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OUR FATAL FOOD ATTRACTION Regulatory Failures and the Civil Justice System

By Jocelyn Bogdan, Associate Director

INTRODUCTION

Imagine walking into your neighborhood Jimmy John's and walking out with E. coli,¹ or eating a burrito from Taco Bell and spending weeks battling Salmonella,² or, worse still, offering your husband some cantaloupe, only to spend the next several months watching him die a slow death from Listeria.³ Each year, tens of millions of Americans battle foodborne illnesses and thousands never recover. Many never even learn that they, like countless others, may have been the victim of a full-blown foodborne illness outbreak.

Currently, food safety regulation and information, which, depending on the situation, involves the Food and Drug Administration (FDA), the United States Department of Agriculture Food and Safety Inspection Service (USDA) and/or the Centers for Disease Control and Prevention (CDC), are failing to keep Americans safe, or even properly informed of foodborne illness dangers. In fact, when it comes to the FDA, some of its most critical functions have been privatized, assigned to corporations subject to corrupting influences that can ultimately result in foodborne illness outbreaks. What's more, even when the CDC is aware that a restaurant caused a large-scale foodborne illness outbreak, it has the discretion to conceal this information from not only the public, but also the actual victims of the outbreak.

When private corporations and the government fail to keep the public safe from food poisoning, the civil justice system can

step in. Lawsuits can provide an additional layer of accountability and help shed light on issues and information that private companies and the government are complicit in hiding from the public. Lawsuits have also allowed the public to gain information integral to public safety that consumers can then use to make informed market decisions. In addition, they provide much needed compensation to the injured.

Regulation and lawsuits can and should work hand-in-hand to reduce the risk of foodborne illness outbreaks.

FOOD SAFETY FACTS

According to the CDC, one in six Americans falls ill from foodborne diseases every year. That's 48 million people whose illnesses could have been prevented. Of those 48 million, 128,000 are hospitalized and 3,000 die each year.⁴ The total health-related cost of foodborne illness in the United States falls between \$51 billion and \$77.7 billion per year.⁵

Foodborne Illnesses

Some of the more common foodborne illnesses linked to recent outbreaks include:

- **Salmonella.** These bacteria affect at least 2 to 4 million Americans each year, and incidences are on the rise. Symptoms include nausea, cramping, diarrhea, fever and headache.⁶ A recent investigation showed that 68 people in 10 states were sickened by a Salmonella outbreak, ultimately traced back to the Taco Bell chain.⁷
- **Listeria.** Though less common than Salmonella, these bacteria are often more severe. In 1987, the most recent year studied by the CDC, the disease affected 1,600 people and killed 415.⁸ Listeria often starts with flu-like symptoms, including fever, nausea, vomiting and can manifest as septicemia, meningitis, encephalitis and cervical infections that can result in miscarriages and/or stillbirths.⁹ In 2011, a Listeria outbreak traced to contaminated cantaloupe killed at least 32 people, led to one miscarriage, and sickened 148 people in 28 different states, making it the deadliest foodborne illness outbreak in 25 years.¹⁰
- **Hepatitis A.** This infectious liver disease, caused by the Hepatitis A virus, is usually mild but can be severe. Symptoms include fever, nausea, abdominal discomfort and jaundice. While 22,700 cases are reported in the United States each year, as few as 7.3 percent may be food or waterborne. It is usually transmitted by person-to-person contact and results from poor sanitation and crowding.¹¹ However, in February 2012, Idaho's Central District Health Department alerted Cheesecake Factory customers in Boise that diners might have been exposed to the disease through a restaurant employee.¹²
- **E. coli.** There are four classes of E. coli, the most well known being associated with undercooked beef, sprouts, unpasteurized fruit juice and raw vegetables.

Typical symptoms include severe cramping and diarrhea that can become bloody. Severe cases can result in renal failure and lead to permanent loss of kidney function.¹³ E. coli causes an estimated 176,000 illnesses and 20 deaths each year.¹⁴ Among recent outbreaks – a baby spinach outbreak in 2006, which included 204 confirmed cases across the United States, and an outbreak in 2011 involving romaine lettuce sold by St. Louis grocery stores.¹⁵ More recently, in February 2012, the sandwich chain Jimmy John’s pulled sprouts from their menu after the Michigan Department of Community Health confirmed two E. coli cases and announced five suspect cases.¹⁶

- **Norwalk Virus.** Also known as viral gastroenteritis, this virus is second only to the common cold in terms of reported illnesses in the United States. Symptoms include nausea, vomiting, diarrhea and abdominal pain and, in some cases, headache and fever. It is most commonly transmitted through contaminated water and food.¹⁷

Who’s in Charge?

The CDC plays a critical public health role in terms of food safety. It is instrumental in tracking cases of foodborne illnesses and investigating outbreaks in order to prevent further illness, disability and death. Additionally, its Food Safety Office serves “as a facilitator between FDA, USDA, other parts of the CDC and other partners, including state and local officials on various cross-cutting food safety issues related to investigations, harmonizing public health messages, capacity building, and public health policy.”¹⁸

When it comes to actually regulating food processors, the Federal Meat Inspection Act (FMIA) gives the USDA authority over food products made of meat, poultry and processed egg products. The USDA also includes an Agricultural Marketing Service that “administers programs that facilitate the efficient, fair marketing of U.S. agricultural products, including food, fiber, and specialty crops.”¹⁹ Thus, while the USDA does not regulate fruits and vegetables, it is responsible for monitoring a program that collects information regarding the “incidence, number, and species of important foodborne pathogens and indicator organisms on domestic and imported fresh fruits and vegetables.”²⁰

However, when it comes to regulation, everything besides meat, poultry, catfish and processed egg products falls under the FDA.

A simplified breakdown of who is in charge of regulating what is below.

U.S. Food and Drug Administration (FDA)	U.S. Department of Agriculture Food and Safety Inspection Service (USDA)
<ul style="list-style-type: none"> • Processed Foods • Produce • Fish (except catfish) • Seafood • Eggs (except egg products) • Bottled Water • Labeling of Food Products 	<ul style="list-style-type: none"> • Meat (except wild game) • Poultry • Egg Products (eggs that have been removed from their shells for processing at “breaker plants”) • Catfish (treated separately from other fish)

Obviously, things can get complicated when foods are comprised of products that fall under both agencies. Even though the USDA generally has authority over anything that includes a meat or poultry ingredient, food with less than two percent of cooked meat or less than three percent of raw meat may not be considered meat or poultry products and therefore would fall under FDA jurisdiction. Additionally, there are exemptions from USDA regulations for products like poultry broth, bullion cubes and gravies, as well as poultry and meat in closed-face sandwiches.²¹

Such distinctions make it difficult for the industry, let alone consumers, to determine whose jurisdiction certain food falls under, which is what ultimately determines who is responsible for inspection and safety. After all, “hotdogs wrapped in bagel dough are FDA’s, hotdogs wrapped in cornbread are USDA’s. Dried meat soups under FDA jurisdiction, dried poultry soups under USDA’s.”²² Pizza falls under the FDA unless the meat used on the pizza meets the two percent or three percent threshold.

While these examples seem extreme and even amusing, the difference is as stark as a product being inspected daily by the USDA versus once every five years by the FDA. That’s because, by law, the USDA is required to ensure a full-time food safety inspector in every meat plant, while the FDA is typically only required to inspect facilities every five to ten years. In 2012, President Obama requested \$863 million for FDA food-safety programs – significantly less than the \$1 billion the USDA spends on food safety each year.²³ The USDA has 7,500 food-safety inspectors, which means they have more inspectors than slaughterhouses and processing plants to inspect, while the FDA has only 1,000 full-time inspectors. This explains why the FDA and their contractors inspected a mere 6 percent of the 421,000 facilities under their jurisdiction in 2010.²⁴

Though the abundance of USDA inspectors does not necessarily mean they are efficient or effective, the fact is that more and more food safety outbreaks are coming from FDA-regulated foods. According to the Center for Science in the Public Interest, seafood and produce were linked to the most foodborne illness outbreaks from 1990 to 2003. And in 2011, the CDC found nuts and fruits were linked to the most illnesses.²⁵ Thus, while the USDA is hardly perfect,²⁶ this paper focuses its attention on the majority of foods regulated by the FDA.

THE FDA: PRIVATIZING FOOD SAFETY FUNCTIONS

On July 25, 2011, James Dilorio of agricultural auditing company, Bio Food Safety, audited Jensen Farms, a family-run farm that has grown and packaged cantaloupes for the past twenty years. After a four-hour inspection, Dilorio gave Jensen Farms a superior rating of 96 percent, despite noticing some serious problems: wood on the unloading and packing tables; a lack of hot water at handwashing stations; and doors left open that could allow pests to enter the facilities.²⁷

About a week later, the first victim of what became a major *Listeria* outbreak was identified by the CDC and eventually traced back to Jensen Farms. When the FDA made an unannounced visit to the farm on September 10, 2011 – less than two months after the Bio Food Safety audit – inspectors found that 13 samples they collected throughout the facility were contaminated by *Listeria*. In their next visit on September 22, 2011, FDA inspectors discovered multiple problems including “the lack of a pre-cooling step to remove field heat before the cantaloupes were moved into cold storage; the inability to easily clean the packing facility floor and packing equipment; facility design flaws that allowed water to collect in proximity to equipment and employees walkways; and washing and drying equipment that was originally used on a different agricultural commodity.”²⁸ Thus, only two months after Bio Food Safety gave Jensen Farms a superior rating, the FDA discovered contamination that had led to a deadly *Listeria* outbreak leaving at least 32 dead and 146 sickened,²⁹ and multiple potential causes for that contamination.

The Jensen Farms/Bio Food Safety case is not an isolated incident. In 2008, private inspection company, the American Institute of Baking (AIB), was paid by the Peanut Corporation of America to conduct an audit of its facilities; AIB gave Peanut Corporation a superior rating. It took federal investigators to discover that the plant was overrun with salmonella and had been shipping tainted products for at least nine months, causing an outbreak that sickened thousands and killed at least nine.³⁰

Similarly, in 2010, AIB audited Wright County Egg facilities, awarding the company a superior rating and “recognition of achievement.” After an outbreak of *Salmonella* in Wright County Eggs, the FDA found serious food safety violations including “barns infested with mice, chicken manure piled eight feet high, and uncaged hens tracking through excrement.”³¹

When private companies are given critical food inspection responsibilities, public health and safety are clearly in danger. As the *New York Times* put it, “An examination of the largest food poisoning outbreaks in recent years – in products as varied as spinach, pet food, and a children’s snack, Veggie Booty – show that auditors failed to detect problems at plants whose contaminated products later sickened consumers.”³² The question is – why were companies like Bio Food Safety and AIB given responsibility for auditing plant safety in the first place?

As noted earlier, the FDA typically inspects facilities every five to ten years and has only a fraction of the number of inspectors employed by the USDA, even though it regulates every food product except meat, poultry, processed egg products and catfish. However, retailers who purchase food from farms require audits of growers and producers. To satisfy this demand, an industry of private third-party auditors has developed. For example, in the case of the Jensen Farms audit, a major retailer provided a list of 10 third-party auditors to Frontera Produce. Frontera passed the list onto Jensen Farms who contracted with Primus Labs. Primus Labs then hired Bio Food Safety as a subcontractor to run an audit of Jensen Farms.³³

While one might think that there is every incentive for the food industry to catch and fix problems right away, in this privatized system there are other incentives operating against food safety. The first incentive is productivity. Growers and producers obviously value productivity – the more they produce, the more they sell and they certainly would prefer not to limit productivity, if possible. These same supply and demand factors are at work with regard to buyers, who may also feel pressure “to purchase from sources without a clear safety margin.” And, there is nothing illegal about this.³⁴

But the question remains as to why any grower or producer would risk a foodborne illness outbreak with a slipshod audit, which could shut down a plant with a far more substantial impact on productivity. Food safety expert, Robert LaBudde, who has consulted with food companies for 30 years, put it this way: “The only thing that matters is productivity... [Y]ou only get in trouble if someone in the media traces it back to you, and that’s rare, like a meteor strike.”³⁵ He told the *New York Times* that he was once hired to determine the species of bacillus in meat and the owner refused to complete the testing. “I called them ‘anthrax sausages’ and said they could be killing older people in the state, and still they wouldn’t do it.”³⁶

Another major problem with third-party auditors are conflicts of interest created by their need for repeat business. Third-party auditors are ultimately chosen and paid for by the very grower or producer they are auditing. Because auditors know that producers hate to limit productivity, “This creates a conflict for the auditor: a failing audit has significant economic implications for the producer, to the extent an auditor applies more demanding food safety standards, and it may be less likely to be hired by a given producer.”³⁷

In fact, visits by third-party auditors are often pre-arranged so the farm or producer has time to prepare in advance of the visit, making it even less likely they will find problems. The Bio Food Safety visit to Jensen Farms in early September 2011 was scheduled at least two weeks ahead of time and a representative from Frontera Produce visited before the audit to make sure everything was in order.³⁸ Additionally, the Bio Food Safety visit took only four hours. (When the FDA came, it took several days to inspect the farm.) And once there, the audits often do not go nearly far enough. They rarely “test the actual food products for pathogens, even though gleaming production lines can turn out poisoned fare.”³⁹

These kinds of corrupting financial interests are not the only problems created by FDA failures to properly oversee food safety. First of all, the FDA does not currently offer trainings or classes for third-party auditors.⁴⁰ Eugene A. Hatfield, the AIB inspector who

audited Peanut Corporation's Georgia plant, was an expert in fresh produce but had no idea that peanuts were susceptible to Salmonella.⁴¹

In addition, when the FDA regulates in this area, it often does so by issuing "guidelines," which private auditors may essentially ignore.⁴² As Jerry Walzel, the president of Bio Food Safety, explains, "[C]onsistent with Primus Labs policy – the audits only deducted from the score if the method or technique was inconsistent with FDA regulations; they did not deduct from the score if FDA guidance was not being followed."⁴³

Nor is there any requirement that growers and producers follow an auditor's recommendation. Take the case of Nebraska Beef, which was linked to an outbreak of E. coli that sickened at least 17 people in 2006. The U.S. Department of Agriculture learned that auditors who found problems at the plant made recommendations to Nebraska Beef yet the company never carried out any of those recommendations.⁴⁴

Complicating this problem is the fact that there is no requirement that third-party auditors report their findings to any government agency so there is virtually no accountability for what they do. For example, "While Primus Labs has performed tens of thousands of audits since the mid-1990s, the firm indicated that it has never reported any of its findings to FDA, state authorities, or local health officials. This remains true even in cases where Primus Labs found a deficiency that was so egregious that the auditor ended the audit immediately and automatically failed the company."⁴⁵

SECRECY: THE GOVERNMENT'S LACK OF TRANSPARENCY

Imagine an outbreak of food poisoning that sickened nearly 70 people with Salmonella throughout 10 states and required more than 20 hospitalizations. Now imagine, after a detailed investigation, the CDC determined the source of the contaminated food. But instead of immediately making the information available to the public, they simply referred to the source as "Restaurant Chain A," refusing to publicly reveal the identity of the restaurant that caused the outbreak. That's exactly what happened in January 2012, when the CDC released a report after a three-month investigation of a Salmonella outbreak. They included all the relevant information – except for the most relevant detail – the name of the restaurant.⁴⁶

As *The Atlantic* pointed out, this seemed "like odd behavior from an agency whose responsibility is to save lives, protect Americans, and save money through prevention."⁴⁷ Choosing to hide the identity of the restaurant prevents the public from avoiding the establishment and protecting themselves. It also shields the restaurant from negative publicity, which is the reason behind the CDC's omission.

Dr. Robert Tauxe, the CDC's Deputy Director of the Division of Foodborne, Waterborne and Environmental Diseases explains that the practice of withholding the information "aims to protect not only public health, but also the bottom line of businesses that could be hurt by bad publicity."⁴⁸ While the policy seems counterintuitive in terms of public safety, Tauxe goes on to explain that the CDC doesn't want "to compromise the cooperation that we'll need."⁴⁹ In other words, reasons the CDC, if a restaurant or

company comes forward and provides information to the CDC about an outbreak voluntarily, and is then exposed, chances are, next time they'll stay silent. Thus, the CDC will opt to conceal their identity to ensure their cooperation in the future.

Equally disturbing is that a restaurant has no responsibility to come forward even if it's aware it caused a food poisoning outbreak. As the *New York Times* reported in January 2012, "There is no requirement for restaurants to report when their diners are affected by food-borne illnesses even when large numbers of people get sick."⁵⁰ Dr. Rajiv Bhatia, San Francisco's Director of Environmental Health, disagrees with this policy and has urged the need for stricter rules, arguing that "reporting of potential outbreaks should be mandatory for supermarkets, restaurants, schools, and workplace cafeterias, even though this is not a requirement under current law."⁵¹

The above example involving "Restaurant Chain A," which left 68 people with Salmonella, was eventually traced to Taco Bell but not because Taco Bell alerted the public and not because the CDC ultimately put public safety above business interests, though the CDC did acknowledge that the outbreak came from a "Mexican chain." Taco Bell was identified through the efforts of tenacious reporters, who eventually dug up a document called "Summary of Supplemental Questionnaire Responses Specific to Taco Bell Exposure of Oklahoma Outbreak Associated Cases Multistate Salmonella Enteritidis Outbreak Investigation."⁵² Taco Bell has yet to take responsibility.

The CDC contends that they will publicly identify a company when it allows people to take specific actions to protect their health. In the Taco Bell case, because the contamination had run its course, they saw no need to come forward. However, even if the outbreak was over, the question remains, should the CDC decide what information the public has the right to know? There may be customers who would choose not to eat at a restaurant or food chain after a major food outbreak – particularly when it's not the first time it has been the source of illness, as is the case with Taco Bell.

For example, in 2006, the CDC found that Taco Bell was responsible for an *E. coli* outbreak that sickened more than 70 people in the Northeast.⁵³ They were also responsible for a Salmonella outbreak in 2010 that sickened 155 people in 21 states – that time their culpability was revealed only because their name was accidentally released to media outlets.⁵⁴ Yet, despite the fact that Taco Bell has caused three outbreaks of different diseases in the past five years, the CDC decided that identifying Taco Bell as the source of the 2011 Salmonella would do nothing to help consumers protect their health.

THE ROLE OF THE CIVIL JUSTICE SYSTEM

Victims of foodborne illnesses may choose to file lawsuits for a number of reasons. The high costs of their illness is the most obvious – often victims need compensation for their medical bills and/or changes in their quality of life.

In addition, lawsuits can shed important light on food safety problems that private companies and the government are complicit in hiding from the public. For example, attorney Bill Marler explains that his firm has been successful enough through the years

that they can go toe-to-toe with corporations like Cargill and ConAgra in discovery. This gives them the ability to gain important facts about the causes of foodborne illnesses – facts they can then share with the public.⁵⁵ In other words, by bringing civil lawsuits, lawyers and clients have the opportunity to obtain information integral to public safety that the public can then use to make informed market decisions. Yet, bringing a lawsuit isn't always easy.

Putting aside the lack of transparency mentioned above, foodborne illness victims start out at a major disadvantage. They may not be aware they have a foodborne illness that is part of an outbreak and, even if they suspect they do, it may be difficult to determine. The first step in identifying a foodborne illness is a clinical laboratory analysis of the victim's stool sample to isolate and identify bacteria as foodborne, like Salmonella. However, if the individual has no health insurance or it is not extensive enough to cover these kinds of lab costs, then s/he is probably out of luck (unless they have money to pay a lab).

If a stool sample analysis can be done and a foodborne illness is identified, the lab will alert the doctor.⁵⁶ While the victim receives medical treatment, the clinical laboratory should send the bacteria to the state public health lab. Whether or not this happens may depend on whether or not the state in which the victim lives has an adequately funded and staffed public health lab.⁵⁷ As the Association of Public Health Laboratories explains on its website, every U.S. state and territory has a central public health lab, and many have local public health labs as well, but these range in size “from large metropolitan laboratories with hundreds of scientists to small rural laboratories with one or two staff.”⁵⁸ State public health labs “face a shortage of laboratory professionals entering the workforce, pay discrepancies between public and private sector laboratory staff positions, a scarcity of scientists with the experience and credentials needed to assume management roles, and an aging worker population that is rapidly entering retirement.”⁵⁹

Assuming the capacity exists, the public health lab will run additional tests on the bacteria, including a serotyping test and DNA fingerprinting. According to the CDC,

- **Serotyping** identifies the specific strain of bacteria based on markers on the surface of the bacteria. ...When several strains have the same markers or serotype all at the same time, and there are more with that one serotype than is expected, that's a sign of a possible outbreak.
- **DNA fingerprinting** identifies the bacteria's specific genetic pattern or DNA fingerprint. ...State labs report their DNA results to the PulseNet database. Coordinated by the CDC, PulseNet is a network of public health labs and agencies that do DNA fingerprinting. By looking at the PulseNet database, health officials can identify clusters of illnesses caused by bacteria with the same fingerprint at the same time, even if the ill people are spread across many counties or states. This is especially useful when the number of illnesses in any one county or state is not big enough by itself to point to a possible outbreak.⁶⁰

For obvious reasons, if a victim lacks adequate insurance, if the state public health lab lacks adequate staff or funding, or if for some reason the test is negative or doesn't match

up, s/he might never learn that they're part of a foodborne illness outbreak. In many cases, even when victims' stool samples test positive, no one calls to tell them who's to blame for their illness, even when there is an obvious outbreak. Victims may never know who's responsible.⁶¹ In addition, the CDC does not make it easy to learn about outbreaks.

However, when victims do learn this information and lawsuits can be brought, they have important implications. Take the case of 22-year-old Leah Smith, who ate at a Taco Bell on November 3, 2011. By November 5th she was experiencing abdominal cramps and diarrhea, with her condition worsening throughout the day. The next day Smith was diagnosed with a viral illness at an emergency clinic and released, but her symptoms continued to intensify. She developed bloody diarrhea and, after seeking additional medical attention, delivered a stool sample that tested positive for Salmonella. Smith remained sick for two weeks, at the height of which she had problems staying hydrated because her diarrhea occurred every five to ten minutes.

Despite knowing of a multi-state outbreak of Salmonella infections from Taco Bell food, the CDC refused to identify the restaurant's name in their report about a 2011 Salmonella outbreak, choosing instead to call it "Chain A."⁶² In contrast, both the Michigan and Oklahoma State Health Departments identified "Chain A" as Taco Bell in early February 2012.⁶³ After Smith spoke with state and local health department officials, state health officials ultimately confirmed that the strain of Salmonella she had was the one implicated in the Taco Bell outbreak.⁶⁴ On February 17, 2012, Smith filed a lawsuit against Taco Bell.⁶⁵

Her complaint alleges, among other things, that Taco Bell is strictly liable for her injuries because the food she ate, "which had been produced by the defendant, was contaminated with Salmonella and was, as a result, defective and unreasonably dangerous." Smith also argues that Taco Bell "breached duties owed to its customers by committing the following acts and omissions of negligence:

- Failed to adequately maintain or monitor the sanitary conditions of their products, premises, and employees;
- Failed to properly operate their facilities in a safe, clean, and sanitary manner;
- Failed to apply their food safety policies and procedures to ensure the safety and sanitary conditions of their food products, premises, and employees;
- Failed to prevent the transmission of Salmonella to consumers of their food products;
- Failed to properly train their employees and agents how to prevent the transmission of Salmonella on its premises, or in its food products;
- Failed to properly supervise its employees and agents to prevent the transmission of Salmonella on its premises, or in its food products."⁶⁶

When contacted about the case, Taco Bell's VP of Public Affairs told *HuffPost Food*, "We expected that one or more lawyers, especially one who's been focused on this topic, would sue over this incident. And they're doing so despite the fact that the CDC did not name us in their report. We stand behind our restaurants, our team members and our food."⁶⁷

Smith was able to access a law firm that handles food safety issues. Unfortunately, not many attorneys can afford to take cases against the food industry. From 1993 to 2007, Marler Clark was one of the only law firms taking on food poisoning cases against companies whose food was identified as causing illness and today it remains the only firm exclusively focused on the issue.⁶⁸ Marler Clark represented many victims of the nationwide Peanut Corporation of America (PCA) Salmonella outbreak, a powerful illustration of the impact of regulatory failures and the importance of the civil justice system in helping victims.

For years, PCA's Blakely, Georgia plant was a breeding ground for Salmonella. The plant's roof leaked whenever it rained, allowing Salmonella to thrive; the roaster wasn't calibrated to kill deadly germs; there were rats and cockroaches; workers put on their uniforms at home, potentially dragging contaminants into the plant; and contaminated raw peanuts were likely stored beside finished peanut butter.⁶⁹ In fact, PCA's own tests found Salmonella in products from the Blakely plant 12 times in 2007 and 2008.⁷⁰ Yet, as noted earlier, the company was not required to alert anyone about Salmonella in their plant. According to a *New York Times* investigation, "Interviews and government records show that state and federal inspectors do not require the peanut industry to inform the public – or even the government – of salmonella contamination in its plants."⁷¹

At that point, the FDA had conducted no inspections of the plant, which is the norm. Instead, the agency relied on inspections by Georgia's Department of Agriculture to ensure that standards were being enforced. But as Donald Zink, an FDA food scientist explained to the *NYT*, because state inspectors visit different kinds of facilities, they might not know what is needed in a peanut butter facility versus another facility.⁷² Moreover, Georgia had only 60 agents to monitor 16,000 food-handling businesses.⁷³ And, like third-party auditors, Georgia's Department of Agriculture never tested for pathogens. Instead they found problems they described as "minor" – rust and gaps in the door large enough for rodents. They were not concerned.

Yet the FDA should have been concerned, having been on notice of problems at other peanut butter plants. For example, in 2007, a ConAgra Foods peanut butter plant 75 miles from Blakely was responsible for a Salmonella outbreak that sickened hundreds. A whistleblower had come forward three years earlier, in 2004, revealing that ConAgra's own laboratory tests found Salmonella in peanut butter at the Sylvester, Ga. plant. When plant officials refused to release the tests, the FDA failed to act. Finally three years later, after hundreds were harmed by Salmonella-tainted peanut butter from the Sylvester plant, the government demanded the records and verified the whistleblowers' claim. While ConAgra ultimately improved conditions at its plant and increased testing, those safety measures were never imposed on other peanut butter facilities.⁷⁴

In November 2008, the CDC began monitoring incidences of Salmonella in 12 different states. A few weeks later, incidences of Salmonella had spread to 16 states and the FDA and CDC began taking a closer look at the illnesses. CDC Assistant Surgeon General Ali Khan later told the U.S. Senate that “the early epidemiologic evidence suggested an association with peanut butter served in institutions as a possible explanation for at least part of the outbreak.”⁷⁵ At this point, in addition to other cases of Salmonella, 10 people in two Minnesota nursing homes had become sick and one had died. Notably, nursing homes were among the places that the Blakely plant had shipped pails of peanut butter directly, in addition to schools and military bases.⁷⁶

In early January 2009, Minnesota health officials “confirmed that Salmonella found in a five-pound container of peanut butter genetically matched the bacteria involved in the nationwide outbreak.”⁷⁷ The peanut butter they tested was made by PCA and the nationwide outbreak was ultimately traced back to the plant in Blakely. On January 9, 2009, the FDA finally inspected the Blakely plant and noted the dangerous conditions listed above. But, perhaps more disturbing, they realized that even though the company’s own tests found Salmonella in its products 12 different times in 2007 and 2008, it kept retesting until it got the “no contamination” results it wanted and continued shipping the contaminated products. And, despite the tests, PCA never cleaned up the plant. “The practice of initially obtaining a positive sample and subsequently of getting a negative result and not having’ cleaned up the plant is illegal,” Michael C. Rogers, Director of the FDA’s Division of Field Investigations, told the *New York Times*.⁷⁸

On January 13, 2009, after the FDA’s involvement, PCA issued a nationwide recall. Two weeks later, the recall was expanded to include every peanut product processed in the Blakely plant over the last two years.⁷⁹ By October 2009, nearly 4,000 different products had been recalled⁸⁰ – too little too late for the more than 630 people who were sickened by the outbreak and the nine people who died.

Among those seeking justice in the civil courts:

- Three-year-old Jacob Hurley, who began suffering from lethargy, vomiting, cramping and bloody diarrhea in January 2009. A doctor tested his stool sample and found he had Salmonella. It took a home visit from Dr. William Keene, Oregon’s Chief Epidemiologist, to discover the source: Austin Toasty Crackers, a Kellogg’s product whose peanut butter came from PCA. The crackers tested positive for Salmonella.⁸¹
- Clifford Tousignant, a 78-year-old Korean War veteran and winner of three Purple Hearts, who suffered for weeks and later died after eating tainted PCA peanut butter at his nursing home. His family filed suit against Kanan Enterprises, the makers of King Nut peanut butter; King Nut used peanuts manufactured by PCA.⁸²
- Shirley Mae Almer, 72, who died in December 2008 after eating Salmonella-laced PCA peanut butter on toast. Her family sued PCA and King Nut for negligence.⁸³ As one of Almer’s daughters told the *Minneapolis Star-Tribune*, the family filed a lawsuit to make the government take notice. “I really believe there

needs to be reforms and speaking out is the best way to do it,” she said. “I know my mom would be proud of what we are doing right now.”⁸⁴

- Seven-year-old Christopher Meunier, who spent six days in the hospital with a fever, diarrhea, and vomiting and continues to suffer from a weakened immune system after eating crackers made with contaminated PCA peanut butter. His mother filed a lawsuit to hold PCA accountable for the pain her son endured.⁸⁵ Marler Clark added Kellogg’s to the suit since they made the crackers Christopher ate. As attorney Bill Marler explained, “Kellogg’s states that they received reports grading the Blakely plant as ‘superior,’ which is odd, given that other reports show the facility as having rampant problems. The way to ensure that all paperwork related to the plant is brought into the open is to include Kellogg’s in the legal process.”⁸⁶

Faced with immense liability exposure for “knowingly shipping out tainted products to save money regardless of the health consequences”⁸⁷ and the costs of the recalls, PCA filed for bankruptcy in February 2009,⁸⁸ a fitting end to a company that likely should not have been in business at all. PCA surrendered its \$12 million insurance policy to the bankruptcy court to be used to settle claims, and Kellogg’s agreed to contribute towards the settlements as well.⁸⁹ In August 2010, a \$12 million settlement was recommended in the case against PCA, which involved 125 victims, with the largest payouts going to the most vulnerable. In addition to the nine people who died, 45 children and many nursing home residents were sickened.

Cause of Action Against Third-Party Auditors

Typically it is difficult, or even impossible, to hold third-party auditors liable for a foodborne illness outbreak. Understandably, holding an auditor responsible for something that happens after a visit is difficult. But there are exceptions.

In November 2011, Florence Wilcox’s sons filed a complaint in New Mexico’s Fifth Judicial District Court that included a negligence cause of action against Primus Labs and Bio Food Safety⁹⁰ for the death of their mother. According to the complaint, 96-year-old Wilcox was active and lived independently until she became a victim of the Listeria outbreak traced to Jensen Farms cantaloupes. A week or so after eating a tainted cantaloupe, she came down with “fever and chills, bloody stools, weakness, and general malaise.” Her blood sample tested positive for Listeria. Wilcox continued to deteriorate and was transferred to a different hospital where she was moved into intensive care. There she “developed extremely high fevers, her speech became fragmented, and she exhibited obvious pain and discomfort”; she was later diagnosed with meningitis. Wilcox died on September 15, 2011, seven days after she got sick from the Listeria-laced cantaloupe.⁹¹

The complaint alleges, among other things, that Bio Food Safety auditor James Dilorio’s July 25, 2011 audit of the Jensen Farms packing facility was “not done with reasonable care.” It states that “Mr. Dilorio’s various acts and omissions of negligence in the conduct of the audit include specifically, but not exclusively, his failures to identify that

the equipment and facility design and maintenance generally posed an unreasonable risk of harm to consumers of the facility's cantaloupes because the equipment and facility design and maintenance encouraged bacterial growth and proliferation, and ultimately contamination of cantaloupes."⁹²

If the case succeeds, it would be the first successful lawsuit against a third-party auditor. Food safety attorney, Bill Marler, explains that the difference between this case and cases in the past is that here the auditor was actually on the farm while the cantaloupes were being contaminated. There wasn't a gap of several weeks between when the auditor visited and the contamination occurred, thus the audit could have made a difference.⁹³

FOOD SAFETY MODERNIZATION ACT

The reason that buyers and distributors use third-party auditors is primarily because the FDA does not have the mandate, the manpower, or the funding to prevent outbreaks by regularly inspecting every grower and producer of food in this country. Unlike the USDA, which requires that their inspectors be present at meat and poultry plants they regulate during operating hours, the FDA had no such mandate. "As a result, lapses of as long as 10 years were not uncommon."⁹⁴

As Larry Goodridge, Associate Professor at the Center for Meat Safety and Quality at Colorado State University, told Colorado farmers, the "deadly *Listeria* outbreak traced to Colorado cantaloupe proved that they cannot rely on third-party inspections to guarantee their produce is safe."⁹⁵ He went on to state, "Each farm or processing facility has to be able to access their own risks," adding, "Everybody who produces food has to be responsible for the safety of the food they produce. You cannot rely on third parties. You just can't."⁹⁶ But while the intent to improve food safety with better FDA oversight may exist, the funding and resources do not.

In December 2010, Congress passed the Food Safety Modernization Act (FSMA), which was signed into law in January 2011. Margaret A. Hamburg, Commissioner of Food and Drugs, stated, "This law makes everyone responsible and accountable at each step in today's global food supply chain. Under this new law, FDA will now have new prevention-focused tools, as well as a clear regulatory framework, to help make substantial improvements in our approach to food safety."⁹⁷

However, the current FDA does not have the funding to implement important aspects of the FSMA and Congress is not doing much to change this. The FDA recently asked Congress "to approve a \$220 million increase funded by new fees on food processors and handlers, money that would go to bolster inspections and implement new guidelines on how food should be grown and packed."⁹⁸ Yet it's unclear if the budget will go through because, while the increase is favored by growers and producers, "Congress has recently blocked FDA initiatives by slashing the requests."⁹⁹ Regardless, even with this funding increase, the FDA would not be able to send inspectors to farms in advance of outbreaks even under the FSMA because they lack the personnel.¹⁰⁰

Still, the FSMA is important legislation geared toward improving food safety. In listing key facts about the FSMA, the FDA notes¹⁰¹:

- The legislation transforms FDA’s approach to food safety from a system that far too often responds to outbreaks rather than prevents them. It does so by requiring food facilities to evaluate the hazards in their operations, implement and monitor effective measures to prevent contamination, and have a plan in place to take any corrective actions that are necessary.
- It also requires the FDA to establish science-based standards for the safe production and harvesting of fruits and vegetables to minimize the risk of serious illnesses or death.
- The new ability to hold food companies accountable for preventing contamination is a significant milestone in the efforts to modernize the food safety system.

Practically, this means that the FDA would, with the help of state partners, “conduct more frequent and targeted inspections that will include verification that facilities are properly implementing preventative controls.”¹⁰² According to the Act, any high-risk domestic facility will be inspected within five years of enactment and every three years thereafter.¹⁰³ Additionally, the Act gives the FDA the authority to issue a mandatory recall when a company fails to do so voluntarily. Until now, the FDA has not had this ability. It “also gives the Centers for Disease Control and Prevention new responsibilities to enhance federal, state, and local surveillance systems for foodborne illness” so they can “identify and control outbreaks more quickly while gaining the scientific knowledge to prevent future ones.”¹⁰⁴

This appears to be a positive step. However, the financial impediments and resource challenges are enormous in our deficit-cutting political environment. Congress is already pushing back on the FDA’s proposed budget, which isn’t adequate anyway.¹⁰⁵ The FDA is currently responsible for 421,000 domestic and foreign facilities, yet “inspections account for the full-time work of just 1,000 employees.”¹⁰⁶ So while the intent to improve the industry exists, it remains unclear how much of the FSMA can actually be implemented.

To make matters worse, even the minimal food safety measures that do exist are facing budget cuts. For example, the U.S. Agriculture Department’s Microbiological Data Program (MDP) is the nation’s only program that regularly tests fruits and vegetables for deadly pathogens, but President Obama’s proposed budget would eliminate it.¹⁰⁷ While the MDP only has a \$5 million annual budget, the United Fresh Produce Association and other major trade association have been pushing to get rid of the testing program because it costs growers millions of dollars in food recalls.¹⁰⁸ They want more private sector testing.

Even the CDC’s Dr. Robert Tauxe, referenced above as defending the agency’s practice of shielding restaurants from responsibility for food poisoning outbreaks, recognizes the importance of the MDP, pointing out that “the 120,000 food samples the program has collected in the last decade have offered public health officials important clues when they

are probing the source of food poisoning outbreaks,” information not easily replaced.¹⁰⁹ It appears likely that if the program is cut, the trade associations would prevail and testing would be left to the private sector.

CONCLUSION

With the FSMA’s current lack of funding and the majority of Congress’s apparent lack of interest in improving food safety regulations, the civil justice system remains as important as ever for victims of foodborne illness.

However, systemic changes are also necessary to improve the safety of our food supply. In addition to writing members of Congress, urging them to support the FSMA, it is important to stay educated on food safety issues. Fortunately, today that is easier than ever because of the many food safety attorneys and advocates who regularly write and blog on the issue.

Among the blogs and websites to follow:

- **The Marler Blog** provides commentary on food poisoning outbreaks and litigation: <http://www.marlerblog.com/>
- **Food Safety News** is a resource created by Marler Clark that reports on food safety news and foodborne illness outbreaks: www.foodsafetynews.com. To get the latest information on food recalls check here: <http://www.foodsafetynews.com/sections/food-recalls/>
- **Appetite for Profit** is Michele Simon’s website. She is a public health lawyer who has written about the food industry since 1996: <http://www.appetiteforprofit.com/>
- **Food Politics** is a blog by Marion Nestle, a Public Health and Sociology Professor at New York University: <http://www.foodpolitics.com/>
- **US Food Safety** is an award-winning food safety blog: <http://blog.usfoodsafety.com/>
- **Mark Bittman’s New York Times column** often focuses on food safety: http://topics.nytimes.com/top/reference/timestopics/people/b/mark_bittman/index.html

There are also organizations working hard to disseminate information on these issues:

- **Food and Water Watch**’s website has a comprehensive section on food safety: <http://www.foodandwaterwatch.org/food/foodsafety/>
- **Center for Food Safety**’s mission is “to protect human health and the environment by curbing the proliferation of harmful food production technologies

and by promoting organic and other forms of sustainable agriculture”:
<http://truefoodnow.org/about/>

With enough pressure on Congress, our fatal food attraction may someday end. In the meantime, staying informed is a critical first step.

Notes

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² Joe Satran, “Taco Bell Lawsuit Alleges Chain’s Food Gave Salmonella to Leah Smith, Oklahoma Woman,” *Huffington Post*, February 22, 2012, found at http://www.huffingtonpost.com/2012/02/22/taco-bell-lawsuit_n_1293515.html. (According to her lawsuit, two days after eating at Taco Bell, Leah Smith fell ill with salmonella.)

³ Michael Booth, “Listeria outbreak traced to Colorado leaves damaged survivors in its wake,” *Denver Post*, December 1, 2012, found at http://www.denverpost.com/news/ci_19445309. (Penny Hauser, who served her husband cantaloupe, had only one wish: for her husband to become lucid enough for her to apologize. He died February 21, 2012.)

⁴ These numbers represent known victims; the numbers of actual foodborne illness victims are potentially much higher.

⁵ Robert L. Scharff, “Economic Burden from Health Losses Due to Foodborne Illness in the United States,” *75 Journal of Food Protection* 123, 128 (2012), found at www.marlerblog.com/uploads/image/s18.pdf. (According to the study, while these figures include the largest categories of health-related costs, some costs, including thyroid disease and irritable bowel syndrome, were not included. Additionally, the costs to the industry and public health agencies were not included in the study.)

⁶ U.S. Food and Drug Administration, “Salmonella spp.,” *Bad Bug Book: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook*, found at <http://www.fda.gov/food/foodsafety/foodborneillness/foodborneillnessfoodbornepathogensnaturaltoxins/badbugbook/ucm069966.htm>; Andrew Martin and Michael Moss, “Food Problems Elude Private Inspectors,” *New York Times*, March 5, 2009, found at <http://www.nytimes.com/2009/03/06/business/06food.html>. In 2009, anywhere between 691 and 22,500 were sickened with salmonella and 9 died, as the result of tainted peanuts from a Peanut Corporation of America plant in southwest Georgia. Barry Estabrook, “Restaurant A: How Bill Marler Tied Taco Bell to Salmonella Outbreaks,” *Atlantic*, February 9, 2012, found at <http://www.theatlantic.com/health/archive/2012/02/restaurant-a-how-bill-marler-tied-taco-bell-to-salmonella-outbreaks/252778/>.

⁷ Estabrook, *supra* n. 6.

⁸ According to www.foodborneillness.com, Listeria is currently estimated to cause 1,591 illnesses and 255 deaths per year.

⁹ U.S. Food and Drug Administration, “Listeria monocytogenes,” *Bad Bug Book: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook*, found at <http://www.fda.gov/Food/FoodSafety/FoodborneIllness/FoodborneIllnessFoodbornePathogensNaturalToxins/BadBugBook/ucm070064.htm>.

¹⁰ Committee on Energy and Commerce, U.S. House of Representatives, *Report on the Investigation of the Outbreak of Listeria monocytogenes in Cantaloupe at Jensen Farms*, January 10, 2012, found at http://democrats.energycommerce.house.gov/sites/default/files/documents/Report_Listeria_01.10.11.pdf.

¹¹ U.S. Food and Drug Administration, “Hepatitis A Virus,” *Bad Bug Book: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook*, found at <http://www.fda.gov/Food/FoodSafety/FoodborneIllness/FoodborneIllnessFoodbornePathogensNaturalToxins/BadBugBook/ucm071294.htm>.

¹² “CDHD warns Cheesecake Factory customers about hepatitis A infection,” *KTVB.com Boise*, February 10, 2012, found at <http://www.ktvb.com/news/local/CDHD-warns-Cheesecake-Factory-customers-about-hepatitis-A-alert-139096274.html>.

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¹⁵ *Meyer v. Schnuck Supermarkets* (St. Louis County Cir. Ct., MO), complaint found at <http://www.marlerblog.com/uploads/image/final%20meyer%20complaint.pdf>.

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¹⁹ United States Department of Agriculture, Agricultural Marketing Service, “Welcome to the Agricultural Marketing Service,” found at <http://www.ams.usda.gov/AMSv1.0/>.

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²⁴ *Id.*

²⁵ *Id.*

²⁶ Issues with the USDA include that while inspectors are in each plant, they primarily look for carcass defects on assembly lines, instead of focusing on what some say is a larger problem, microbial contaminations. Additionally, while the largest outbreaks have been in the produce industry, studies indicate that meat and poultry continue to pose serious threats. *Id.*

²⁷ *Report on the Investigation of the Outbreak of Listeria monocytogenes in Cantaloupe at Jensen Farms*, *supra* n. 10.

²⁸ *Id.* (citing U.S. Food and Drug Administration, *Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis*, October 19, 2011).

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³⁰ Martin and Moss, *supra* n. 6.

³¹ Committee on Energy and Commerce, U.S. House of Representatives, Letter to the Honorable Margaret Hamburg, Commissioner for the U.S. Food and Drug Administration, January 10, 2012 at 6, found at http://democrats.energycommerce.house.gov/sites/default/files/documents/Letter_Hamburg_01.10.11.pdf.

³² Martin and Moss, *supra* n. 6.

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³⁵ Martin and Moss, *supra* n. 6.

³⁶ Martin and Moss, *supra* n. 6.

³⁷ Letter to the Honorable Margaret Hamburg, *supra* n. 31.

³⁸ *Id.* at 4 (citing House Committee on Energy and Commerce, Interview of Eric Jensen and Ryan Jensen, November 8, 2011).

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⁴⁰ Costa, *supra* n. 34.

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- ⁴² While the FDA currently relies on guidelines rather than regulations, since 2010 the agency has been working on Produce Safety Regulation, which is mandated by the Food Safety Modernization Act signed into law January 4, 2011. “This regulation will establish mandatory, science-based, minimum standards for the safe growing, harvesting, sorting, packing, and storage of fresh fruits and vegetables.” U.S. Food and Drug Administration, “Safer Fruits and Vegetables: FDA Aims to Set Production Standards,” found at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm262031.htm>.
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- ⁴⁵ Letter to the Honorable Margaret Hamburg, *supra* n. 31 at 4 (citing House Committee on Energy and Commerce, Interview of Robert Stovicek, November 7, 2011).
- ⁴⁶ JoNel Aleccia, “Who’s behind that outbreak? Sometimes, CDC won’t say,” *MSNBC.com*, January 31, 2012, found at http://vitals.msnbc.msn.com/_news/2012/01/31/10274541-whos-behind-that-outbreak-sometimes-cdc-wont-say.
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- ⁴⁹ *Id.*
- ⁵⁰ Scott James, “Unreported Cases of Food Poisoning Reflect a Gap in Food Supply Safety Net,” *New York Times*, January 5, 2012, found at <http://www.nytimes.com/2012/01/06/health/nutrition/unreported-food-poisoning-at-san-francisco-restaurant-spotlights-absence-of-law.html>. (While this is true federally, policies may differ in different states.)
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- ⁵² Estabrook, *supra* n. 6.
- ⁵³ *Id.*
- ⁵⁴ Aleccia, *supra* n. 48.
- ⁵⁵ Center for Justice & Democracy interview with Bill Marler, February 24, 2012.
- ⁵⁶ Centers for Disease Control and Prevention, “Foodborne Outbreak Investigations,” found at <http://www.cdc.gov/outbreaknet/investigations/detection.html>.
- ⁵⁷ Interview with Bill Marler, *supra* n. 55.
- ⁵⁸ Association of Public Health Laboratories, found at <http://www.aphl.org/AboutAPHL/aboutphls/Pages/default.aspx>.
- ⁵⁹ Association of Public Health Laboratories, *State Public Health Laboratories: Sustaining Preparedness in an Unstable Environment* (March 2009) at 20, found at http://www.aphl.org/aphlprograms/phpr/ahr/Documents/APHL_SurveyFinalEPR.pdf.
- ⁶⁰ “Foodborne Outbreak Investigations,” *supra* n. 56.
- ⁶¹ Interview with Bill Marler, *supra* n. 55.
- ⁶² Satran, *supra* n. 2.
- ⁶³ *Smith v. Taco Bell*, (Cleveland Co. Dist. Ct., OK), complaint found at <http://www.marlerblog.com/uploads/image/Taco%20Bell%20Complaint-Final.pdf>.
- ⁶⁴ *Id.*
- ⁶⁵ As in the case brought by Florence Wilcox’s decendants, Marler Clark is involved in bringing Leah Smith’s case.
- ⁶⁶ *Smith v. Taco Bell*, *supra* n. 63.
- ⁶⁷ Satran, *supra* n. 2.
- ⁶⁸ Interview with Bill Marler, *supra* n. 55.
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