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Testimony of Caroline Smith DeWaal
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before the
Senate Committee on Agriculture, Nutrition, and Forestry

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Good morning Mr. Chairman, Ranking Member Chambliss 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.

The Time to Repair our Food Safety System Is Now

Thank you for asking me here today to discuss the lessons learned from the latest food-borne disease outbreak linked to peanut products produced by the Peanut Corporation of America (PCA). Let me say that the first lesson we have learned is that the American public cannot wait any longer for solutions to address a seriously broken food safety system.

Over the last two years Congress has conducted seventeen oversight and legislative hearings on food safety that followed outbreaks caused by spinach tainted with *E. coli* O157:H7, peanut butter contaminated with *Salmonella* Tennessee, canned chili sauce with deadly botulism spores, and pet food containing ingredients intentionally adulterated with melamine. In every case, the hearings revealed flaws both in the food manufacturers' processes and in the Food and Drug Administration's oversight. With evidence of both unintentional and intentional

contamination leading to large-scale outbreaks, it is little wonder the Government Accountability Office has highlighted the inadequate state of our food regulatory system and placed food safety in its high risk category three years in a row.[1]

Successive outbreaks caused by tainted spinach, lettuce, salad mixes, tomatoes, peppers, pot pies, peanut butter, ground beef, chili sauce, and now numerous products made with contaminated peanuts have demonstrated that our hundred-year-old legal foundation and outdated strategies are inadequate to protect our citizens. Twenty-month-old "CJ" Minto from Mobile, Alabama, contracted *Salmonella* poisoning after eating peanut butter cracker sandwiches that are now part of the recall.[2] CJ's symptoms continued for two weeks, including one week when the child was unable to eat. He was treated with antibiotics for nearly constant diarrhea and vomiting until he resumed eating. Believe it or not, CJ was luckier than some. Shirley Mae Almer was a 72-year old survivor of cancer surgery and radiation therapy. Her family planned to bring her home from a nursing home for Christmas, but she died on December 21 from salmonellosis linked to the peanut butter. A family member said that the death seemed so ironic, "With all the battles she overcame- to have a piece of peanut butter toast take her."[3]

The evidence that FDA reform is needed has been crystal clear in Congressional hearings, victims' stories, and stakeholder agreements. I think you will hear from all the witnesses today that the time for reform is now. Let's begin. And, let's get it right.

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[1] Gov. Acct. Off., *High Risk Update: Revamping Federal Oversight of Food Safety*, Rep. No. GAO-09-271, Jan. 2009.
[2] Jane Akre, Salmonella Victim Speaks Out, Injuryboard.com, Jan. 30, 2009, *at* http://www.injuryboard.com/national-news/salmonella-victims-speak-out.aspx?googleid=256366.
[3] David Shaffer, *Heartbreak Lawsuit; The Family of a Perham, Minn., Woman Who Died of a Salmonella Infection is Suing a Peanut Butter Manufacturer and Asking for Safer Food*, Minn. Star Tribute, Jan. 27, 2009.

Peanut Corporation of America Is the Latest Proof of a Broken Food Safety System

The outbreak of *Salmonella* Typhimirum started in September 2008. The illnesses peaked in December 2008, affecting consumers in 43 states. Though the illnesses have declined since the first announcement on January 10, 2009 that the suspected cause was peanut butter, they have not abated. The *Salmonella* strain has been linked to contaminated products from Peanut Corporation of America. As of January 29, 2009, there have been eight deaths and 550 illnesses linked to PCA's products.[4]

The Peanut Corporation of America supplied peanut butter to nursing homes, schools, hospitals and other institutions, and made peanut paste which became an ingredient in many products. Starting in June 2007, PCA's Blakely, Georgia plant began detecting *Salmonella* in its products and over the next year had 12 occasions when it shipped products that had initially tested positive for *Salmonella*. In each of these 12 separate occasions, instead of addressing the source of the contamination, PCA retested its products to obtain a negative result and then shipped the product.

During this same period, Georgia state inspectors, acting under contract with the FDA, detected a number of violations, but the tests conducted by the state in 2007 failed to detect any contaminants. Georgia inspectors were apparently unaware of the company's own positive tests.

In April 2008, Canada rejected a shipment of peanuts from PCA as unfit for food. PCA attempted to clear the peanuts for sale in the U.S., but FDA rejected its test results and eventually the peanuts were destroyed. FDA did not follow up with an inspection of the plant.

During this period, PCA distributed the contaminated products to more than 100 consignee firms. The peanut paste was used as an ingredient in hundreds of different products,

[4] Centers for Disease Control, *Investigation Update: Outbreak of Salmonella Typhimurium Infections, 2008–2009*, (accessed Feb. 3, 2009) at http://www.cdc.gov/salmonella/typhimurium/update.html.

such as cookies, crackers, cereal, candy, and ice cream.

What Must Be Done to Repair Our Food Safety System

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 safety operating plan. The company did not respond appropriately to repeated positive *Salmonella* findings. The state of Georgia failed to provide effective inspection, in part because they lacked full access to the plant's food safety records, and FDA failed to provide oversight for the state inspection program. In fact, even when FDA received a clear signal of problems in the plant from its own import alert system, the agency failed to send out inspectors to conduct a review of the plant. Finally, the penalties available to FDA to prosecute the company are not adequate to deter future violations of the Act.

1. Absence of a Food Safety Plan and Response to Positive Test Results

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 the 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 and access to company records.

Additionally, 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.

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

2. The State of Georgia and FDA did not provide effective inspection oversight

The failures to detect and correct the unsafe practices at PCA highlight how FDA's infrequent inspections (averaging one visit in 10 years)[5] and the agency's oversight of state-contracted inspections contribute to illness outbreaks. FDA hadn't inspected the PCA plant in eight years. Meanwhile, press reports show inspections by the Georgia Department of Agriculture found minor violations that may have pointed to larger problems. It's particularly troubling, though, that the FDA didn't seek either the company's records or the Georgia inspection reports – information that might have prevented the outbreak from occurring - even after it found that some of the products had been rejected by a firm in Canada.

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 inspection rates would still be well below the rate established for restaurant inspections of

[5] House Comm. on Gov't Reform, *Fact Sheet: Weaknesses in FDA's Food Safety System,* (Oct. 30, 2006), *at* http://oversight.house.gov/documents/20061101115143-67937.pdf.

once every six months.[6] 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.[7] 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.[8] 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.[9]

FDA and state inspectors are also hampered in conducting inspections by restricted access to plant records that could have identified problems at PCA. After the outbreak, FDA obtained records of 12 tests that were positive for *Salmonella* in the year leading up to the outbreak that had not been disclosed to inspectors. PCA was within its rights under current law to refuse to disclose the tests even if asked by inspectors in the plant. This is because inspectors cannot access records unless the requirements of the Bioterrorism Act are met and the inspector presents a written demand.[10] We saw this same situation play out in the 2007 Peter Pan peanut butter outbreak where, had inspectors been given access to test records, they would have been alerted to test the plant for *Salmonella*.[11] Even after the PCA outbreak was ongoing, the FDA

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[6] Center for Science in the Public Interest, *Dirty Dining: Have Reservations? You Will Now*., 2008, at http://cspinet.org/new/pdf/ddreport.pdf.
[7] *Id*.
[8] Andrew Bridges & Seth Borenstein, *AP Investigation: Food Safety Inspections Lanquish*, Associated Press, Feb. 29, 2007, *at* http://abcnews.go.com/Health/wireStory?id=2905819.
[9] FDA Science Board Subcommittee on Technology, *FDA's Mission at Risk: Estimated Resources Required for Implementation*. Feb. 25, 2008.
[10] 21 U.S.C. § 374(a)(1)(B); FDA, Regulatory Procedures Manual 2008, § 10-4-3.
[11] Two years before the outbreak, the plant manager refused an oral request from FDA inspectors to see company records of a positive *Salmonella* test telling them they would need a written request. Marion Burros, *Who's Watching What We Eat*, N.Y. Times, May 16, 2007, *at* http://www.nytimes.com/2007/05/16/dining/16fda.html.

had to invoke the Bioterrorism Act to access PCA's records. This is unacceptable. To fix this, the law needs to be changed so that inspectors during routine inspections have access to the results of tests conducted by the plant. The ability to access plant food safety records during inspections is an essential tool to identifying problems. As it turned out, PCA , instead of fixing the problem, fixed the tests, something FDA could have determined had it been given access to the records.

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. 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 training and grants.

While federal and state inspections and surveillance can be improved, they will never be perfect. Congress also should consider leveraging concerned citizens as a means of detecting and preventing situations that can lead to outbreaks. We should protect responsible citizens who come forward to reveal hazards that could affect public health. Whistleblower protections would prevent bureaucratic and corporate hazing of workers to prevent them from coming forward with information about misconduct. We cannot know whether a concerned worker may have come forward in the case of PCA to reveal the positive tests had he or she been protected from

retaliation. But all necessary tools to prevent a similar outbreak should be considered.

3. FDA does not have effective penalties for PCA and for deterring similar actions by other companies

The punishment for committing a prohibited act under the Food, Drug and Cosmetic Act is up to a year in jail, a $1,000 fine or both.[12] 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[13] it is hard to see how a misdemeanor fine serves as an incentive for companies to improve their food safety practices. With over 500 people reported sick, more than 100 hospitalized and eight dead as a result of PCA putting contaminated product on the market, such trivial fines – even if found for numerous violations – do not appear fair.

Criminal liability is also a burden on the agency inspectors, as it must conduct a criminal investigation, coordinate prosecution with the Justice Department, and then go through a criminal trial to recover a fairly modest fine or sentence a culpable individual to a misdemeanor jail term.[14] Another approach Congress should consider is to provide the agency with authority to impose substantial civil penalties that can get the attention of managers and be sustained if violations are continuous. Civil liability provides a flexible deterrent 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.[15] It is time to bring FDA's penalties for food violations in line with what is used for drugs and medical devices.

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[12] 21 U.S.C. § 333(a)(1).
[13] Peanut Corporation of America Company Profile, Bizjournals.com, (accessed Feb. 3, 2009), *at* http://www.bizjournals.com/gen/company.html?gcode=904819E282CB4C8B9DAE476F9A3F632D.
[14] For a description of FDA's procedures for prosecuting a case see section 6-5 of the Regulatory Procedures Manual, *supra*, note 9.
[15] Civil penalties for pesticide residue are found at 21 U.S.C. § 333(f)(2).

4. FDA does not require effective traceability systems, and lacks adequate authority to protect consumers by detaining and ordering recalls of unsafe food.

The ability to trace products and their ingredients is essential to speeding up response when an outbreak occurs. Under the Bioterrorism Act, food companies must maintain a record of the immediate previous source and the immediate subsequent recipient of food.[16] The effort to identify the source of the PCA outbreak illustrates areas where traceback could be improved.

The process of determining the source of an outbreak is difficult and time consuming. The Minnesota Department of Health has one of the best epidemiology programs in the country. Faced with nine reports of *Salmonella* poisoning in the State, the department began interviewing victims and comparing data to find a source. The interviews turned up peanut butter, but because PCA provided ingredients to many manufacturers, the epidemiologists could not identify a single brand. As one investigator said, "We had a lot of peanut butter eaters, but none of the brand names were matching up well."[17] A traceability systems that requires processors to recorded the sources of ingredients and provide those records to investigators could have turned up the correlation between the various brands and their single supplier, PCA.

While all of the companies involved in the peanut recall have acted responsibly, CSPI continues to believe 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."

[16] 21 U.S.C. § 350c(b).
[17] Gardiner Harris & Pam Belluck, *New Look at Food Safety After Peanut Tainting*, NY Times, Jan. 3,0, 2009.

Conclusion

President Barack Obama has promised a "government that works," and recently promised a complete review of the FDA's food safety program. Luckily for the President and the public, Congress has been investigating problems at the 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 the FDA more authority and funding. Structural reforms are also essential. Although the 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 the 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, which oversees the FDA. 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.

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.[18] Bipartisan legislation introduced in the Senate in the last term of Congress further demonstrated readiness to address problems with FDA's food program. That bipartisanship emerged at the same time coalitions of traditionally estranged consumer and industry organizations, like the Alliance for a Stronger FDA, are appealing to many in Congress to rebuild the agency. With both the public and the regulated industries clamoring for change there is no reason to delay. Preventing future illnesses and deaths – future CJs and Shirley Maes – is within our grasp.

[18] Food and Drug Administration Amendments Act of 2007, Pub. L. 110-85 § 1005, 121 Stat. 823, (2007).