Foodborne Illness Litigation

by Steven R. Kramer, Esq.

Foodborne illness litigation moves like regularly paced litigation; what is not regularly paced, however, are the events leading up to the commencement of litigation. Reports of illness surface, local health officials become involved, reports are escalated to state health officials and soon the federal FDA and CDC intervene. This system is known as “notifiable disease surveillance program.” These events can take place in a matter of weeks. Indeed, the FDA itself states “[q]uick action is critical...” At some point, the FDA arrives for an unannounced inspection of a food entity’s facility and testing takes place. The FDA then calls the entity, advises of the results of the testing, and demands it undertake a recall.

Litigation has not even started at this point. But negative publicity begins and events take off. Plaintiff lawyers quickly mobilize and file a wave of lawsuits piggy-backed on the government’s work. Indeed, the FDA in its recently proposed Food Safety Modernization Act (FSMA) regulations acknowledges, “the Foodborne Outbreak Online Database (FOOD) allows the public direct access to information on foodborne outbreaks reported to the CDC.” Food entity defendants should also search electronic databases: FOOD, Reportable Food Registry (RFR), National Outbreak Reporting System (NORS), Food Emergency Response Network (FERN), and Foodborne Disease Active Surveillance Network (FoodNet).

The wave of lawsuits is premised on two critical assumptions: (1) All of the entity’s food product was contaminated; and (2) plaintiffs’ injuries were caused by the food product. These two assumptions must be rigorously analyzed and, if appropriate, challenged.

In some cases, for example, food product is contaminated well after it left an entity’s control. A good example of this fact is salad bars, which are touched and handled by numerous customers and employees. Contamination can occur due to human interaction. The CDC admits this phenomenon. In its study entitled “Salmonella Litchfield Outbreak associated with a Hotel Restaurant—Atlantic City, New Jersey, 2007,” MMWR, July 18, 2008/57(28); 775-779, the CDC stated: “[T]he cause of the outbreak was an ill restaurant worker who handled the fruit salad, and possibly other food.”

Some media reports suggested the entire food product was contaminated. That simply is not true in almost every instance. Food product testing is a function of sample-based testing. Lots are tested and, of the lots, samples are tested. Different tests results are common when testing lots. The key is to determine which lots tested positive for the presence of contamination and then trace the lots backwards and forwards (from "farm to fork").

Legal Framework

A plaintiff must prove the food product was defective (i.e. adulterated). In the past, they proceeded on traditional negligence, breach of warranty, and strict liability theories. Which of these theories are the most dangerous to an entity depends upon the substantive law of a particular state (i.e. whether due care principles are considered or strict liability imposed). Plaintiffs have begun to push and assert a private right of action based on the Food Drug and Cosmetic Act’s (FDCA) non-adulteration provision.

Strict Liability - Private Right of Action. According to the FDCA, the following acts are prohibited.

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.
(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.
(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

The Act has a criminal enforcement mechanism, but plaintiff lawyers have latched on to the statute because it imposes strict liability. There is a vigorous legal debate whether plaintiffs can allege a private right of action under the Act or whether plaintiffs can boot-strap the Act by alleging a negligence per se claim (violation of a statute can constitute negligence).
Buried in the FDA’s 600-plus page proposed FSMA regulations might be a nugget for defendants to use in rebutting plaintiffs’ arguments. The FDA states “whatever types of preventive controls a facility chooses to use in its operations, the requirement…is risk-based. Establishing risk-based preventive controls involves consideration of the available scientific data and information to determine appropriate risk-based preventative controls…” Similarly, the FDAs proposed regulations would require a hazard analysis to “[i]nclude an evaluation of the hazards…to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur.” If the FDA acknowledges the test is “appropriate risk-based preventative controls” for “hazards likely to occur,” why then should courts impose strict liability?

**Due Care and the FSMA of 2011.** Assuming due care principles apply, all entities in the distribution chain will be judged by their compliance (or non-compliance) with the following: Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs), and Hazard Analysis and Critical Control Points (HACCP) plan. They will also be judged on whether they are part of the voluntary Global Food Safety Initiative (GFSI) and their compliancy with GSFI guidance documents and Safety Food Quality (SFQ) codes.

The government long ago waded into the arena by issuing GMP “guidance documents.” The FDA issued a guidance document in the 1970s, and revised it in 2004. Plaintiff lawyers can use the document to establish whether an entity’s GMP was “state-of-the-art.” Now, the government has gone further with the enactment of the FSMA. The FSMA contains a long list of required acts and required forms by entities in the food distribution chain. The required documents will be key in any case and will be treated as the minimum standard of care.

**Does the Entity Comply with the Required Government Programs?** Registered food facilities are required to conduct hazard analyses and develop and implement written preventive control plans. The written plan must contain the following elements: a hazard analysis (which must be re-analyzed every three years), preventive controls (including controls at critical control points), monitoring, verification, correction actions, and record keeping.

These mandated documents will likely end up being part of a plaintiff’s document request and, depending on the entity’s position in the distribution chain, part of a upstream/downstream document request.

It is anticipated any deposition will key upon the definition of term “preventive controls”:

> "Those risk-based reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis…and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis."

As the FDA put it, “we propose to establish qualification requirements for a ‘qualified individual’…a ‘qualified individual’ would be required to successfully complete training with a standardized curriculum or be otherwise qualified through job experience to develop and apply a food safety system.” The "qualified individual" would certainly be the target of a plaintiff’s deposition notice (and likely to be the corporate designee witness).

And at deposition, the plaintiff could refer to the FDA’s comments to the proposed FSMA regulations:

- "A written food safety plan is essential for the facility to implement the plan consistently, train its employees, and periodically reanalyze and update the plan."
- "It [the written food safety plan] is also essential to a facility’s food safety team, to auditors, and to inspectors."
- "Designing a plan requires an individual who is knowledgeable in the concepts of preventive controls, with associated monitoring and corrective actions….Such knowledge requires scientific and technical expertise developed through training, experience, or both."

**Supplier Verification.** Minimization and prevention of hazards is the touchstone. Again, the government has waded into the debate. The USDA charted the National Advisory Committee on Microbiological Criteria for Foods (the “Advisory Microbiological Committee”) to provide guidance on the components of HACCP.

One might think the hazard guidelines are restricted to manufacturers, but the Advisory Committee placed the following burden upon importers:

> "Each facility should assure that its suppliers have in place effective GMP and food safety programs. These may be the subject of continuing supplier guarantee and supplier HACCP system verification."

> "All raw materials and products should be stored under sanitary conditions and the proper environmental conditions such as temperature and humidity to assure their safety and wholesomeness."

> "Supplier control" is a huge issue because an importer under the FSMA is now charged with verifying the GAPs and GMPs of their suppliers. Stated bluntly, importers cannot (and should not) turn a blind eye to the sanitary conditions of their supplier’s fields, manufacturing plants and packaging operations. As the FDA notes, “We determined that 36.9 percent of the 960 Class I and Class II recalls were directly linked to lack of supplier controls.”

It follows then that an importer should anticipate a discovery request and deposition question asking, “What did you do to verify your supplier’s level of GAPs/GMPs?” A real example follows: One of the fresh produce outbreaks was...
caused by pickers’ children being present in the field and their fecal matter contaminating the produce during harvesting/packaging. Plaintiffs asserted the importers failed to exercise due care in selecting and monitoring their supplier. The claims had “class warfare” overtones—you picked this supplier because of its low cost and knew the low cost was driven by lack of money being spent on housing and sanitary stations.

Since an importer cannot physically visit each of its foreign suppliers, an entire industry has emerged—third-party auditors. Now, the FSMA provides that the government will decide who is “accredited” to be a third-party auditor. The FDA plans to establish a system in which it recognizes accreditation bodies, which in turn would accredit eligible third-party auditors.

FSMA was supposed to take foreign supplier verification to the “next level.” The FDA was required as of Jan. 4, 2012 to promulgate regulations and the FDA advises its program might include “[m]onitoring records for shipments and lot-by-lot certification compliance...”

The government missed the 2012 deadline. As we write, the FDA still has not promulgated FSVP regulations. But the appendix to the FDAs recently proposed FSMA regulations sheds light on the FDAs thinking. The FDA stated:

“A facility receiving raw materials or ingredients from a supplier must ensure that the supplier (or a supplier to the supplier) has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient unless the receiving facility will itself control the identified hazard.”

Challenging the Assumptions
The determination of likely sources of contamination (when and where) is challenging. It certainly is not as straightforward as some suggest. As we noted, plaintiffs will piggy-back on the government’s work. This makes a defendant's causation defense very difficult. Like most technical cases, experts (and early retention of them) will be key.

The following disciplines should be retained: (1) an epidemiologist, (2) a standard of care expert in food handling requirements, regulatory requirements and industry practices, and (3) a medical causation clinician with expertise in infectious diseases. Depending on the scope of the outbreak and severity of reported illness, consideration should be given to challenging the plaintiffs' number one underlying presumption—the government’s conclusions were correct. An expert may be needed to determine the reliability or shortcomings of an FDA investigation.

When and Where Did The Contamination Enter The Food Chain? One must trace the food product from “farm to fork” and examine each physical and human interaction. An example provides insight on real-world sleuthing for the source of contamination: A food product is harvested in a foreign country and shipped in sealed bags to the U.S. The importer does not re-package the product, but ships it to a number of downstream purchasers. Testing reveals contamination of lots at each purchaser. None of the downstream purchasers re-packaged the product. Working backwards, the source of contamination can be likely eliminated—the downstream purchasers. That would lead to the question did the contamination occur during manufacture, packaging, or shipping? One must examine the specifications of the manufacture process (application of heat, amount of heat and its duration) to determine if contamination could have been “killed” during the manufacture process. If so, that would point the source of contamination to the packaging facility (or during shipping).

The above example would become much more complicated if the product was re-packaged or became incorporated into another food product. That kind of sleuthing would involve experts (and be very expensive).

Causation. Specific causation, that the food product actually caused the injury, is required. Causation is an inference analysis—a stack of cards. One court hit the nail on the head when it stated “Mere use of the product and subsequent injury...are not a sufficient basis from which to infer causation.” As another court put it, “However, in order for Plaintiffs to succeed in their differential diagnosis, they must ‘rule out’ potential causes.”

The Rare Case – Objective Proof. If a plaintiff went contemporaneously to a physician, a plaintiff’s causation case may be able to rest on the government’s work—“Pulse Net” testing. Pulse net is shorthand for pulsed-field gel electrophoresis (PFGE) testing. PFGE testing is a form of DNA testing in which the contaminant is “fingerprinted” and then patient samples (typically stool) are tested to determine if they contain the same pattern as the contaminant. If the sample does, then proof exists.

The Normal Case – Inferences. In most cases, it is inference upon inference. “[E]pidemiology addresses whether an agent can cause a disease, not whether an agent did cause a specific plaintiff's disease.” As a result, other possible causes of injury must be ruled out in order to establish specific causation. When did the plaintiff consume the food product and when did plaintiff's symptoms begin? Other potential sources need to be examined—other foods consumed and environmental exposures. Travel locations, restaurants, retail food store purchases, pets and other considerations all need to be examined.

Is There Temporal Causation? Plaintiffs themselves truly believe the "last thing they ate" caused their illness. But that belief ignores science because different pathogens have different incubation periods. When did the onset of illness occur in relation to consumption of the food product? For example, E. coli 0157:H7 has an incubation period of at least 24 hours. Sometimes a claim of immediate onset of illness can be subject to scientific causation challenge.
Is There Physical Process Causation? Some pathogens can be "killed" by application of heat or other types of sterilization processes (pasteurization, irradiation, and propylene oxide fumigation). An expert needs to examine physical processes along the entire distribution chain—including the end user (i.e. the consumer).

Conclusion
Foodborne illness litigation rests upon two critical assumptions: All of the food product was contaminated, and the food product caused the plaintiff's injuries. These two assumptions should be rigorously analyzed. It is hard work, but it is the only way to determine the true scope and nature of the claim. We await the final FSMA regulations, but we know they will have a major impact in foodborne illness litigation.

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