, this leaves FDA with no fulltime official who is fully in charge of the FDA food safety program and empowered to provide the on-going, senior leadership that is needed for FDA and HHS to be successful. Today, no one is realistically accountable for the success, or failure, of the FDA food safety program.

Moreover, important food safety surveillance and outbreak investigation functions of HHS are, organizationally and managerially, entirely separate from the FDA food safety program. At the federal level, these functions are performed by various offices in CDC, but without clear accountability for meeting the essential information needs of the FDA officials responsible for designing and implementing preventive measures; and federal surveillance and outbreak efforts are highly dependent on state and local agencies, which tend to be under-staffed and poorly integrated with the federal agencies.

The fragmented and disempowered leadership and management structure for food safety within HHS will make it virtually impossible for the Department to lead transformation of the national – and global – food safety system, as contemplated by the reform bills introduced in the 110<sup>th</sup> Congress.

### **The Difference a New Leadership Structure Would Make**

The proposal by Rep. DeLauro to create a Food Safety Administration within HHS would address the leadership and management problem by unifying and elevating current FDA food safety programs so that the administrator of that agency would report to the Secretary, have the responsibility and authority to lead the overall HHS food safety program, and be accountable for the program's success. Such an organizational structure would improve food safety by:

- Providing the HHS food safety program with empowered, fulltime and accountable leadership;
- Enabling HHS to speak with a single voice on food safety with the public, other federal departments and Congress;
- Improving HHS management of multi-state foodborne illness outbreaks;

- Enabling HHS to more effectively drive new regulatory initiatives, such as the promulgation of overdue produce safety standards;
- Providing a focal point within HHS for implementing administratively the recommendations in the Obama bill (S.3358) to better integrate the efforts of CDC and FDA on food safety and otherwise improve coordination of food safety data collection, research and analysis to inform food safety prevention efforts;
- Improving priority setting and the use of scarce resources to improve food safety across all HHS food safety programs;
- Providing a focal point for leadership to better integrate federal, state and local food safety efforts; and
- Strengthening the HHS and U.S. leadership position on food safety in bilateral dealings with China and other major trading partners and in the United Nations' Codex Alimentarius Commission and other international bodies.

### **Benefits for FDA's Medical Product Programs and Oversight of Tobacco**

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

Furthermore, Congress is expected in the coming year to pass a tobacco regulation bill and to lodge responsibility for this major new regulatory program with FDA. Placing FDA's food program under separate management would help clear the management decks at FDA and make it feasible for the agency to take on its new and challenging responsibility for regulating the tobacco industry.

### **Phasing In Structural Change**

Ultimately, the creation of a new Food Safety Administration within HHS would require legislation. The Secretary of HHS has substantial authority, however, to change reporting relationships within FDA and to establish new leadership positions within HHS. The Secretary could thus, by administrative order, go a long way toward unifying and elevating the HHS food safety program, thereby strengthening the Department's ability to address immediate food safety challenges while Congress develops a permanent legislative solution.

For example, the Secretary could issue a directive vesting in a single HHS official line management authority, including budget and program responsibility, for all food safety activities in HHS. The Secretary could direct that this official:

- Serve in the dual capacity of FDA deputy commissioner for foods and senior advisor to the Secretary for food safety and be directly accountable to the Secretary;
- Be housed in FDA with a charge to lead FDA food safety initiatives, including the prompt initiation of rulemaking to set produce safety standards and minimum risk-based, preventive safety standards for all foods;
- Develop a plan to integrate CFSAN, CVM and the food-related activities and resources of ORA into a cohesive food regulatory agency with an effective standard-setting, inspection and compliance program;
- Be charged with making the food safety epidemiology programs of CDC an integral part of efforts to prevent foodborne illness, as called for by then-Sen. Obama's Food-borne Illness Surveillance and Response Act of 2008 (S.3358);
- Develop a plan, including any needed legislative proposal, for better integrating federal, state and local food safety programs and ensuring that agencies at all levels have the capacity they need to manage a science-based, cost-effective food safety system; and
- Lead on behalf of the Secretary and the administration legislative efforts to modernize the HHS food safety mandate and authority and create within HHS a Food Safety Administration.

With these changes in responsibility, authority and reporting relationships, HHS could begin immediately to provide needed leadership on food safety, while taking the time to plan and implement gradually and in collaboration with Congress the permanent organizational change needed to ensure the long-term success of the HHS food safety program.

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