SEPARATING THE WHEAT FROM THE CHAFF

The reality of proving a foodborne illness case

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I have been litigating foodborne illness cases for nearly two decades. The key to my success has been to find a quick, reliable method of distinguishing between legitimate food poisoning claims and suspect ones. In my experience, the food industry, from farmer to retailer to restaurant, tends to over-emphasize the specious claim and under-value the legitimate claim. It is an unfortunate situation that increases the likelihood of the industry missing important measures to improve food safety.

By failing to improve food safety, the industry runs the risk of actually poisoning consumers and attracting expensive litigation that often results in public relations nightmares. My goal has been to bring forth only legitimate claims that have caused substantial personal damages and force the food industry to think about the real costs of food safety.

The Chaff – Cases We Turn Away Every Day

At Marler Clark, people who have been sickened, and believe that their illness resulted from consumption of a particular food item, contact us virtually every day. The vast majority do not make it through our initial screening process, due to a lack of a reliable link between the illness and a specific source. There are a number of methods for recognizing suspect food poisoning claims, but it begins with understanding the science.

Incubation Period

Although incubation periods—the time between ingestion of a foodborne pathogen and the onset of symptoms—are only ranges, and wide ones at that, they can still be used to identify a suspect food poisoning claim. For example, the claimant who insists that an *E. coli* O157:H7 illness was sparked by the hamburger eaten an hour before the onset of illness does not have a viable case. The incubation period of *E. coli* O157:H7 is one to ten days, typically two to five days.

Incubation Periods of Common Foodborne Pathogens

PATHOGEN	INCUBATION PERIOD
Staphylococcus aureus	1 to 8 hours, typically 2 to 4 hours.
Campylobacter	2 to 7 days, typically 3 to 5 days.
E. coli O157:H7	1 to 10 days, typically 2 to 5 days.
Salmonella	6 to 72 hours, typically 18-36 hours.
Shigella	12 hours to 7 days, typically 1-3 days.
Hepatitis A	15 to 50 days, typically 25-30 days.

Listeria	3 to 70 days, typically 21 days.
Norovirus	24 to 72 hours, typically 36 hours.

When I screen a case, the incubation period is one of the first things I scrutinize. To illustrate my point, here is a case my firm turned away:

"Within Two Hours of Eating"

> *"After getting out of church yesterday morning, Sunday, December 12 I stopped at [a restaurant] to grab a sandwich and a small Dr. Pepper at 12:02 pm. I still have my receipt. I had not eaten anything prior to eating the sandwich, and I still am unable. Within two hours of eating that sandwich I became very ill. My fever went up from 98.6 to 100.2; I got diarrhea, stomach cramps, headache and chills. I am still very sick, I'm very weak, I can't really eat anything, and I'm having chills. I'm at work trying to work and I feel like crap...I don't know what to do, I called the restaurant and the manager is supposed to be calling me back when he gets in. Can you please help me?"*

A quick consultation of the chart above reveals that this person's lunch is most likely not the source of the illness. The incubation period is too short. A diagnosis of *Salmonella*, *Shigella*, *Campylobacter*, or *E. coli* O157:H7, for example, all of which have incubation periods longer than two hours, would also effectively rule out the meal as a source of the illness.

It is possible that the person became ill after ingesting *Staphylococcus aureus*—a pathogen with an average incubation period of 2-4 hours—but given the prevalence of the bug, and without knowledge of other ill persons who also consumed food at the same restaurant around the same time, it is very difficult to establish a causal connection between the meal and the illness.

"The Food Looked/Smelled/Tasted Funny"

In most situations, pathogenic bacteria are completely undetectable to the consumer. Customers who complain that they know they got a foodborne illness from a particular meal because the food tasted funny are, very likely, wrong.

Many consumers with legitimate complaints tend to retroactively assign a negative connotation to a meal once the health department has identified it as a source of an outbreak. This common instinct should not tear down an otherwise viable claim. But a claim that something tasted funny, without other proof linking a particular food to illness, is suspect. For example, here is another case we turned away:

> *"I have recently read articles and lawsuits that you have pursued regarding contaminated food. I am hoping that you may be able to give me your professional advice or recommendation. My husband recently opened a bottle of salsa and smelled an unusual odor but chose to eat it regardless, thinking that it*

was just his nose. After taking two bites and tasting rather badly, he found what appeared to be a rather large piece (approx. the size of the back of an adult's fist) of human or animal flesh. Even though he didn't seek medical attention, he did become very nauseated. I do feel that the manufacturer should be held responsible for this mishap. Thank you for your time and consideration."

"Gross-Out" Claims

Another situation that is fertile for false claims is the alleged discovery of something other than food in a food container. While certainly not the type of thing a food processor may want on the news, claims centered on finding, but not eating, some undesirable agent in food rarely have value. This example illustrates the point well:

"I opened a box of Buffalo wings and dumped them out on a plate to be cooked in the microwave. An unusually shaped piece caught my eye and I picked it up. When I saw that the "piece" had a beak, I got sick to my stomach. My lunch and diet coke came up and I managed to christen my carpet, bedding and clothing. I want them to at least pay for cleaning my carpet etc. What do you think?"

In Between the Quickly Dismissed and the Clearly Compelling

How does one evaluate a legitimate foodborne illness claim? I rely on four primary tools. All four are important. Combined, they can establish an airtight case.

1. Health Department Investigation of an Outbreak or Incident
2. Prior Health Department Inspections
3. Medical Records
4. Lab Results

The Health Department Investigation of an Outbreak:

While statutes and regulations vary from state to state, all states have agencies tasked with monitoring bacterial and viral illnesses associated with food consumption. The illnesses monitored include *E. coli* O157:H7, *Campylobacter, Salmonella, Shigella, Listeria,* Norovirus, and Hepatitis A. For most of these pathogens, a positive lab result from a human sample (blood or stool) triggers a mandatory report to the local health authority and some type of follow-up investigation.

The scope of the investigation varies from case to case depending on the pathogen involved, the type of food, the associated illness, the number of persons who are or may be sick, and the local jurisdiction. These factors determine the strength and quality of documentation associated with an outbreak. In most situations, the results of the investigation are either made public by the health authorities or can be obtained through public records requests under disclosure Acts, like the Freedom of Information Act. The information in those reports can be used to support a legitimate foodborne illness claim.

It is very difficult to dispute a Health Department confirmed outbreak or even an isolated case. In litigating thousands of food poisoning claims arising out of scores of outbreaks, I have seen many defendants take issue with some or all of the health department's conclusions regarding an outbreak. But I have yet to see a defendant successfully avoid liability where the health department concluded that the defendant's food was the source of an outbreak. One likely reason for this is that, in general, health departments do good and careful work. Despite the occasional disagreement from the pinpointed member of the food service industry, most would agree that health departments are rather cautious and conservative.

In our experience, health departments do not prematurely point the finger. In addition, health departments are operating with a much higher burden of proof than that required by the civil justice system. Most epidemiologists will not confirm an outbreak without 95% confidence in a particular conclusion. Juries in a civil trial, on the other hand, only have to conclude that a company is more likely than not (51%) responsible for an outbreak. Finally, it has also been our experience that the jury is likely to accept the "neutral" determinations of the health department over the opinions of a defendant's paid experts.

Example: Finley School District *E. coli* O157:H7 Outbreak

An excellent example of a jury's faith in a health department's investigation and conclusions was a case that I tried in 2001, *Almquist et al. v. Finley Sch. Dist*. The case arose out of an *E. coli* outbreak in the Tri-Cities area of eastern Washington State in October 1998.

Local and state health officials investigated the *E. coli* O157:H7 outbreak. They concluded that the source was a ground beef taco meal prepared and served by the Finley School District at Finley Elementary School. The eleven plaintiffs—all minors—were identified as either "confirmed" or "probable" members of the outbreak.

All but one of the plaintiffs attended Finley Elementary School. Four of the children developed a severe complication of *E. coli* O157:H7, hemolytic uremic syndrome ("HUS"), which resulted in varying degrees of permanent kidney damage.

The child with the most severe injuries (F.M.) was the only plaintiff who did not attend the school and did not eat the implicated meal. F.M.'s older sister, however, did attend Finley Elementary and had eaten the taco meal. It was the plaintiffs' position that this non-student had acquired an *E. coli* O157:H7 infection through exposure to her sister or another ill student. This phenomenon is known as "secondary infection."

The defendant took issue with nearly every facet of the plaintiffs' case and, in doing so, took on the task of attacking the health department's conclusions, which were supportive of the plaintiffs' case. For instance, the defendant disputed the health department's conclusions that the taco meal was the source of the *E. coli* O157:H7 outbreak. The defendant also disputed that F.M. had actually suffered an *E. coli*

O157:H7 infection. F.M.'s stool did not culture positive for the *E. coli* O157:H7 bacteria, which is not uncommon. She had been diagnosed as having been infected, and the health department deemed her a "probable" secondary case. Finally, the defendant took the position that, even if F.M. had an *E. coli* O157:H7 infection, there was insufficient evidence to demonstrate that the taco meal was the source of her illness.

The case was bifurcated for trial, meaning liability and damages were tried separately. The liability portion of the trial lasted four weeks, and it resulted in a plaintiffs' verdict. After trial, the jury was interviewed by the parties. Testimony from many of the health department officials involved in the investigation was, in the jury's collective mind, highly persuasive.

Can the Plaintiff Make a Case Without Health Department Support?

Health departments will not report a "confirmed" outbreak, or pinpoint a restaurant as the "confirmed" source of a food illness, without statistical certainty. Without 95% confidence in a particular conclusion, health departments are likely to define individuals or outbreaks as "possible." This is the case even where the confidence in a particular conclusion is well above the legal standard of more likely than not.

If the health department has investigated and found a claimant's illness did not come from a particular source, the plaintiff will face the same uphill battle taken on by so many defendants. It is possible, however, for a plaintiff to make a claim for damages without a health department's confirmation of an outbreak. In these cases, reliable expert opinion or examination of the health department investigators themselves can establish the source of a plaintiff's illness with sufficient certainty to meet the legal burden of proof.

Proving a Case Using Prior Health Inspections/Violations

A common difficulty in investigating foodborne illness cases stems from the fact that the contaminated food has almost always been consumed by the time the source of an outbreak has been identified. In other words, the vehicle of transmission is gone. One way of overcoming this problem is by documenting a food service establishment's sordid past. This is accomplished by compiling investigative reports of prior incidents or accusations of food contamination. Similarly, a history of failed health inspections or recurring problems with food production and service procedures can help build a case, using circumstantial evidence.

Supportive documents can be acquired through the discovery process afforded by litigation or through the Freedom of Information Act. The uncovered documents will help the plaintiff make his case in a variety of ways. Sometimes, there may be documentation of improper food handling procedures that can circumstantially prove the manner of contamination. In other situations, a list of improper techniques and code violations can serve as a tool for limiting a defendant's trial options, or it can position a case for early and favorable settlement. Finally, particularly egregious or repetitive examples of

improper food handling techniques can build a punitive damages case, in jurisdictions where such damages are available.

Identifying the Improper Procedure that Led to the Contamination of the Food

It is a rare case, at least with respect to restaurant-based food poisoning claims, when contaminated leftovers can be located by the time investigative agencies or lawyers are on the scene. This missing piece of the puzzle can be supplied, however, by identifying specific errors in the preparation of the suspected food or foods.

Improper Cooking Procedures

In 2007, a young girl suffered a particularly severe *E. coli* O157:H7 infection that left her with permanent kidney damage. She had eaten a hamburger purchased from a midsized southern California fast-food chain. Hamburgers have been commonly viewed as the source of *E. coli* O157:H7 infections in humans and nothing else in the child's food history was a likely source of the infection.

By the time health department officials investigated, however, the case of hamburgers responsible for the girl's illness was long gone. The health department did not find any food on site that tested positive for *E. coli* O157:H7. A thorough review of the restaurant's current and prior inspections though, revealed a serious flaw in its cooking method that provided an explanation for the client's exposure. According to the inspection report:

> *Hamburger buns are toasted on the grill immediately adjacent to the cooking patties, and it is conceivable that, early in the cooking process, meat juices and blood containing active pathogens might possibly splash onto a nearby bun.*

In fact, on six separate occasions over a three-year period, the management of the restaurant had been advised of the dangers of cross-contamination of the hamburger buns by hamburger juices. Prior inspection reports also revealed that the chain's cooking methods presented a high risk of cross-contamination. Once the plaintiff's expert reviewed the documents and presented the findings, the matter settled quickly.

Improper Refrigeration

In another case, a Chinese restaurant in Ohio was the suspected source of an *E. coli* O157:H7 outbreak in the fall of 2002. Again, no leftover food was available for testing. In addition, the restaurant was buffet-style, which complicated the identification of a single contaminated food item. During the investigation, however, it was revealed that a disproportionate number of ill patrons were children, and it began to appear that the culprit food might in fact be Jell-O. The health department investigation report provided the answer to the obvious question: how might Jell-O have become the source of an *E. coli* O157:H7 outbreak?

The report noted a host of food handling errors in the restaurant, none more important than this one: “raw meat stored above the Jell-O in the refrigerator.” Officials concluded “the likely source of *E. coli* O157:H7 in the Jell-O was from raw meat juices dripping on the Jell-O while it was solidifying in the refrigerator.” The defendant never seriously contested liability once plaintiffs obtained the report.

Improper Storage and Cooking Procedures

In 2006, a group of people who had attended a banquet hosted by a restaurant in Washington State fell ill days later. Many of the banquet goers tested positive for *Salmonella*, but leftover food items had either been discarded or had tested negative. The health department’s subsequent investigation of the event provided the information necessary to establish liability.

The food service establishment had violated state food regulations by “pooling” dozens, if not hundreds, of raw eggs in a single bucket for storage overnight. This process allows bacterial contamination from a single egg to taint exponentially larger amounts of food, thereby placing many more consumers at risk. The establishment subsequently used the raw eggs as a “wash” on a specialty dessert. Then, once again in violation of food code, the food workers failed to cook the egg thoroughly. When these actions were taken together with the fact that raw eggs are a particularly notorious source of *Salmonella*, the smoking gun was back in the defendant’s hands.

Patterns of Poor Food Handling Practices

In some circumstances, damaging inspection documents can also dissuade a defendant from contesting liability in front of a jury. In a situation where defending the case from a liability standpoint is a less than certain undertaking, defense counsel may be wary of admission of evidence that will make the defendant look bad in the eyes of the jury.

Improper Sanitation

In 2000, a producer and distributor of high-end fresh food items were identified by various health agencies as the source of a large *Shigella* outbreak on the West Coast. The firm, a relative newcomer to the food industry, operated with a marketing stance and inward belief in the high quality of its products. Health department inspections, however, revealed serious problems at the company’s production facilities, including the lack of fully operational bathrooms for employees, insects near food production sites, and evidence of rodents in the facility.

Through discovery, it was also uncovered that a major commercial purchaser of the firm’s product had conducted its own inspection of the facilities, and had refused to purchase any more products until a number of significant upgrades were made to the facility.

In another case two years later, health officials suspected a Seattle-area restaurant as the source of a medium-sized outbreak of food poisoning. Even though one of the patrons experienced an unusually severe acute illness, medical practitioners and health officials were unable to pinpoint the particular pathogen that had sickened the various individuals.

The defendant and its insurer were initially unwilling to concede liability in part based on the unidentified causative agent in the outbreak. But prior inspection reports revealed a consistent pattern of poor food-handling practices. The repeat occurrences of numerous health code violations led the health department to close the restaurant and temporarily revoke its license. In the end, the proposition of contesting liability proved too risky for the defendant.

Punitive Damages

Punitive damages are damages intended to punish and dissuade the offending defendant (and others like it) from engaging in particularly egregious behavior. Much in the same manner as other products liability cases, evidence of knowledge of prior incidents of improper behavior can be the cornerstone of a punitive damages claim in a foodborne illness case. Because a food establishment must sign off on its inspection reports, these documents are useful in establishing both prior violations and the defendant's prior knowledge.

For example, in 1996, fresh juice manufacturer Odwalla was identified as the source of a major outbreak of *E. coli* O157:H7 on the West Coast. Through discovery requests, my firm sought documentation of inspections of Odwalla products by governmental agencies. After overcoming strong opposition by Odwalla, we uncovered previously undisclosed inspection reports, including a report from the United States Department of the Army. The report revealed that the Army had inspected Odwalla's production methods prior to the outbreak and, based on those inspections, refused to buy its products. In a letter to Odwalla, the Army stated:

> *"We reviewed deficiencies noted in the report, which our inspector discussed with you at the time of the inspection. As a result, we determined that your plant sanitation program does not adequately assure product wholesomeness for military consumers. This lack of assurance prevents approval of your establishment as a source of supply for the Armed Forces at this time."*

Through further discovery, we recovered internal company emails reacting to the U.S. Army's inspection and subsequent refusal to purchase products from the company. One employee suggested implementing a microbiological testing program to address some of the problems uncovered in the inspection. The following is a portion of an email responding to the employee's suggestion:

"…why are we doing it, why now, what do we WANT TO PROVE…IF THE DATA is bad, what do we do about it. Once you create a body of data, it is subpoenable… you should look at this as though the Fresno Bee [a Sacramento newspaper] has looked into the results and asked a lot of questions…"

At the time of the *E. coli* O157:H7 outbreak, the company had not adopted the suggested testing regimen. We filed a motion to apply California law regarding punitive damages due to Odwalla's prior knowledge that its product was unsafe. With the punitive damages motion pending, the cases were resolved.

Proving a Case Using Medical Records

Medical records, assuming that one did in fact have treatment, become critical in proving a foodborne illness case. Evidence of a possible foodborne illness source can sometimes be found in the person's medical treatment records, such as an Emergency Room notation of a suspected food or drink item, or a lab test result confirming an infection from a specific pathogen. Documentation is the key.

What Type of Medical Evidence Can Help Make a Case?

Laboratory testing of stool cultures, and less commonly blood cultures, can identify the particular pathogen causing a claimant's illness. In reviewing a claim, it is important to recognize that lab test results are not always available, as health care providers do not always order laboratory testing.

Each foodborne pathogen carries with it an expected incubation period—the amount of time expected to transpire between exposure to the pathogen and the onset of symptoms. The incubation period for some pathogens is very long, resulting in a large possible exposure window, and might be unhelpful in certain situations.

In most situations, however, it can still be useful. For example, people often assume that the last meal they consumed before falling ill was the culprit. With many pathogens, however, this is very unlikely. The typical incubation for *E. coli* O157:H7, for example, is 2-5 days, with an incubation range of 24 hours to 10 days.

Most common bacterial and viral pathogens found in food share reasonably similar symptoms—nausea, vomiting, diarrhea, fever, aches, chills, and the like. Isolated on their own, these symptoms cannot be used to determine the specific pathogen affecting a claimant. But they can be part of the puzzle. For example, yellow skin and eyes, or jaundice, often characterizes Hepatitis A infections. *E. coli* O157:H7 infections are most often characterized by excessively painful, bloody diarrhea.

Proving a Case Using Lab Tests

Health care providers may, in some instances, order testing of an ill person's blood or stool to help determine the cause of illness. In most circumstances, a positive

result must be reported to a local public health agency pursuant to statute or regulation. Many states require reporting of positive tests for a number of pathogens, including *E. coli* O157:H7, *Salmonella, Shigella, Listeria, Hepatitis A, Campylobacter,* and others. It is the reporting of these positive test results that often triggers health department investigations and creates awareness of outbreaks.

When a sample of a form of bacteria, such as *E. coli* O157:H7, *Salmonella*, or *Shigella*, is taken from a stool sample, or a piece of contaminated food product, it can be cultured to obtain and identify the bacterial isolate. Bacterial isolates can be further broken down into their various component parts, creating a DNA "fingerprint."

The process of obtaining the DNA fingerprint is called Pulse Field Gel Electrophoresis, or PFGE. It operates by causing alternating electric fields to run the DNA through a flat gel matrix of an agarose, a polysaccharide obtained from agar. The pattern of bands of the DNA fragments—or "fingerprints"—in the gel after the exposure to the electrical current is unique for each strain and sub-type of bacteria. By performing this procedure, scientists have been able to identify hundreds of strains of *E. coli*, as well as strains of *Listeria*, *Campylobacter*, and other pathogenic bacteria.

Proving a Case Using PFGE

The PFGE pattern of bacteria isolated from contaminated food can be compared and matched to the PFGE pattern of the strain isolated from the stool of infected persons who consumed the contaminated product. When PFGE patterns match, they, along with solid epidemiological evidence, are proof that the contaminated product was the likely source of the person's illness.

When paired, PFGE and epidemiological evidence are extremely potent evidence to support causation. This is particularly true if the PFGE pattern has not been reported elsewhere. For example, suppose two unrelated persons both test positive for a genetically identical, unique strain of *E. coli* O157:H7 in a given town within a matter of days. If the subsequent, mandatory health department inquiry into these two illnesses reveals no other common exposures between the two people other than a hamburger from the same restaurant on the same day, finding a credible, alternate explanation for their illnesses can prove nearly impossible.

Proving a Case with PulseNet

PulseNet is a national network of public health laboratories that performs DNA "fingerprinting" on bacteria that may be foodborne. The network identifies and labels each "fingerprint" pattern and permits rapid comparison of these patterns through an electronic database at the CDC to identify related strains.

In 1993, a large outbreak of foodborne illness caused by *E. coli* O157:H7 occurred in the western United States. In this outbreak, scientists at the Centers for Disease Control and Prevention (CDC) performed DNA "fingerprinting" by PFGE and

determined that the strain of *E. coli* O157:H7 found in patients had the same PFGE pattern as the strain isolated from hamburger patties served at Jack in the Box restaurants.

A more prompt recognition of this outbreak and its cause may have prevented more than the estimated 750 illnesses. As a result, the CDC developed standardized PFGE methods and, in collaboration with the Association of Public Health Laboratories, created PulseNet, an early warning system for outbreaks of foodborne disease. Scientists at public health laboratories throughout the country can rapidly compare the PFGE patterns of bacteria isolated from ill persons and determine whether they are similar, thus indicating an outbreak linked to exposure to a common source of bacteria.

At present, PulseNet tracks five foodborne disease-causing bacteria: *E. coli* O157:H7, nontyphoidal *Salmonella, Shigella, Campylobacter* and *Listeria Monocytogenes.*

The Impact of a Negative Test

While the lack of a laboratory test or a negative test result may detract from the strength of a claimant's case, it can sometimes be easily explained by other factors.

Antibiotics

The consumption of antibiotics, whether or not related to the illness at issue, essentially renders a stool culture worthless. A negative result after commencement of antibiotics is common.

Untimely Testing

For different pathogens and different people, the speed with which the pathogen exits the body varies widely. The symptoms can continue well after the pathogen has been expelled from the body. Testing that occurs more than a few days after the onset of symptoms is unreliable, and a negative result at that time is not necessarily indicative that the pathogen had not been previously present.

No Test Given

Health care providers do not order blood and stool cultures for all, or even most, cases of gastroenteritis. In many cases, there simply will not be testing to include in the determination of the source of illness.

Looking at the circumstances as a whole

With an isolated illness, the lack of a positive stool culture may be problematic for a claimant. In the context of most outbreaks, however, it is not a significant problem. Circumstantial evidence may easily compensate. One such example is where one member of a dining party does not get tested, and others do. Three of four persons who all ate

together fall ill with the same, documented pathogen. The fourth demonstrates the same symptoms in the same time frame, but his or her doctor did not order stool cultures. Liability can still be established without the positive stool culture.

Testing the Food

In food poisoning cases, there is generally no food available to test because, not surprisingly, it was eaten. But when leftover food or uncooked portions of the food that were eaten is available and does test positive for the given bacteria or virus, it is powerful evidence that the food likely caused of the illness. This is especially true if the bacteria or virus in the food is a PFGE match to the ill person's stool culture isolate.

Legitimate Cases: What does a legitimate foodborne illness claim look like?

Real cases with real injuries will get a company's attention and drive changes in behavior. Here are four cases that illustrate that point:

1. The Case of the Ammonia Chicken Nuggets

The plaintiffs were a group of school children and teachers who consumed chicken contaminated with ammonia on November 24, 2002 at the Laraway Elementary School in Joliet, Illinois. The poisoning resulted from the acts and omissions of three corporate entities. In 2001, the State of Illinois, through the Illinois State Board of Education (ISBE), contracted with Tyson to have United States Department of Agriculture (USDA) commodity bulk chicken processed into chicken tenders for the National School Lunch Program (NLSP). The processing was completed at the Tyson plant located in New Holland, Pennsylvania. The state of Illinois also contracted with Lanter Refrigeration to warehouse the chicken tenders.

For an as yet unknown reason, Tyson's delivery of the chicken greatly exceeded Lanter's shipping and storage capacity. Lanter then contracted with Gateway Cold Storage to house the overflow chicken products at its facility in St. Louis, Missouri. The tenders were stored at the facility along with large amounts of other food intended for consumption at Illinois schools.

On November 18, 2001, there was a large anhydrous ammonia leak on the 6th floor of the Gateway St. Louis facility. Massive amounts of food destined for the school lunch program, including the chicken tenders, were exposed to ammonia.

Inexplicably, Gateway and Lanter notified neither the local health authorities, nor the Illinois State Board of Education. Even more remarkably, Gateway and Lanter continued shipping food from the facility, without any concern for the leak or the obvious risks it presented to consumers – particularly school-aged children. According to officials at the St. Louis City Health Department (SLCHD), Lanter and Gateway shipped approximately 800,000 pounds of product from the facility after the leak without any notice to consumers.

In fact, it was a shipment of potato wedges to Illinois schools that first alerted authorities in Illinois to the leak. On November 27, nine days after the leak, schools began complaining to the ISBE that they had received potato wedges that stunk of ammonia. Once complaints about the potato wedges had prompted an inquiry about the storage/condition of the food, Gateway and Lanter admitted over the phone to the ISBE that a leak had in fact occurred.

On November 27, 2001 ISBE sent a letter to Lanter. The letter acknowledged the leak and stated, "[A]t the advice of the IDPH, any food coming in direct contact with the ammonia leak should be destroyed." The letter advised Lanter to place all food connected with the ISBE on hold, pending further evaluation.

The FDA at this time "determined to place all product stored at Gateway at time of ammonia leak on hold until procedures are established for clean-up and treatment of products to dissipate ammonia odor."

Gateway and Lanter immediately began devising a plan that would allow them to release product that had been exposed to the ammonia leak. The original plan submitted to the FDA by Gateway and Lanter was rejected. The Missouri Department of Health complained, "the firm did not commit to any testing for ammonia residue in the product."

On or about December 7, 2001, the FDA approved a plan for the testing and release of FDA-regulated products, i.e. fruits and vegetables. It is not clear when, if ever, any agency approved any plan for release of the chicken tenders.

At this point, Gateway began shipping food to the schools again. The chicken tenders, however, were apparently not ready for release. There were 361 boxes of chicken tenders, each with 20-22 pounds of product in 5 individual plastic bags. The boxes were cardboard, and were labeled as Tyson product. The tenders had been so thoroughly exposed to the ammonia leak that the boxes and labels were either destroyed, saturated with ammonia and the ammonia smell, or both. Gateway, Lanter, and Tyson made the decision that rather than destroy the food, and swallow the small loss associated, that they would re-box, re-label, and "recondition" the boxes, and then send them on to the schools. The original plan was to re-box the tenders some time in February 2002.

In the meantime, it was becoming evident that other product shipped from the Gateway facility still stunk of ammonia, and was being rejected by schools and other public programs that received it. In January of 2002, a cafeteria worker in Champaign, Illinois complained about the powerful smell in some beef patties, and refused to serve them to school children.

In March of 2002, ISBE reported that a number of schools were rejecting products from the Gateway facility due to the odor of the boxes. ISBE noted that "some commodities are not in tightly sealed vapor proof packaging and the food itself has an odor." ISBE eventually asked and received permission from the USDA to use the rejected

food as animal feed. Officials at Lanter and Gateway were informed of the schools' complaints.

The re-packaging of the chicken tenders did not occur in February 2002. Piecing together the exact manner in which the chicken tenders were eventually re-boxed is complicated by the discrepancies in reports given by Lanter to health agencies after the students' illnesses.

Nonetheless, it is clear that in late June 2002, the chicken tenders were shipped from the Gateway facility to Lanter. At the same time, a request was made that Tyson send new labels for each box. The labels were designed to look exactly like the original labels on the chicken tender boxes. When the boxes were shipped, Lanter noted "some of the cases were in 'bad' shape and just did not look good, probably due the handling during the reconditioning." Apparently the product had already been through a reconditioning process designed to remove the ammonia smell from the boxes and product. While this process was designed to remove the smell, which might alert the recipient to the presence of ammonia, nothing was done to actually remove any ammonia from the product.

In the same time frame, a Tyson Representative visually inspected the product. He suggested that samples of the product be sent to Tyson for ammonia testing at the Tyson lab in Springfield, Arkansas. While it is not clear if the testing was ever actually completed, Tyson nonetheless contacted the ISBE and informed them the chicken was safe. Tyson called ISBE on July 3, 2002 and "notified [ISBE] the product is fine and [they] will change the casing." Either the testing was never done despite the representations to ISBE, or was done so poorly as to miss what would later prove to be ammonia levels more than 100 times the legal limit. Either way, Tyson's blessing on the chicken helped move it closer to the Laraway Elementary School.

The chicken tenders were re-boxed and re-labeled in early July 2002. When questioned by the IDPH, Lanter originally stated that it had no knowledge of the re-packing, and that no one at Lanter had participated. Shortly thereafter, Lanter told IDPH investigators that it had been "determined" that Lanter did in fact rebox roughly 320 cases of Tyson chicken tenders that were received from Gateway in three loads on June 24 and 25, 2002. Lanter said that the re-boxing was done at a Lanter warehouse on July 5, 2002.

New labels from Tyson were affixed to the boxes of chicken tenders. Although the original plan had called for the presence of a USDA employee at the re-boxing, the process went forward without supervision. Following the re-boxing, Lanter began shipping the chicken tenders to schools in Illinois. The evidence of their ammonia exposure, i.e. the smell and the damage to the packaging, had been removed, but the threat to the students remained.

When school began in August 2002, so did complaints to ISBE regarding food that smelled of ammonia. These complaints were, as a matter of course, passed on to

Lanter. At this time, the complaints did not involve the chicken tenders, which had apparently not yet arrived. In October of 2002, the Chicago Heights school rejected chicken tenders due to an ammonia smell. Lanter was notified but none of the defendants took any action to notify schools that had received the chicken tenders of the re-boxing, or of the complaint from Chicago Heights. Other schools joined in with complaints shortly thereafter. Still, the defendants did nothing to warn the other recipients of the chicken, despite having a list of those schools in their possession.

On November 25, 2002, the chicken tenders were served to students at Laraway elementary school. Within minutes of consuming the chicken 157 students, roughly half the school fell ill. The scene verged on total chaos. Students and teachers were running into the halls vomiting, with their throats and noses burning. Students panicked. School administrators called in ambulances, and children were taken to five local hospitals.

The IDPH would later verify the obvious—that the illnesses were caused by high concentrations of ammonia in the chicken. The chicken was the Tyson product that had been shipped by Lanter, and stored at the Gateway facility during the 2001 leak. Remarkably, even without considering the leak, the food should never have reached the students, as it had been in holding well past the 270-day legal limit. According to the USDA, Lanter had a consistent problem with rotating stock to avoid such problems.

On December 2, 2002, the Food Safety and Inspection Service (FSIS), a branch of the USDA, verified very high ammonia levels in the chicken tenders through its own laboratory analysis. This verified an independent laboratory at the behest of IDPH conducted testing. The tests revealed contamination of the tenders with ammonia at 500-2,000 ppm. According to the IDPH the legal limit for such concentrations is 15 ppm.

2. The Case of the Restaurant with No Hot Water

On June 30, 2003, the Lake County Health Department (LCHD) received a report from Lake Forest Hospital indicating that a patient was ill with a *Salmonella* infection. The LCHD immediately contacted the patient and interviewed him, using a questionnaire that is standard for the epidemiological investigation of foodborne illness outbreaks. One of the first things learned by the interviewer was that the patient had recently eaten at the Chili's Grill & Bar in Vernon Hills, Illinois.

About an hour after receiving this first report, a second person contacted LCHD to report that a family member had become ill after eating at Chili's in Vernon Hills. This prompted the LCHD to send investigators to the restaurant to inspect it. What they found was disturbing. The restaurant's dishwashing machine was broken and corroded; the tube that fed chlorine into the machine was plugged, preventing proper sanitization of dishes. Employees told the investigators that the machine had not worked properly for at least a week.

In fact, according to the LCHD Final Report, "[e] mployees had wrapped plastic bags around the line to stop the chlorine from spraying into the air." Despite the obvious

broken condition of the dishwasher, the restaurant management still had done nothing to get the machine repaired—that is, until they were caught by the health department.

During their inspection, the investigators also found food not stored at proper temperatures in the cooler. And following questioning of the on-duty manager, investigators learned that three employees, plus another manager, had called in sick that day with flu symptoms.

The next day, LCHD received two new reports of individuals with *Salmonella* infections who had eaten at Chili's on June 26, while Chili's management reported six more ill employees. With evidence of the outbreak-source growing increasingly clear, investigators returned to the restaurant to instruct employees on hand-washing procedures, to require the use of nailbrushes, and to issue a glove-use order. This meant that no further bare-hand contact of food was to be allowed at the restaurant.

The investigators also collected stool samples from the employees in addition to interviewing each one of them regarding gastrointestinal symptoms. As a result of these interviews, investigators discovered thirteen employees who had been allowed to work despite suffering from diarrhea and other symptoms.

Because of the large number of infected employees identified, the LCHD ordered the restaurant to close. A statement issued by LCHD Executive Director Dale Gallassie announced that:

> *"Due to the large number of ill employees, and the high potential for spread of this illness, Chili's was required to cease all operation or face suspension or revocation of its food service permit, at which time Chili's management made the decision to voluntarily close the establishment."*

On July 2, investigators returned to Chili's and collected 50 more employee stool samples, then issued a press release advising the public of the outbreak. People who had eaten at the restaurant between June 23 and July 1 were instructed to seek medical help if ill, and to report their illness to the health department. Just a few hours later, LCHD was flooded with telephone complaints of illness from people who had eaten at the restaurant. LCHD had to enlist the aid of two additional communicable disease nurses to help interview all of the people calling in about the outbreak.

The next day, on July 3, LCHD received a call from a customer that had dined at Chili's on June 27. She informed LCHD that the establishment had no running water while she had been there for lunch. The customer estimated that Chili's had no water for at least an hour or two. This was information that Chili's management had not thought necessary to share with investigators at the time of their initial interviews.

On July 7, LCHD received notice from the lab that the stool samples of seventeen employees had cultured positive for *Salmonella*. One of the employees had also worked at the Chili's restaurant located in Gurnee, which was immediately inspected. This was

the fourth restaurant potentially implicated in the *Salmonella* outbreak as a result of infected Chili's employees working at more than one restaurant.

Returning to the Vernon Hills Chili's restaurant, LCHD investigators interviewed restaurant managers again and confirmed that there had been no water during the lunch rush on June 27, and no hot water the entire day before. No one could explain why the decision was made to keep the restaurant open in violation of food-safety regulations requiring that hot water be available at all times during a restaurant's operation.

On the afternoon of July 8, LCHD issued a statement announcing that 31 cases of *Salmonellosis* had by that time been confirmed, and well over 100 cases were suspected to be related to the Chili's outbreak. Of the confirmed cases, 14 had eaten at the restaurant, and 17 others were employees.

Investigators inspected the restaurant on July 10, and then again on July 11 right before it's reopening. LCHD staff provided a hand-washing demonstration for Chili's employees, and then formally gave approval to operate. Chili's reopened at 11:00 a.m. for lunch. The restaurant had been closed for over two weeks as a result of the outbreak.

At the time of the restaurant's reopening, a total of 19 employees and 67 patrons had been confirmed positive for *Salmonella*, with an additional 128 cases suspected to be linked to the outbreak. Of the total cases so far, nine had been serious enough to require hospitalization.

On July 16, the results of microbiological testing performed on food samples from the restaurant, and from leftovers provided by customers, came back from the lab. Only two food samples had tested positive for *Salmonella*, both from customer leftovers: one from the Vernon Hills restaurant, and one from the Gurnee restaurant.

By July 18, LCHD concluded its investigation and determined the outbreak was under control. No secondary cases had been reported, but over 300 individuals had been sickened as a result of consuming contaminated food at Chili's. Of those, 141 customers and 28 employees had tested positive for the *Salmonella* bacteria, while 105 other infected individuals met the LCHD's definition of a probable case.

Infected employees who contaminated food with *Salmonella* as a result of poor sanitary practices and improper food handling caused LCHD issued a preliminary report that concluded the outbreak. It was by this time also determined that the *Salmonella* associated with the outbreak was *Salmonella* serotype *javiana*, a relatively rare and virulent strain often associated with foodborne transmission.

Once the LCHD believed the outbreak was controlled, the department sent a letter by certified mail informing the restaurant's management of a hearing scheduled for July 31 to discuss their failure to cease operations during periods where no hot water, or no water at all, was available, failure to adequately monitor their employees' health, and the steps management had implemented to prevent future outbreaks. Following the hearing,

LCHD stated that Chili's had violated local ordinances by remaining open and serving customers while without available water.

3. The Case(s) of *E. coli* Contaminated Leafy Greens

The 2006 outbreak of *E. coli* O157:H7 linked to Dole Spinach garnered national attention ultimately sickening over 200 and killing five. The outbreak became the most notorious in a long list of outbreaks traced to leafy greens, and led to a re-examination of the leafy greens industry.

E. coli O157:H7 outbreaks associated with lettuce or spinach, specifically "pre-washed" and "ready-to-eat" varieties, are by no means a new phenomenon. Here is just a small sampling of the twenty or more *E. coli* O157:H7 outbreaks since 1995 in which spinach or lettuce was the source:

- In October 2003, thirteen residents of a California retirement home were sickened, and two people died, after eating *E. coli*-contaminated, pre-washed spinach;
- In September 2003, nearly forty patrons of a California restaurant chain fell ill after eating salads prepared with bagged, pre-washed lettuce; and
- In July 2002, over fifty young women fell ill with *E. coli* O157:H7 at a dance camp after eating "pre-washed" lettuce, leaving several hospitalized and one with life-long kidney damage.

Several more outbreaks linked to contaminated leafy-produce, including most recently the September 2005 Dole packaged lettuce outbreak, are identified in the chart below, which is based on information gathered by the Center for Science in the Public Interest:

Date	Vehicle	Etiology	Reported Cases	States/Provinces
Aug. 1993	Salad Bar	*E. coli* O157:H7	53	1:WA
July 1995	Lettuce (leafy green; red; romaine)	*E. coli* O157:H7	70	1:MT
Sept. 1995	Lettuce (romaine)	*E. coli* O157:H7	20	1:ID
Sept. 1995	Lettuce (iceberg)	*E. coli* O157:H7	30	1:ME
Oct. 1995	Lettuce (iceberg; unconfirmed)	*E. coli* O157:H7	11	1:OH
May-June 1996	Lettuce (mesclun; red leaf)	*E. coli* O157:H7	61	3:CT, IL, NY
May 1998	Salad	*E. coli* O157:H7	2	1:CA
Feb.-Mar.	Lettuce (iceberg)	*E. coli*	72	1:NE

Date	Vehicle	Etiology	Reported Cases	States/Provinces
1999		O157:H7		
July-Aug. 2002	Lettuce (romaine)	*E. coli* O157:H7	29	2:WA, ID
Oct. 2003-May 2004	Lettuce (mixed salad)	*E. coli* O157:H7	57	1:CA
Apr. 2004	Spinach	*E. coli* O157:H7	16	1:CA
Sep. 2005	Lettuce (romaine)	*E. coli* O157:H7	32	3:MN, WI, OR

This history of repeated outbreaks gave Dole reason to know, prior to the 2006 spinach outbreak, that a problem existed within the leafy-greens industry—a problem that was affecting, sometimes killing, the very people responsible for Dole's substantial market share in the industry. If track record is any indication, Dole's response, if it had one, was woefully inadequate. This same sentiment had been articulated time and again by the Food and Drug Administration.

Here We Go Again: Another Dole *E. coli* O157:H7 Outbreak

Official word of the spinach outbreak broke with the FDA's announcement, on September 14, 2006, that a number of *E. coli* O157:H7 illnesses across the country "may be associated with the consumption of produce. Preliminary epidemiological evidence suggests," the statement continued, "that bagged fresh spinach may be a possible cause of this outbreak." By the date of the announcement, fifty cases had been reported to the CDC, including eight cases of hemolytic uremic syndrome (HUS) and one death. States reporting illness included Connecticut, Idaho, Indiana, Michigan, New Mexico, Oregon, Utah, and Wisconsin.

The much-publicized outbreak grew substantially over the next several days. By September 15, the FDA had confirmed 94 cases of illness, including fourteen cases of HUS and, sadly, one death. Recognizing the lethality of the developing outbreak, the FDA's September 15 Release warned people should "not eat fresh spinach or fresh spinach containing products."

Press releases over the ensuing days announced steady growth in the number of people sickened, hospitalized, and suffering from HUS as a result of the outbreak. There were 109 cases from nineteen states by September 17, and 131 cases from twenty-one states just two days later. The latter statistic included 66 hospitalizations and twenty cases of HUS.

Meanwhile, the FDA and CDC, in conjunction with local and state health agencies from across the country, worked feverishly to figure out the brand names associated with the illnesses. Early statistical analysis suggested that many brands were

implicated, but the spinach sold under the several brand names had all come from the Natural Selection Foods processing center in San Juan Batista, California.

Accordingly, Natural Selection recalled all of its spinach products with "use by" dates from August 17 to October 1, 2006. The recall, of course, included Dole brand spinach. But further data and study ultimately narrowed the possible sources of the outbreak down to one brand of packaged greens: Dole.

Though epidemiological evidence had already strongly linked Dole to the outbreak, the FDA found the proverbial "smoking gun" on September 20. The bag of Dole baby spinach had been purchased and consumed by an Albuquerque, New Mexico woman, and testing by the New Mexico State Health Department had confirmed that the product was contaminated with *E. coli* O157:H7 bearing the same genetic marker as the outbreak strain. The FDA announced the critical finding on September 21, 2006—also disclosing the "best by" date on the positive Dole bag of August 30—thereby giving a worried public a bit more information on what spinach products to eat, if any, and what to avoid.

By the date of the FDA's September 21 announcement, the number of confirmed cases had swelled to 157 people from twenty-three states. Ultimately, the FDA confirmed 204 outbreak-related cases, with 102 hospitalizations, thirty-one cases of HUS, and three deaths, though the actual number of people affected by the outbreak was certainly much larger. In addition to the elderly Wisconsin resident, the FDA stated that the outbreak had claimed the lives of two-year-old Kyle Algood, from Chubbuck, Idaho, and also 81-year-old Ruby Trautz, from Bellevue, Nebraska. The tragedy of this outbreak can hardly be overstated.

Epidemiological and laboratory evidence, which had already proved the link to Natural Selection and Dole, soon revealed that the contaminated spinach had been grown at Paicines Ranch in San Benito County, California. More specifically, investigators had traced the source of the contaminated spinach to one field on the ranch that had been leased by Mission Organics.

Once identified as the likely source for the outbreak, Mission Organics became host to health officials looking for the outbreak strain of *E. coli* O157:H7. State and federal investigators took hundreds of environmental samples and swabs from the vicinity of the implicated spinach field, which was fifty acres in size, including from a nearby cattle pasture and water source.

Investigators also sampled the intestinal lining of feral pigs that had been killed as part of the investigation. Samples from a variety of sources, including the pigs, the water, and cattle feces, tested positive for the same strain of *E. coli* O157:H7 that had by then been isolated in over 200 people nationally. Finally, the outbreak strain of *E. coli* O157:H7 was ultimately isolated in at least thirteen separate bags of Dole baby spinach.

The Final Report on Dole: Blame Enough For Everyone

Once the investigation was completed, a final report on the outbreak was prepared by the California Food Emergency Response Team (CalFERT), a team comprised of members from the FDA and the California Department of Health Services. The Final Report is replete with facts damning of all those involved in the growing, harvesting, processing, distribution, and sale of the implicated spinach products. For example, speaking of the NSF processing facility, it states:

> *During the production week from August 14-19, 2006, the NSF South facility had the highest weekly production volume of the month. Between August 13-20, 2006 production email exchanges revealed a string of personnel shortages, including nine absent employees on Sunday, August 13, the date of the weekly-extended sanitation shift. Personnel records revealed that a number of absences were due to illness or illness in the family. NSF did not conduct ATP testing on a daily basis as required by the firm's SOP. No ATP testing was conducted from August 15-25, 2006. One ATP test collected from a scale vibrator failed on August 10, 2006, and no retest was documented.*

The Final Report also faulted NSF's procedures for monitoring the quality of processing-water, it's record keeping, and its inability to demonstrate that harvesting bins were being washed to prevent cross-contamination.

As for the Mission Organics growing operation, the findings were even more disturbing. The Final Report found that the land on the ranch where the spinach was grown "was primarily utilized for cattle grazing." Moreover:

> *Investigators observed evidence of wild pigs in and around the cattle pastures as well as in the row crop growing regions of the ranch….Potential environmental risk factors for E. coli O157:H7 contamination identified during this investigation included the presence of the wild pigs in and around spinach fields and the proximity of irrigation wells used for ready-to-eat produce to surface waterways exposed to feces from cattle and wildlife.*

And despite the fact that Dole had the right to inspect both NSF's processing facility, and the Mission Organics fields, it failed to do either, amply demonstrating that Dole did nothing to protect its customers.

Conclusion

Decision makers in the food industry must be prepared to quickly and accurately assess potential foodborne illness claims. To make such an assessment, one must have an understanding of the epidemiological, microbiological, and environmental health issues at play. Rash action to disregard or deny a legitimate claim could very well be

damaging to the company, and to the public at large. There need be no significant risk, and little cost, associated with a careful evaluation of a claim. Thus, an understanding these basics of claim evaluation is an essential tool.

About the Author

William (Bill) Marler is the nation's leading attorney representing victims of foodborne illness and a stalwart advocate for improved food safety in the United States and abroad. His work began in 1993 when, as a young lawyer, he won record settlements for the families of children made seriously ill in the infamous Jack in the Box *E. coli* outbreak. He has since lead his law firm, Marler Clark, to the apex of the legal world by representing thousands of victims of food poisoning.

Marler has continued to litigate against the food industry and to attract clients who need his services. In 2007, a 19-year-old dancer, Stephanie Smith, sickened by *E. coli*-tainted hamburger was left brain damaged and paralyzed. Her story found its way to the front page of the New York Times in 2009 and landed the paper and its investigative reporter, Michael Moss, a Pulitzer Prize. Her case against Cargill settled shortly before trial in 2010 for an amount "to care for her for life."

In 2009 Linda Rivera, a 57 year old mother of six from Nevada was stricken with what Dr. Siegler described as "the severest multi-organ (bowel, kidney, brain, lung, gall bladder, pancreas) case of *E. coli* mediated HUS I have seen in my extensive experience." Linda's story hit the front page of the Washington Post and became Senator Harry Reid's touchstone for moving the Food Safety Bill in 2010.

Working with industry, academia, and government, Marler's efforts to create a safer food supply have transcended the courtroom. His spends roughly half his time speaking around the world on the need for improved food safety. To bring discussion to the public, he publishes the acclaimed online newspaper *Food Safety News* and shares his own opinions and insights on his blog, www.marlerblog.com, which is read by over one million people annually.

Marler has petitioned the USDA to increase foodborne pathogen regulation and has commissioned private studies to test for unregulated pathogens in the food supply. In Congressional testimony, he has asked the United States government to "Put me out of business", calling on it to pass updated, meaningful food safety laws. In 2011, his work was credited in the passage and signing of the Food Safety Modernization Act, the first major food safety update in decades.

Though his efforts to reform the food industry have come at the price of long hours and frequent travel, when he is at rest he can be found spending time at his Bainbridge Island home with his wife Julie and three daughters, Morgan, Olivia, and Sydney.

Marler Clark Resources

Botulism Blog

- Botulism Blog

Campylobacter

- About Campylobacter
- Campylobacter Blog

E. coli

- E. coli
- About Hemolytic Uremic Syndrome
- E. coli Blog
- E. coli Lawsuits & Litigation

Hepatitis A

- About Hepatitis A
- Hepatitis A Lawsuits & Litigation
- Hepatitis A Blog

Listeria

- About Listeria
- Listeria Blog

Norovirus

- About Norovirus
- Norovirus Blog

Salmonella

- About Salmonella
- Salmonella Lawsuits & Litigation
- Salmonella Blog

Shigella

- About Shigella
- Shigella Lawsuits & Litigation
- Shigella Blog

Complications of Foodborne Illness

Guillain-Barre Syndrome
Hemolytic Uremic Syndrome
Irritable Bowel Syndrome
Reactive Arthritis

General Foodborne Illness Information

Foodborneillness
Outbreak Database

See Also

Marler Clark
Bill Marler's Blog
Food Safety News
Food Poison Journal
Real Raw Milk Facts
Fair Safety