

**Testimony of Caroline Smith DeWaal
Representing the Safe Food Coalition
before the
Subcommittee on Health of the
House Committee on Energy and Commerce**

**Washington, DC
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Good morning Mr. Chairman, Ranking Member Deal and Members of the Subcommittee. My name is Caroline Smith DeWaal, and I am the Director of Food Safety at the Center for Science in the Public Interest (CSPI). My testimony today is offered on behalf of the consumer, public health and victim advocacy organizations listed below that are members of the Safe Food Coalition.¹

Thank you for this opportunity to talk to you about the consumer community's views on the Food Safety Enhancement Act. Let me begin by saying that we believe this is a strong bill that will improve public safety.

- It requires food companies to build safety into their processes by conducting a regular hazard analysis and instituting preventive controls;
- It provides a modern framework for food safety oversight to replace the antiquated and unworkable food safety laws that have hamstrung the Food and Drug Administration (FDA);
- It gives FDA essential new authorities and resources to carry out a new mission focused on preventing food-borne illnesses and outbreaks, including a requirement that FDA inspect food processors much more frequently than at present; and
- It addresses the issue of funding urgently needed program improvements with a modest registration fee.

Consumers want Congress to pass meaningful food safety legislation this year. Polling shows the public has lost confidence in the safety of the food supply. The percentage of consumers confident in the safety of the food supply fell to 22.5 percent earlier this year, according to The

¹ The Safe Food Coalition members endorsing this testimony are: Center for Foodborne Illness, Research and Prevention, Center for Science in the Public Interest, Consumer Federation of America, Consumers Union, Food & Water Watch, Government Accountability Project, National Consumers League, The Pew Charitable Trusts, Safe Tables Our Priority, and Trust for America's Health.

Food Industry Center.² CSPI's polling of its members confirms this, finding a majority are very concerned about food safety. With the public's trust in both government and industry in the disaster zone, consumers are demanding change.

Each year 76 million Americans get sick, 325,000 are hospitalized, and 5,000 die from food-borne disease, according to the Centers for Disease Control and Prevention (CDC). People like Ashley Armstrong, who at three years of age suffered acute kidney failure and months of dialysis after eating *E. coli*-tainted spinach, and Shirley Almer, who overcame cancer only to be felled by *Salmonella*-contaminated peanut butter. These are just two of the many victims who personally or represented by family members have testified before Congressional committees and visited your offices to tell personal stories about the tragedy of food-borne disease.

With responsibility for 80 percent of food supply, FDA's food program is a critical element in reducing this public health burden. But when foods that consumers think of as "safe", like spinach or peanut butter, become deadly, it sets off alarms for consumers. They become concerned that they can't rely on either the government or industry programs to protect their families. Two hundred illnesses and several deaths from spinach contaminated with a deadly strain of *E. coli*; two outbreaks with 1,200 illnesses and nine deaths from peanut butter tainted with *Salmonella*; pet food adulterated with toxic chemicals; imported peppers identified with almost 1,500 illnesses in 43 states – each of these tragedies has demonstrated different weaknesses in our ability to manage food safety. More importantly, these issues have confirmed for consumers and the Congress that the federal food safety system is broken. As President Obama has emphasized, "At a bare minimum, we should be able to count on our government keeping our kids safe when they eat peanut butter.... I don't want to worry about whether [Sasha's] going to get sick as a consequence of eating her lunch."

The Committee Has Built the Record for the Food Safety Enhancement Act

Since 2007, Congress has conducted 24 oversight and legislative hearings on food safety. Today's hearing is the fourth held by the Health Subcommittee on specific legislation to reform FDA. Along with being informed by extensive hearings into food safety problems and potential solutions, the bill rests on a foundation of over a decade of legislative development by its lead sponsors. Chairman Frank Pallone first introduced the Consumer Food Safety Act of 1998 in the 105th Congress. In that same term of Congress, Chairman Emeritus John Dingell introduced his Imported Food Safety Act of 1998, which eventually became the FDA Globalization Act of 2009. Those bills became the basis for the draft legislation we are discussing today, each of which have been fully vetted through hearings in this Subcommittee since 2007.

The legislation before us is also a product of Chairman Henry Waxman's leadership and concern for improving food safety. As Ranking Member and then-Chairman of the Oversight and Government Reform Committee, he investigated weaknesses in FDA's inspection system and regulatory failures in its regulation of fresh produce safety. To address problems documented in those reports, the bill provides new resources for hiring additional inspectors,

² Press Release, *Consumer Confidence in Food Safety Plunges in Wake of Peanut Butter Contamination, University of Minnesota Study Finds*, UMNews, Feb. 23, 2009, at http://www1.umn.edu/news/news-releases/2009/UR_RELEASE_MIG_5325.html.

gives FDA clear authority to set produce safety standards, and sets inspection frequencies of six to 18 months for the highest risk foods. This recognition of varying inspection frequencies reflects new recognition of the complex job that FDA is assigned, and the fact that when it comes to food, the agency can not take a “one size fits all” approach.

Beginning in 2007, Chairman Bart Stupak led a series of hearings in the Oversight and Investigations Subcommittee that investigated failures in FDA’s oversight of the food supply. Those hearings focused on major outbreaks such as melamine in pet food; *E. coli* in bagged spinach; *Salmonella* in peppers; and botulism in canned foods and identified systemic failures in our food safety laws. To name of few of the findings the hearings disclosed:

- The ability of facility managers to deny inspectors access to company records that showed contamination problems at the plant (addressed in section 106 on records access);
- The fact that facilities don’t have to report tests that are positive for pathogenic contamination (partially addressed in section 112 on the reportable food registry); and
- Questionable testing practices that allow companies to shop for a lab that is most likely to provide favorable tests (addressed in section 110 on accrediting laboratories).

Other members of the Energy and Commerce Committee, Republican and Democrat, have contributed to the bill through their insightful questioning of witnesses, willingness to negotiate agreements, and desire to ensure the safety of the American public. Certainly, we thank the Committee leadership for reaching out to take advantage of the long-standing expertise and interest of non-committee members like Rep. Rosa DeLauro in crafting this legislation. Her support is also vital to ensure that the agency is fully funded to implement its new authorities. The purpose of this too brief history is to highlight that the Food Safety Enhancement Act is a well-vetted, mature bill backed by a strong record of oversight and legislative hearings.

The bill builds on current industry practices, refocuses FDA’s role on preventing outbreaks and meets the reform criteria of consumers. We are not so naïve in our outlook as to say this legislation alone will end outbreaks, but it gets the authorities right, gives the watchdog some teeth, and puts in place a modern food safety system that will reduce the number of illnesses linked to tainted foods.

The Food Safety Enhancement Act Aligns with Consumer Goals

The strength of the bill is also measured through how it addresses specific areas of weakness at FDA. In 2007, CSPI released a white paper, “Building a Modern Food Safety System for FDA Regulated Foods.” It described 11 areas of reform that are essential to improve FDA’s ability to prevent contaminated food from sickening the public. Below, the Food Safety Enhancement Act is compared to each area identified in the white paper.

Preventive Controls: the Heart of a Modern Food Safety System

The heart of any effective reform effort lies in prevention, and fittingly the heart of the Food Safety Enhancement Act is its hazard analysis and preventive controls section. Section 102 requires every registered food plant to build safety into its processes by conducting an analysis of

biological, chemical or other hazards that may enter food it is processing. This analysis serves as a basis for implementing preventive controls. Validating, monitoring, verifying and documenting the effectiveness of the controls complete the prevention system. The system described in the legislation is built on the framework of the industry-designed Hazard Analysis and Critical Control Points (HACCP) program. It is embraced by the food industry and implemented in many food processing plants already (although not always adequately). Notably however, the bill provides important new mechanisms, like written plans and access to processing records that will allow government inspectors to review conditions in the plant over time, not just on the day when inspectors are in the facility.

The access to plant records is essential and it sets the Food Safety Enhancement Act apart from other bills by giving FDA much greater access to monitoring and verification records. It also provides FDA with authority to evaluate safety plans and direct changes where needed to protect public health. Additionally, when a company becomes aware that contaminated food has left its control, it must report that to the Reportable Food Registry along with any product or environmental sampling and testing it has done. The Committee needs to preserve and strengthen these important provisions.

Record access is a passive approach, however. Mandatory reporting of positives would permit FDA to identify potential risks, and through inspection and oversight, to avoid illnesses and deaths linked to contamination problems known to the facilities. Section 112 has helpful – but limited – authority that requires positive reporting of test results if there is a direct threat of severe adverse health consequences or death. Reporting of positives whenever they are encountered in a facility would alert FDA to potential problems. This could prevent another Peanut Corporation of America by giving FDA an early warning that problems may exist within the facility before contaminated food is put on the market. The tragedy of the recent outbreak linked to the Peanut Corporation of America clearly illustrates why the groups endorsing this testimony support the addition of a provision requiring facilities to conduct testing as part of its preventive control plan and report positives directly to FDA. Such a system of mandatory reporting is used by the Environmental Protection Agency to monitor the safety of drinking water, and it would be appropriate as a protection in the food supply as well.

As we saw in both the 2007 and 2009 outbreaks linked to peanut products, facility operators knew from internal testing that *Salmonella* was present. Yet, in neither case did they report this finding to FDA or state inspectors. With this information, inspectors would have been in a much better position to identify to potential problems and inquire about steps each facility had taken to resolve those problems.

Mandatory reporting could also alert FDA to emerging risks. Little was known of *Salmonella's* ability to survive in peanut butter prior to the 2007 outbreak. Perhaps if FDA served as a centralized repository for this information across the food industry, the agency could identify problems before an outbreak occurs. We look forward to working with the Committee on refinements that will ensure that a company like the Peanut Corporation of America will test its products and report its findings promptly to FDA.

Enforceable Performance Standards

FDA's ability to set performance standards for the most serious hazards and to require food processors to meet those standards is essential to ensure that food is produced in a sanitary manner that limits the likelihood of disease-causing contamination. When I talk to safety experts from industry, I am frequently told the biggest challenge is deciding what the best measures to evaluate a HACCP system are. But an FDA-established performance standard helps eliminate the guess work for the companies and provides a level playing field for similar products. Section 103 addresses this need by requiring FDA to review epidemiological data, identify significant contaminants, and issue performance standards that minimize, prevent or eliminate the hazard. While we would like to see a more structured program at FDA for reviewing and issuing performance standards, we believe the language in the bill is the minimum necessary and we urge the committee not to weaken it.

Inspections: Essential to Compliance

It is a common adage that you can't detect what you don't inspect. Random and frequent risk-based inspection by public officials sworn to protect public health is a necessary component of an effective food safety system. It is not surprising that with FDA's current average inspection frequency of one visit in 10 years,³ misconduct at Peanut Corporation of America (inspected by FDA once in eight years) went undetected.

This legislation, in Section 105, divides food companies into three categories based on risk, and directs FDA to inspect high-risk facilities no less than once every six to 18 months, low-risk facilities every 18 months to 3 years and warehouses at least every three to four years. These inspection rates are far lower than the monthly inspections that two-thirds of the American public, when polled on the issue by Consumers Union, believe is appropriate.⁴ While this is a vast improvement over FDA's existing program, we continue to believe that more frequent inspections than called for in this bill are needed—particularly of high-risk facilities. We understand that, though not perfect, the bill attempts to strike a reasonable balance between the realistic budget and workforce constraints at FDA, and an ideal inspection system.

However, we think it is important for the Committee to understand the need to look at the concept of risk-based inspection across the entire spectrum of food products, not just those regulated by FDA. Thus, any definition of high risk must start with the understanding that slaughter and processing raw meat and poultry are exceptionally high-risk activities. Most meat and poultry slaughter fall under USDA's responsibility and that Department is required to inspect these functions on a continuous basis. The Food Safety and Inspection Service (FSIS) is present in every plant every day. That is appropriate for meat and even seafood processing because of the risk of zoonotic disease and pathogens. FDA's responsibility with regard to meat or poultry is limited to slaughter and processing of animals and birds not specifically itemized in the FMIA and PPIA. Oversight of processing game birds and animals is FDA's primary activity in this area.

³ House Comm. on Gov't Reform, *Fact Sheet: Weaknesses in FDA's Food Safety System*, Oct. 30, 2006.

⁴ Food-Labeling Poll 2008, available online at http://www.consumersunion.org/pub/core_food_safety/006298.html.

The USDA system of continuous inspection of these high risk products provides important protection that is not in the discussion draft, and we urge the committee to address it. First the bill should explicitly recognize the need for continuous inspection of very high risk raw animal products, and second it should authorize FDA to contract with USDA to have the Agriculture Department's inspectors provide continuous inspection for the very limited number of such plants currently under FDA's jurisdiction. Such authority could be used if FDA determines that it does not have a sufficient number of inspectors to allow for continuous inspection of the small number of plants that slaughter so-called "non-amenable species" of animals, or that process raw meat from such animals for sale to the public (such as plants grinding fresh venison).

Import Certification

Imported foods make up approximately 13 percent of a typical consumer's total diet each year, and during certain seasons, the majority or virtually all of certain foods (such as some types of fresh fruits) are imported. Although USDA regulated foods are subject to certification as meeting our safety standards, no such system exists for FDA-regulated foods. Instead the agency relies on a border inspection program that captures only one in 100 shipments. As a result, imported berries, melons, peppers, even green onions, coming from areas with substandard hygiene practices, have sickened thousands of Americans.

We believe that all imported food should be produced under conditions and meet standards that apply to domestically produced foods and the bill gives FDA many new tools to meet that objective. For the first time, foreign suppliers as well as domestic ones would be required to comply with the hazard analysis and preventive controls and agricultural standards in the bill. Section 109 establishes a system for requiring certification of certain incoming products, such as high-risk foods, and foods from countries or regions with weak government controls. Such certification provides assurance from a foreign government or agent approved by FDA that the food complies with U.S. standards. Section 204 creates a dedicated corps of foreign inspectors charged with inspecting foreign facilities for compliance. Finally, under section 203, FDA can refuse to admit food from a facility or country that obstructs an inspection.

Research and Education

FDA, as a science-based agency, must have a vigorous program for research that includes a system for conducting public health assessments through improved surveillance and through improved data sharing across agencies to provide a more accurate picture of the trends, sources, demographic distribution and outcomes of foodborne disease. Section 121 requires the Secretary of Health and Human Services to conduct a public health assessment, building on existing surveillance networks that will be capable of integrating and linking multiple diverse data sources within the Department of Health and Human Services (HHS). Included with the assessment are provisions for creating a public education and advisory system (section 122) that will better define the potential impact and risk of foodborne illness. In Section 123, the agency will be required to conduct research into ways to improve food protection by investigating important food safety topics, such as multi-drug resistant pathogen strains, and by developing important research tools, such as a foodborne illness health registry. We believe the Secretary

should have clear direction to also coordinate with other Federal and State agencies on development of the surveillance system, and conduct of the health assessment, educational outreach and research.

Protecting our Produce

Since 1998, fresh fruits and vegetables have been linked to an increasing number of outbreaks. Given the central role of fresh produce consumption in a healthy diet, consumers need to be confident that raw agricultural products are safe to eat. Outbreaks from spinach, lettuce, tomatoes, peppers and sprouts in recent years have shaken that confidence. Section 104 requires FDA to write safety standards for raw agricultural products that will minimize the risk of serious adverse health consequences or death. We support these safety standards and believe they can assist farmers in managing safety to protect their customers from preventable illnesses. However, as appropriate, Congress should make clear that when setting standards, FDA should take into account the needs of small organic and small diversified farms selling to local markets.

Enforcement Tools

The bill greatly improves FDA's ability to address system failures when they occur with a variety of enforcement tools:

Mandatory Recall. Section 111 establishes authority, sought by FDA and consumer organizations, that permits the agency to order a recall of food that may cause adverse health consequences or death. It also adds additional authority to issue an emergency recall order in the case of a food item that may cause serious adverse health consequences or death.

Traceback. The current traceability system based on one-up/one-down recordkeeping has proven inadequate. Section 107 fixes gaps in the one-up/one-down system by requiring FDA to develop a system for tracing the full pedigree of a food item, with an appropriate exemption for farmers selling directly to local consumers.

Detention. The current detention provision has proven unworkable. Detention is an important precautionary authority that allows inspectors to apply their knowledge and experience to identify and prevent potentially unsafe food from entering commerce. Section 132 replaces the evidence standard that has hampered inspectors in exercising this authority with a reasonable belief standard that is more appropriate to a precautionary detention, the purpose of which is to allow time to develop evidence.

It also gives FDA needed new authorities to punish companies, like the Peanut Corporation of America, that may choose to disregard the law.

Criminal Penalties. FDA needs a greater range of penalties to punish violators. The punishment for committing a prohibited act under the Food, Drug and Cosmetic Act is one year in jail and/or fine, a Class A misdemeanor.⁵ As demonstrated by the recent case

⁵ 21 U.S.C. § 333(a)(1).

involving Peanut Corporation of America, which had annual revenues of \$17.5 million,⁶ the threat of a misdemeanor sentence and fine did not serve as a deterrent to alleged misconduct. Section 134 raises the crime of knowingly committing certain prohibited acts to a felony punishable by up to 10 years in prison and a fine.

Civil Penalties. FDA is severely restricted in the food area in its use of civil fines.⁷ Civil fines provide a flexible response to corporate misconduct that can be tailored to the violation and are available to address violations by drug and device manufacturers. These remedies are not the food side except for illegal pesticide residue. Section 135 fixes this deficiency and will permit FDA to address problems found during inspections before they fester into criminal violations.

Whistleblower Protections. Interviews with Peanut Corporation of America employees revealed they witnessed dangerous practices at the plant but did not come forward because in a small town with few employers they could not risk being fired.⁸ Personal job security should not trump protecting public health and whistleblower protections can be critical to finding and preventing an outbreak. Section 208 ensures that employees who do the right thing are protected from the threat of being fired, demoted, suspended or harassed for helping in the investigation of a violation of a food safety law.

Other Critical Considerations

A number of provisions need to be especially mentioned because they represent areas where the bill may be weakened if amended, or – conversely – could be strengthened to better protect public health.

Adulteration Standard

We agree with basing enforcement actions on the adulteration and misbranding provisions in sections 402 and 403 of the Food, Drug, and Cosmetic Act. Many of the food safety bills currently being discussed rely on the prohibited acts section, which would limit the use of enforcement tools discussed above such as detention, seizure, and mandatory recall. Importantly, using the prohibited acts section – rather than adulteration or misbranding – would provide FDA with little ability to respond to unsafe imports. We urge the committee to resist changes that would weaken enforcement of sections 101, 102, 103, 104, and 109.

Registration Fees

Registration fees should not be allowed to supplant appropriations for FDA as the principle support for food safety activities. The registration fee, as proposed in section 101 is appropriate, and at \$1,000 per facility should provide FDA with an additional \$325 million in resources for food safety activities.⁹ Consumers greatly prefer registration fees over inspection

⁶ Peanut Corporation of America Company Profile, Bizjournals.com, (accessed Feb. 3, 2009), at <http://www.bizjournals.com/gen/company.html?gcode=904819E282CB4C8B9DAE476F9A3F632D>.

⁷ Civil penalties for pesticide residue are found at 21 U.S.C. § 333(f)(2).

⁸ Dahleen Glanton, *Inside 'Nasty' Nut Processor: Ex-employees Say Rodents, Roaches and Mold Commonplace*, Chicagotribute.com, Feb. 3, 2009.

⁹ Based on a reported 325,000 domestic and foreign facilities currently registered with FDA.

fees and the food industry should as well.¹⁰ If the prevention efforts and government oversight reduced the likelihood of an outbreak, it would pay off for any company producing an impacted product – for example, all spinach or peanut butter processors – that are saved from losses at the time of a recall and, most importantly, consumers who experience the medical costs, lost work and suffering of an illness.

Let's put the \$1,000 registration fee into context. To promote their brands, Kraft General Foods spent \$1.5 billion, General Mills spent \$955 million, and ConAgra foods spent \$384 million on advertising in 2007. That same year, the outbreak of *Salmonella* Tennessee in Peter Pan peanut butter cost ConAgra in excess of \$140 million.¹¹ Meanwhile, in the Peter Pan outbreak, the Economic Research Service estimates that the average cost per victim reporting an illness was \$2,650.¹² Clearly, a \$1,000 fee on each facility is more than reasonable, and hardly sufficient to cover the costs of the food safety activities of FDA. As structured, the registration fee provides the government with resources equal to much less than the advertising budget of a single major food processor and yet cost each facility less than half of the average cost borne by a single victim.

Moreover, claims that food safety activities are a public good for which the industry receives little benefit are wrong. As Congressional investigations and hearings have documented, when resources fall short of needs at FDA, broad segments of the food industry suffer collaterally from outbreaks and recalls. Weak oversight results in an uneven playing field for good processors when bad actors – realizing the risk of detection is slight – scrimp on safety and undercut their more responsible rivals.¹³ To the extent registration fees support additional food safety activities, industry will benefit from better safety oversight.

Improving Oversight of Antibiotic Resistance in Agriculture

The food safety challenge in the United States is compounded by the growing crisis of antibiotic resistance. Many antibiotic-resistant strains of bacteria include those that cause common food-borne illness. For example, nearly 1.4 million people in the U.S. contract *Salmonella* infections annually, and of those, roughly one-fifth (272,000) of the infections are antibiotic-resistant. There are about 2.4 million *Campylobacter* infections in the U.S. annually, and roughly half (more than 1.2 million) of those are resistant to at least one antibiotic. The World Health Organization, American Medical Association, American Public Health

¹⁰ Among the organizations endorsing this testimony, there were diverse opinions on the appropriateness of a flat fee for registration. Several groups, including Food & Water Watch and Safe Tables Our Priority, support a sliding scale based on the production volume of a facility.

¹¹ Mike Hughlett, *E. coli Outbreak Kills Meat Company: Huge Costs Seen in Fixing Problems*, The Chicago Trib., Oct. 6, 2007, http://www.chicagotribune.com/features/lifestyle/health/chi-sat_toppsoct06,1,4231570.story.

¹² Estimated using the USDA Economic Research Service cost calculator and accounting for the hospitalization of 20 percent of the 628 reported illnesses, as reported by the Center for Disease Control and Prevention. The cost calculator may be accessed at http://www.ers.usda.gov/Data/FoodBorneIllness/salm_intro.asp.

¹³ The outbreak caused by lax safety at Peanut Corporation of America is estimated to have cost peanut producers \$1 billion in lost profits and sales. Elizabeth Weise, *Salmonella Outbreaks Lead to Food-safety Changes*, USA Today, April 2, 2009, at http://www.usatoday.com/news/health/2009-04-01-nuts-salmonella-food-safety_N.htm. Other segments of the peanut industry also suffered with sales of peanut butter reportedly falling 13 percent in the four week period ending Feb. 21 relative to the same period in 2008. *Consumers Still Shun Peanut Butter*, Wall Street Journal, March 11, 2009.

Association, Pew Commission on Industrial Farm Animal Production, and others point to the overuse of human antibiotics in food animal production as one important contributing factor in the rise of antibiotic resistance, and call for limits on non-therapeutic, or non-disease-treating, uses of human antimicrobials in farm animals. We therefore urge the Committee to include language in the food safety bill that would help to address this serious problem.

GRAS

We are grateful for the effort at improving the transparency and reporting of generally regarded as safe (GRAS) determinations. GRAS substances are a special class of food additives that do not require prior approval by FDA. Instead, food processors may self-affirm that they are safe for the intended use or can apply to FDA for a determination. Under section 142, FDA is required to post the notice and scientific justification for declaring a proposed substance as GRAS on its website. This is a positive first step, but we believe the section as drafted falls short of protecting the public from largely unregulated and potentially dangerous substances. A better approach would be to define safety in terms of health consequences (such as obesity, heart disease, and allergic reaction), require companies to submit a petition for a GRAS determination at least 180 days before using the substance in food, and make the notice and supporting data available for public review. This brief allowance for a reasonable review of a GRAS determination would not slow innovation or prevent use of genuinely safe additives. Failing to make these changes, however, will leave open a door for exposing the public to increased risk for preventable diseases from the food it consumes.

Preemption

Changes made to section 4 make the section unclear and should be reversed. As currently written, it may have an unintended consequence of permitting industry to argue in court that more protective state food safety laws are preempted by FDA actions. A preemption argument was used in *People v. Tri-Union Seafoods* to overturn California's labeling law with regard to methylmercury in canned tuna. While the decision appears anomalous, we are nonetheless concerned it represents a wakeup call for consumers that preemption arguments may become more prevalent in state food safety litigation. Moreover, the language will apply to all areas of FDA regulation, such as drug litigation where preemption continues to generate controversy. Since the preemption issue is controversial and presents an area of special concern to consumers, we urge that you return to the clearly stated non-preemption language that appeared as section 4 of the FDA Globalization Act.

Conclusion

The new legislation provides a new framework for FDA's regulation of the food supply that will deliver many benefits to consumers. We believe that these new authorities will help reduce the incidence of outbreaks and recalls, and over time will help to increase consumer confidence in the food supply.

But in terms of modernizing our antiquated government approach to food safety, Congress and the Obama Administration will need to go beyond giving FDA more authority and funding. Structural reforms are also essential. Although FDA is responsible for the safety of 80

percent of the food supply, the FDA's commissioner must divide her attention among drugs, medical devices, foods and cosmetics – and food issues frequently fall to the bottom of the pile. Food responsibilities are divided among at least three centers within FDA, and there is no single food safety expert in charge of the policies, budget and enforcement staff. This means there is no single credible voice communicating to the public and the industry what can be done to prevent outbreaks. Food safety monitoring within HHS should be separated from drug and device approvals. The agency needs to be divided in two, with a new Commissioner of Food and Nutrition Policy who reports directly to the HHS Secretary. Food safety functions under the Department of Agriculture have this sort of direct reporting, leading to greater involvement by the Secretary of Agriculture when problems arise in the meat area.

But, we understand and respect the Chairman's decision to address the immediate problems in FDA and leave structural changes for later legislation. The Chairman's vision, embodied in the Food Safety Enhancement Act is clear, precise and effective. Earlier this year, members of the Energy and Commerce Committee made commitments to the victims of the Peanut Corporation of America outbreak that change would come to FDA. It is time to move forward with strong legislation that will prevent outbreaks by requiring safety to be built into the processing of food. We believe the Food Safety Enhancement Act is such a strong bill. We urge the Subcommittee and the Committee when they mark up this legislation to reject weakening amendments that would undermine public safety. We urge Congress to pass the Food Safety Enhancement Act.