



**Testimony of Caroline Smith DeWaal**  
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**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 Committee. My name is Caroline Smith DeWaal, and I am the director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 950,000 subscribers to its *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

Thank you for this opportunity to speak about the lessons learned from the most recent outbreak linked to peanut products and how Congress can address these problems. This massive outbreak caused confirmed illnesses of nearly 700 people and the likely deaths of nine from tainted peanut products. Clearly, we don't need further evidence that the food safety system is broken. Much of my presentation today will focus on the recommendations I have made in prior testimony and the proposals in "Building a Modern Food Safety System for FDA Regulated Foods," which CSPI released in 2007.

The Food and Drug Administration (FDA) is operating under an antiquated legal structure. The Federal Food, Drug and Cosmetic Act of 1938 gives FDA responsibility for regulating the safety of 80 percent of the food supply. But this statute is marred by its reactive posture, giving the agency authority to act principally when food is found to be adulterated or misbranded. Even its enforcement provisions, which are more focused on economic adulteration, will likely prove inadequate to address the facts in this case – with evidence that the management intentionally released products believed to have killed nine people.

It is time for Congress to address long-standing deficiencies that are causing a crisis in consumer confidence. In the wake of the Peanut Corporation of America (PCA) outbreak, the University of Minnesota's Food Industry Center reported that only 22.5 percent of consumers were confident the food supply is safer today than a year ago.<sup>1</sup> In another poll released last month, 48 percent of those questioned by Consumers Union in November said their confidence

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<sup>1</sup> *Consumer Confidence in Food Safety Plunges in Wake of Peanut Butter Contamination, University of Minnesota Study Finds*, UMNews, Feb. 23, 2009.

had declined.<sup>2</sup> In July 2008, in the midst of a *Salmonella* outbreak attributed to tomatoes/peppers, an Associated Press-Ipsos poll found that 46 percent of people were worried that they might get sick from eating tainted products.<sup>3</sup> Last fall, a poll conducted by Ipsos-McClatchy reported that 28 percent of those polled believed food safety had gotten worse and 46 percent gave food safety controls a failing grade.<sup>4</sup>

Most specific foods have a high “elasticity of demand,” meaning that shoppers simply switch from one food to another when they lose confidence due to an outbreak or recall. This can have adverse health effects if repeated outbreaks in the fresh vegetable sector, for example, cause consumers to repeatedly switch away from these healthy food choices. And it is felt by the industries that experience losses in the market of hundreds of millions of dollars.<sup>5</sup> Even companies that are not named in a recall experience reduced demand and increased costs, especially if they increase advertising to differentiate their products in the face of a massive product recall, as we observed in the PCA recall.

Since 2007, Congress has conducted 19 oversight and legislative hearings on food safety. These hearings, many within this committee, followed outbreaks caused by spinach tainted with *E. coli* O157:H7, chili sauce canned with deadly botulism spores, and pet food ingredients intentionally adulterated with melamine. In every case, the hearings revealed flaws both in the food manufacturers’ processes and in FDA’s oversight.

With evidence of both unintentional and intentional contamination leading to large-scale outbreaks, it is little wonder the Government Accountability Office has placed food safety in its high risk category three years in a row.<sup>6</sup> The need for action is clear and Congress has developed an excellent record of the gaps and deficiencies that should be addressed.

The first lesson of the 21<sup>st</sup> century is that deregulation doesn’t work. FDA’s approach of relying on what amounts to a food safety honor system is clearly not effective to protect consumers from food-borne illness. It is essential that Congress give FDA strong authority to oversee the safety of the food supply.

### **Peanut Corporation of America: Case Study of a Broken Food Safety System**

The *Salmonella* Typhimurium outbreak caused by PCA is only the latest – and certainly not the last – incident pointing to failures in FDA’s authority. The outbreak is a case study in what is wrong with our food safety system.

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<sup>2</sup> Food-Labeling Poll 2008, Consumer Reports National Research Center, NRC #2008.18, Nov. 11, 2008.

<sup>3</sup> *Tomato growers: Salmonella scare damages industry*, USA Today, July 19, 2008.

<sup>4</sup> Jane Byrne, *US Consumers Concerned About Safety of Food Imports: Poll*, FoodUSA.navigator.com, Oct. 22, 2008, at <http://www.foodnavigator-usa.com/layout/set/print/layout/set/print/content/view/print/224119>.

<sup>5</sup> See, Craig Schneider, *Peanut Creditors Expect Losses; Producer Bankrupt by Salmonella Owes Ga. Businesses*, Atlanta Journal-Constitution, March 7, 2009; Elizabeth Weise & Julie Schmit, *Spinach Recall: 5 Faces. 5 Agonizing Deaths. 1 Year Later.*, USA Today, Sept. 20, 2007.

<sup>6</sup> Gov. Acct. Off., *High Risk Update: Revamping Federal Oversight of Food Safety*, Rep. No. GAO-09-271, Jan. 2009.

## **1. PCA Could Engage in Improper Acts Without Fear of Being Caught**

Because FDA doesn't require companies to have a plan to prevent hazards commonly linked to similar products, the company could engage in what is likely criminal behavior without fear of discovery. Although state agencies visited the plant several times a year, its inspections were only a spot check. Without a written plan and the records to back up the plan, the agency's inspectors lacked information needed to fully assess conditions in the plant.

## **2. PCA Could Hide Its Positive Test Results from Inspectors**

PCA's management intentionally shipped contaminated product on 12 separate occasions because there was no reason to fear regulatory consequences. Georgia inspectors could not determine that *Salmonella* had been detected in the plant because they lacked the ability to require companies to share their production records. Meanwhile, PCA routinely ignored positive *Salmonella* tests and retested samples to get a negative result in the interest of invoicing product.<sup>7</sup> Under the Bioterrorism Act, FDA may only request records when there is a food emergency and it has clear evidence food is adulterated and presents a threat of serious adverse health consequences or death.<sup>8</sup> In most cases, this compels records production only after an outbreak has occurred. It is not sufficient to prevent outbreaks in advance of product release.

## **3. The Absence of Federal Inspections and Inadequate State Inspections Let Problems at PCA Fester**

FDA's last inspection of the PCA plant was in 2001. In 2006, it contracted with the Georgia Department of Agriculture (GDA) to conduct inspections for the federal agency. The GDA cited the plant for unsanitary conditions many times between 2006 and 2008. However the state inspections proved inadequate, failing to find the numerous problems a more thorough FDA inspection turned up in January.

Following the outbreak, FDA conducted an inspection and found numerous deficiencies, such as roaches, mold, dirty utensils and equipment, and open gaps in the roof and doors that allowed rain and rodents access in to the building.<sup>9</sup> The plant was operating in such poor conditions that workers at the plant had to step over puddles of water inside the building after a heavy rain, an environment allowing *Salmonella* to thrive.<sup>10</sup>

### **Elements of a Modern Food Safety System: Moving Forward to Protect Consumers**

The PCA outbreak – like countless episodes in the previous decade – illustrates numerous failures and areas where improvements are needed. The company seemed to have had no food

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<sup>7</sup> See, *The Salmonella Outbreak: The Continued Failure to Protect the Food Supply*: Hearing before the House Subcommittee on Oversight and Investigations, 111<sup>th</sup> Cong. (2009) (October 6, 2008 email from Stewart Parnell to Sammy Lightsey).

<sup>8</sup> *Regulatory Failure: Must America Live with Unsafe Food?*: Hearing before the House Subcommittee on Oversight and Investigations, 110<sup>th</sup> Cong. (2008) (Statement of Dr. Stephen F. Sundlof, Dir., Center for Food Safety and Applied Nutrition); 21 U.S.C. 350c(a).

<sup>9</sup> FDA, *Peanut Corporation of America Inspection Report*, Feb 4, 2009.

<sup>10</sup> Michael Moss, *Peanut Case Shows Holes in Safety Net*, N.Y. Times, Feb. 8, 2009.

safety operating plan. It did not respond appropriately to repeated positive *Salmonella* findings. The state of Georgia failed to provide effective inspection, in part because its inspectors lacked full access to the plant's food safety records, and in part because FDA failed to provide oversight for the state inspection program. Finally, the penalties available to FDA to prosecute the company are not adequate to deter future violations of the Act.

### **1. Preventive Controls Are the Heart of a Modern Food Safety System**

The heart of any effective reform effort lies in prevention, not response. Congress should require every food plant regulated by FDA to have food safety plans detailing that it has analyzed its operations, identified potential hazards, and is taking steps to minimize or prevent contamination. This Hazard Analysis and Critical Control Points (HACCP) style planning is already a requirement for all meat and poultry plants, and it should be a prerequisite for all food processors that want to sell food in the U.S. This establishes the industry's fundamental responsibility for ensuring food safety and provides a foundation for government audit inspections. However, the history of these programs in the seafood area demonstrates that Congress must also give FDA the authority and funding to enforce compliance through regular inspections with evaluation of the plan's implementation and access to company processing and testing records.

### **2. Enforceable Performance Standards Are Essential to Effective Preventive Controls**

FDA needs the authority to set performance standards for the most hazardous pathogens and to require food processors to meet those standards. The standards are used to ensure that food is produced in a sanitary manner that limits the likelihood of contamination by pathogens, chemicals, or physical hazards, like glass or metal. In the case of PCA, performance standards would have provided inspectors with a benchmark for regular sampling of products.

Combining HACCP planning with performance standards would focus food safety activities on prevention and permit more efficient and effective government oversight through analysis of records as well as visual and laboratory inspection.

### **3. Regular and Frequent Inspections Will Assure Compliance**

The failures to detect and correct the unsafe practices at PCA highlight how FDA's infrequent inspections (averaging one visit in 10 years)<sup>11</sup> and the agency's deficient oversight of state-contracted inspections contribute to illness outbreaks. Even when FDA received a clear signal of problems in the plant from its own import alert system, the agency failed to send its inspectors to conduct a review of the plant and instead relied on state inspectors.

To address these problems, legislation should set specific inspection frequencies for all food plants. Higher-risk foods should be inspected at a greater frequency, preferably no less than annually, with lower risk food facilities being inspected at least once in any two year period. Those rates would still be well below the rate established for restaurant inspections of once every

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<sup>11</sup> House Comm. on Gov't Reform, *Fact Sheet: Weaknesses in FDA's Food Safety System*, Oct. 30, 2006.

six months.<sup>12</sup> The rate is also far less than the monthly inspection rate many consumers, when polled on the question, believe is appropriate.<sup>13</sup>

Setting frequencies will require a commitment to fund the agency or find new resources, and some legislative proposals have established a modest registration fee to offset the costs associated with increased inspection oversight. Current FDA funding shortfalls have reached a critical level, leaving the agency with fewer inspectors, even as the workload continues to increase. Since 1972, domestic inspections conducted by FDA declined 81 percent.<sup>14</sup> Just since 2003, the number of FDA field staff dropped by 12 percent, and between 2003 and 2006, there was a 47 percent drop in federal inspections.<sup>15</sup> Just those declines in inspectors and inspections can be traced to an ongoing funding shortfall in the food safety program estimated in the hundreds of millions of dollars.<sup>16</sup>

Improving inspections will also require a different approach. FDA should rely on written records maintained by the plants, including a written food safety plan and the processing records that support that plan. While these records may differ by the type of plant, FDA inspectors need to be able to see sampling results and corrective actions taken in response to production problems.

PCA clearly showed the risk posed to the public in not giving FDA and state inspectors access to records, but the same evidence was presented to this Committee in 2007 after another outbreak linked to peanut butter products.<sup>17</sup> Relying on the Bioterrorism Act to provide records access for food inspectors is too little, too late. Congressional action is warranted and urgent to prevent future problems.

With regard to the shortcomings in state inspection, we must avoid drawing the wrong conclusions. Instead of illustrating that Federal/State cooperation is unreliable, the PCA example argues for improving federal oversight of and assistance to state inspectors who are used to leverage resources for inspections.

In addition to leveraging inspection resources, state health departments are the front line for detecting outbreaks. The Minnesota Department of Health with its innovative approach to epidemiology determined that peanut products were the source of the outbreak.<sup>18</sup> Yet, many states do not have the resources to establish programs modeled on Minnesota's. Congress needs to strengthen the state inspection and surveillance system by providing assistance through

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<sup>12</sup> Center for Science in the Public Interest, *Dirty Dining: Have Reservations? You Will Now.*, 2008, at <http://cspinet.org/new/pdf/ddreport.pdf>.

<sup>13</sup> Food-Labeling Poll 2008, *supra* note 2.

<sup>14</sup> Fact Sheet, *supra*, note 11.

<sup>15</sup> Andrew Bridges & Seth Borenstein, *AP Investigation: Food Safety Inspections Lanquish*, Associated Press, Feb. 29, 2007.

<sup>16</sup> FDA Science Board Subcomm. on Tech., *FDA's Mission at Risk: Estimated Resources Required for Implementation*. Feb. 25, 2008.

<sup>17</sup> *Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?*: Hearing before the House Subcomm. on Oversight and Investigations 110<sup>th</sup> Cong. (2007).

<sup>18</sup> Julie Schmit & Elizabeth Weise, When Food Illnesses Spread, Minnesota Team Gets the Call, USA Today, at [http://www.usatoday.com/money/industries/food/2009-03-04-food-illness-detection\\_N.htm](http://www.usatoday.com/money/industries/food/2009-03-04-food-illness-detection_N.htm) (accessed March 10, 2009).

training and grants.

#### **4. Import Requirements**

Americans eat about 260 pounds of imported foods – approximately 13 percent of their total diet – each year. While imported meat and poultry products must be certified by USDA as meeting safety standards equivalent to those applied to domestic meat and poultry, no such system exists for FDA regulated foods. Imported fruits and vegetables, for example, have caused numerous large and sometimes deadly outbreaks. Imported berries, melons and green onions, coming from areas with substandard hygiene practices, have alone sickened thousands of Americans in the last 10 years. Last year, peppers and possibly tomatoes from Mexico were implicated in an outbreak that caused more than 1,400 illnesses and contributed to two deaths.<sup>19</sup>

FDA must have the authority to establish a system under which imported food is certified as meeting the same food safety standards for production, inspection, labeling, and consumer protection that domestic products must meet. This authority should:

- Require FDA to review and audit foreign national food safety programs regularly;
- Impose strict conflict-of-interest requirements on private third party auditors, where used;
- Allow FDA to withdraw certification from a national or third-party auditor if a food product is linked to an outbreak of human illness or if the foreign importer no longer meets equivalency standards; and
- Give FDA authority to enter and inspect foreign plants and the ability to refuse imports from countries or facilities that obstruct FDA inspections and investigations.

#### **5. Research and Education**

Today, FDA conducts limited research related to pathogenic microorganisms and other contaminants that threaten the safety of food. More FDA-directed research is needed, however, to support both FDA regulatory programs, state food-safety agencies and the food industry. The program of research should include a public health assessment with improvements to our surveillance system, such as stronger coordination and assistance to state programs. Research into effective control and prevention strategies and tools is vital to improving techniques for monitoring and inspecting food. This must include research into more efficient, sensitive and faster methods for detecting contaminants and reducing harmful pathogens. Education efforts should encompass instructions for food preparers in the safe handling of food, and for health professionals to improve diagnosis and treatment of food-related illness and to advise individuals at special risk.

#### **6. On Farm**

Since 1998, fresh fruits and vegetables have been linked to an increasing number of outbreaks. Given the importance of produce consumption and its central role in a healthy diet, it

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<sup>19</sup> Centers for Disease Control, *Investigation of Outbreak of Infections Caused by Salmonella Saintpaul*, Aug. 22, 2008, at <http://www.cdc.gov/salmonella/saintpaul/archive/082208.html>

is imperative that FDA have authority to set specific, mandatory standards that apply to farmers who grow food for human consumption.

## **7. Mandatory Recall**

CSPI believes that giving FDA authority to order a recall if necessary is a critical tool for responding to future outbreaks. Today, when you see the notices of the recall, they often mention that it is voluntary. Unfortunately, while true, this may not compel consumers to act with urgency, because they might reason “If it were serious, FDA would issue a mandatory recall.”

## **8. Traceback**

A traceability system is a recordkeeping system for tracking the flow of product through the production process or supply chain.<sup>20</sup> It should be mandatory across all points and have (1) the *breadth* to catalog each processing step that implicates safety, (2) the *depth* to identify all handlers as well as the ultimate source of the product and its ingredients, and (3) the *precision* to pinpoint the movements of a particular item of food.<sup>21</sup> The current system established under the Bioterrorism Act was inadequate for tracing fresh produce during the *Salmonella* Saintpaul outbreak from April-July 2008, further documenting the need for new traceability requirements.

## **9. Detention**

If an FDA inspector has reason to believe that a domestic or imported food is unsafe, adulterated or misbranded, the agency must have the authority to temporarily detain the food for a reasonable time. The current detention standard of credible evidence has proven too high and unworkable. Detention is an important precautionary authority that allows inspectors to serve like cops on the beat by acting based on their knowledge and experience to prevent unsafe food from entering commerce.

## **10. 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.<sup>22</sup> This punishment, which may have been substantial in 1938, has not kept pace with the modern commercial world. Compared to PCA’s annual revenues of \$17.5 million<sup>23</sup> it is hard to see how the threat of a misdemeanor fine serves as an incentive for companies to improve their food safety practices. With over 600 people reported sick, more than 100 hospitalized and nine dead as a result of PCA putting contaminated product on the market, a misdemeanor charge seems trivial and unfair to the victims. The Committee should consider updating the criminal penalties to make it a felony punishable by up to five years in prison if people are injured by the violation, and 10 years in prison if people die.

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<sup>20</sup> USDA, *Traceability in the U.S. Food Supply: Economic Theory and Industry Studies*, Econ. Research Serv., March 2004.

<sup>21</sup> Breadth, depth, and precision are the key characteristics of good traceability systems. Id. at 3.

<sup>22</sup> 21 U.S.C. § 333(a)(1).

<sup>23</sup> Peanut Corporation of America Company Profile, Bizjournals.com, (accessed Feb. 3, 2009), at <http://www.bizjournals.com/gen/company.html?gcode=904819E282CB4C8B9DAE476F9A3F632D>.

Criminal liability should not be the only option. It is a burden on the agency inspectors, as they must conduct a criminal investigation, coordinate prosecution with the Justice Department, and then go through a criminal trial.<sup>24</sup> For lesser offenses, Congress should provide FDA with authority to impose substantial civil penalties that can get the attention of managers and stockholders, and that can be sustained if violations are continuous. Civil liability provides a flexible response to corporate misconduct that can be tailored to the violation. These remedies are available for addressing violations on the drug and device side of FDA, but not the food side except for illegal pesticide residue.<sup>25</sup> It is time to bring FDA's penalties for food violations in line with what is used for drugs and medical devices.

## **11. Whistleblower**

When an employee or inspector sees problems they should report them. But when reporting may mean loss of a job, a person can be faced with a difficult dilemma – especially in these hard economic times. Interviews with PCA 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.<sup>26</sup> Perhaps if whistleblower protections had been in place, and PCA workers could have informed officials of conditions in the plant without fear of retribution, it might have triggered a clean up of the plant, prevented the outbreak from occurring, and ultimately saved both the company and their own jobs. Employees must be protected from the threat of being fired, demoted, suspended or harassed as result of providing information or assisting in the investigation of a violation of a food safety law.

## **Conclusion**

President Barack Obama has promised a "government that works," and recently promised a complete review of FDA's food safety program. Luckily for the President and the public, Congress has been investigating problems at FDA for several years, and many elements of a reform plan are "shovel ready" – they could be accomplished quickly and deliver real benefits to consumers.

But to deal with the root of the problem, 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 his or 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 credible voice communicating to the public and the industry what can be done to prevent outbreaks.

It is time to elevate the food monitoring function within the Department of Health and Human Services (HHS), which oversees FDA. The agency needs to be divided in two, with a

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<sup>24</sup> For a description of FDA's procedures for prosecuting a case see section 6-5 of the FDA Regulatory Procedures Manual.

<sup>25</sup> Civil penalties for pesticide residue are found at 21 U.S.C. § 333(f)(2).

<sup>26</sup> Dahleen Glanton, *Inside 'Nasty' Nut Processor: Ex-employees Say Rodents, Roaches and Mold Commonplace*, Chicagotribute.com, Feb. 3, 2009.

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.

Now is the time for Congress to fundamentally reform and fully fund our food safety system. Enactment by the end of this year should be the goal. Two years ago, Congress expressed its commitment to adopt a modern regulatory oversight program and fund it adequately to fulfill its mission in the Food and Drug Administration Amendments Act of 2007.<sup>27</sup> Last month, members of this committee made commitments to the victims of the current outbreak that change is coming 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. With both the public and the regulated industries clamoring for change there is no reason to delay. Preventing future illnesses and deaths is within our grasp.

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<sup>27</sup> Food and Drug Administration Amendments Act of 2007, Pub. L. 110-85 § 1005, 121 Stat. 823, (2007).