

# *Was It Something I Ate?*

## Helping Indiana Defense Practitioners Stay in Front of Food Liability Litigation

By Blaire M. Henley\*

“Approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year,” can be attributed to foodborne illness.<sup>1</sup> Foodborne illnesses account for “more deaths each year than the combined total of all 15,000 products regulated by the U.S. Consumer Products Safety Commission.”<sup>2</sup> These numbers are staggering and, unfortunately for the food industry, they have been brought to the forefront of the national consciousness due to several recent high-profile outbreaks. The recent salmonella outbreak involving peanuts from the Georgia company, Peanut Corp. of America, at one time reached forty-three states and Canada.<sup>3</sup> Just two years earlier, ConAgra “issued a voluntary recall of Peter Pan and Great Value peanut butters when the brands were linked to a *Salmonella* outbreak that had sickened 425 people in 44 states.”<sup>4</sup> The previous year, 71 people in five states fell ill after eating at Taco Bell.<sup>5</sup> Earlier in 2006, 199 people were infected with *E. coli* after “consumption of tainted spinach.”<sup>6</sup>

The media extensively covered the outbreaks, which was followed quickly by attention from legislatures. Since January of this year, state legislatures across the nation have introduced more than 600 bills directed at the food industry.<sup>7</sup> One-hundred thirty five of those bills concerned processing, sanitation, and inspection.<sup>8</sup> Another ninety-seven related to “meat, poultry, and fish.”<sup>9</sup> Sixty-three addressed “adulteration of food products.”<sup>10</sup> The remaining bills concerned restaurants.<sup>11</sup>

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<sup>1</sup> Paul S. Mead, et al, *Food-Related Illness and Death in the United States*, Centers for Disease Control and Prevention, available at <http://www.cdc.gov/ncidod/eid/Vol5no5/mead.htm>.

<sup>2</sup> *Id.*

<sup>3</sup> Lyndsey Layton, *Peanut Processor Knowingly Sold Tainted Products, It Found Salmonella 12 Times*, Wash. Post, January 26, 2009, at A01.

<sup>4</sup> Antony B. Klapper and Marilyn A. Moberg, *Marshalling an Effective Defense, Amid Wave of Food Contamination Litigation*, Update - Food Drug Law Institute Update, July/August 2007 at p. 32.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> Jane Zhang, *Hoping to Make Food Safer, States Go it Alone*, Wall. St. J., May 12, 2009, at A13.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

While Indiana has not been a hotbed of foodborne illness claims or legislation aimed at the food industry, recent developments indicate that the issue may hit home in the near future. The intent of this article is to arm Indiana practitioners with an understanding of recent litigation concerning foodborne illness claims and strategies for preventing and defending those claims. While foodborne illness is a hot topic, Indiana practitioners should also be familiar with information on additional litigation facing the food industry, such as claims concerning allegations of misleading or inaccurate labeling. Finally, in order to fully address litigation concerning either foodborne illness or labeling, a practitioner should be familiar with the laws and regulations governing the industry, including any developments in Indiana. Accordingly, this article also provides an overview of those topics.<sup>12</sup>

## A. Recent Cases Involving Foodborne Illness

The recent salmonella outbreak, linked to the Peanut Corporation of America, has already led to a flurry of lawsuits – and there are surely more to come. The family of Clifford Tousignant has filed suit against King Nut, claiming Mr. Tousignant died as a result of tainted peanut butter.<sup>13</sup> A couple in Vermont, the Meuniers, filed suit on behalf of their minor son, who became ill after consuming peanut butter.<sup>14</sup> Not to be outdone, the Hartford has already filed its own lawsuit, asking for a declaratory judgment on the extent of the Hartford’s responsibility under three policies issued to Peanut Corporation of America.<sup>15</sup> While the Hartford has refused to comment on the litigation, it is suspected that the Hartford may be attempting to avoid liability for any intentional acts.<sup>16</sup> Such a position by the Hartford may have a significant impact, given recent news that Peanut Corp. of America knew the products were contaminated.<sup>17</sup> Further, the Hartford’s lawsuit has prompted other plaintiffs to not only sue the Peanut Corporation of America but also companies that incorporated that company’s products. For example, the Meuniers, who had already sued Peanut Corporation of America, recently added Kellogg Co. as a defendant.<sup>18</sup> The couples’ attorney explained that “Kellogg was added as a defendant after it [became] clear that PCA’s assets and limited insurance coverage of between \$28 million to \$31 million would be insufficient once all action had been launched.”<sup>19</sup>

While these cases are in their infancy, others have made their way through the trial and appellate courts. One such case demonstrates how important experts are to foodborne illness cases. In *San Francisco v. Wendy’s Int’l, Inc.*,<sup>20</sup> the San Franciscos alleged that they purchased a hamburger from Wendy’s. After Mr. San Francisco ate a portion of the sandwich, he observed

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<sup>12</sup> Note, however, that this article does not provide an exhaustive explanation of the agencies that regulate the food industry or all regulations promulgated by the industry. It seeks only to alert practitioners to the agencies and regulations that should be considered in order to fully mount a defense of a food industry client.

<sup>13</sup> Bob Von Sternberg, *Family Sues Peanut Butter Maker Over Death Linked to Salmonella Outbreak*, Star Tribune (Minneapolis), April 23, 2009, at 2B; See Jeffrey Scott, *Laws to Tackle Tainted-Food Cases Seem to Lack Much Bite*, Atlanta Journal-Constitution, March 5, 2009, at p. 1C (indicating that attorney Bill Marler has filed “multiple claims against Peanut Corp.”); Diane Levick, *A Limit on Shelling Out?: The Hartford Asks Court to Clarify its Coverage Liability in Salmonella Outbreak, Peanut Recall*, Hartford Courant, February 6, 2009 at A1 (stating Marler has filed lawsuits on behalf of two clients.)

<sup>14</sup> Sarah Crichton, *Kellogg Sued in Salmonella Case*, NEWSDAY, Feb. 5, 2009, at A24

<sup>15</sup> See Levick, *supra* note 13.

<sup>16</sup> *Id.*

<sup>17</sup> See Layton, *supra* note 3.

<sup>18</sup> See Crichton, *supra* note 14.

<sup>19</sup> *Id.* The couple may also add King Nut as a defendant. *Id.*

<sup>20</sup> 656 S.E.2d 485 (W.Va. 2007).

that the hamburger was red and “tasted funny.”<sup>21</sup> He discarded the remainder of the sandwich.<sup>22</sup> Mr. San Francisco became ill shortly thereafter and within “one-and-a-half to two hours,” experienced “vomiting and diarrhea.”<sup>23</sup> Ultimately, he was admitted to the hospital, where he remained for ten days.<sup>24</sup> The San Franciscos filed suit, alleging that the Wendy’s hamburger caused Mr. San Francisco’s illness.<sup>25</sup> In support of their claim, the plaintiffs offered Dr. Gregor, who treated Mr. San Francisco at the hospital, and Dr. Todd, “an expert in food safety and toxicology from Michigan State University.”<sup>26</sup>

Dr. Todd testified that because Mr. San Francisco became ill so soon after eating the hamburger, a typical *E. coli* infection was not the cause – as *E. coli* typically requires a three to seven day incubation period.<sup>27</sup> Dr. Todd opined, however, that “*E. coli* bacteria was present on the ground beef in the Wendy’s hamburger; that the bacteria produced a verotoxin; and that the ingestion of the verotoxin ... produced the rapid onset of Mr. San Francisco’s symptoms.”<sup>28</sup> Dr. Gregor used differential diagnosis to determine that Mr. San Francisco suffered from a foodborne illness.

Wendy’s filed a motion for summary judgment, including contemporaneous motions in limine to exclude both Dr. Gregor and Dr. Todd.<sup>29</sup> The trial court granted the motions in limine and, thus, also granted the motion for summary judgment.<sup>30</sup> On appeal, the San Franciscos argued that Dr. Gregor was qualified, as he was a physician, with a board certification in internal medicine and a “sub-specialty in cardiovascular disease.”<sup>31</sup> Further, during his twenty-three years of practice, Dr. Gregor “treated numerous gastrointestinal conditions, including diagnosing and treating multiple patients suffering from foodborne illness.”<sup>32</sup> Wendy’s challenge to Dr. Gregor was, essentially, that Dr. Gregor was not a gastroenterologist or an epidemiologist.<sup>33</sup> The court explained that while other physicians with other specialties might be more qualified to render an opinion on foodborne illness, this went to the weight of Dr. Gregor’s testimony, not its admissibility.<sup>34</sup> The court rejected Wendy’s argument that Dr. Gregor inappropriately relied on a differential diagnosis to reach his opinion.<sup>35</sup> The appellate court also overturned the trial court’s exclusion of Dr. Todd, holding Dr. Todd’s opinions were supported by the evidence and by medical literature.<sup>36</sup> It should be noted that Wendy’s challenged Dr. Todd’s opinion, in part, on the basis that there was no evidence that Mr. San Francisco was exposed to *E. coli* – no samples taken from Mr. Todd during his hospitalization were tested for a foodborne pathogen.<sup>37</sup> The court explained that it did not require a positive test to proceed with a foodborne illness claim and noted that “food poisoning is a ‘fairly common illness’ for which scientific testing would not

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<sup>21</sup> San Francisco v. Wendy’s Int’l, Inc., 656 S.E.2d 485, 490 (W.Va. 2007). Unfortunately for Wendy’s, the San Franciscos were not the only patrons to bring foodborne illness claims against the company. See Roney v. Wendy’s Old Fashioned Hamburgers of N.Y., 2006 U.S. Dist. LEXIS 11303.

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.* at 491.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* at 496.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.* at 496-97.

<sup>35</sup> *Id.* at 497-500.

<sup>36</sup> *Id.* at 500-02.

<sup>37</sup> *Id.* at 501.

be cost effective, and the ‘emphasis is on the last meal before the event.’”<sup>38</sup> The appellate court determined that the trial court improperly excluded the San Franciscos’ experts; it also overturned the trial court’s entry of summary judgment.<sup>39</sup>

## **B. How to Reduce Clients’ Risk of Foodborne Illness Claims**

The headlines demonstrate that claims of foodborne illness can wreak havoc on a company’s business and its bottom line and the cases show that foodborne illness litigation is especially expensive because it is highly fact sensitive and dependent on testimony from experts. Accordingly, counsel for members of the food industry will want to help their clients to reduce the risk of foodborne illness claims.

Counsel can assist clients in reducing the risk for foodborne illness claims by suggesting proactive measures. The first step is to ensure that the client is aware of, and in compliance with, all applicable laws and regulations. Counsel may also wish to identify particular areas where the client may want a written policy to help ensure compliance with applicable laws and regulations – for instance, a restaurant may have a written policy regarding the proper handling of fish or poultry products whereas a manufacturer may have a policy on how employees should report any concerns regarding adulterated food. Care should be taken, however, to create written policies only on matters or issues that are material and that the client intends to enforce – while a written policy can be an effective means of ensuring compliance with applicable laws and regulations, a written policy disregarded by the company, or its employees, can also be a damning piece of evidence at trial.

Counsel may also advise clients regarding education to employees concerning appropriate food handling or food manufacturing processes. Counsel can also underscore the need to document any such education, as it may later provide evidence of reasonable care.

Further, companies, such as the American Sanitation Institute,<sup>40</sup> the American Institute of Baking,<sup>41</sup> and Silliker<sup>42</sup> perform private audits of facilities for food retailers, distributors, or wholesalers. Counsel may suggest to a manufacturing client that the client arrange for such an audit. The audit will help to avoid foodborne illness by identifying areas for improvement and will, in the unfortunate event of litigation, provide evidence that the company exercised reasonable care to prevent the harm. If a company arranges for such an audit, the records of that audit should be maintained. In addition, counsel may suggest to food companies downstream of retailers, distributors, or wholesalers that they require any vendor to provide a copy of its latest audit results. If the client has the bargaining power, counsel may also suggest that the client require the vendor to provide indemnification for any contaminated food product sold to the client.

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<sup>38</sup> *Id.* (quoting *Bussey v. E.S.C. Restaurants, Inc.*, 620 S.E.2d 764, 767 (2005)). As will be explained in detail in the succeeding sections, the court appears to suffer from a commonly held misconception that foodborne illness can be traced to the last meal consumed, when that is often not the case.

<sup>39</sup> *Id.* at 501-02. Further, foodborne illness is not even limited to humans. Pet food litigation cost as many as twelve manufacturers a combined \$32 million dollars. *See In re: Pet Food Products Liability Litigation*, 2008 U.S. Dist. LEXIS 94603 (D. N.J. 2008)

<sup>40</sup> <http://www.asifood.com>

<sup>41</sup> <http://www.aibonline.org>

<sup>42</sup> <http://www.silliker.com>

Further, counsel, for reasons discussed herein, should notify clients that immediate notification of a potential foodborne illness claim is essential to maximizing the potential for an effective defense.

These steps will likely not only reduce the incidence of contamination and foodborne illness, but will also present a strong defense in the event that an illness and subsequent litigation does occur.

### C. How to Effectively Defend a Foodborne Illness Claim

In the event that a client is faced with a foodborne illness claim, counsel will want to act quickly not only because foodborne illness claims quickly garner unwanted media attention, particularly when multiple persons are sickened, but also because evidence, such as stool or product samples and questionnaire responses, needs to be gathered and preserved.

#### 1. Initial Investigation and Informal Discovery

When counsel receives notice of a foodborne illness claim, he must first determine whether the Indiana Department of Health (“ISDH”) has been notified. If so, contact the ISDH representative in charge of the investigation to determine what evidence has already been gathered. Have the claimants provided a stool sample for testing? Have the claimants filled out a questionnaire about their exposure to particular foods and food facilities?

##### a. Obtaining Necessary Samples

Obtaining a stool sample is particularly important, as tests may reveal what pathogen, if any, has caused the illness. Knowing what pathogen is involved is necessary to identify the incubation period for the foodborne illness, which is incredibly important. Many lay people assume that any given foodborne illness was caused by the last meal consumed before symptoms developed.<sup>43</sup> As evidenced by the table below, that is often not the case, as some foodborne pathogens have incubation periods of several days.

#### MAJOR FOODBORNE ILLNESSES<sup>44</sup>

DISEASE	PATHOGEN	INCUBATION PERIOD/MEAN	DURATION OF ILLNESS
<u>Salmonellosis</u>	<i>Salmonella</i> (facultative) BACTERIA	8-72 hours 18-36 hours	2-3 days

<sup>43</sup> Even courts can fall victim to this misconception. See *San Francisco v. Wendy’s Int’l, Inc.*, 221 W. Va. 734, 750 (W. Va. 2007)(quoting another case and explaining that “[a]s the *Bussey* court indicated, ‘food poisoning is a ‘fairly common illness’ for which scientific testing would not be cost effective, and the ‘emphasis is on the last meal before the event.’” Given the pervasiveness of the misconception, counsel should take every opportunity in the litigation to remind the plaintiff, and the Court, that the identification of the source of a foodborne illness is more complicated than recounting the last meal eaten.

<sup>44</sup> Information taken from the Indiana State Department of Health, FBI Bacteria and Viral Charts, <http://www.in.gov/isdh/21057.htm>, last accessed on May 12, 2009. The charts provided by the Department of Health include additional information regarding symptoms, foods impacted, and type of illness.

<b><u>Shigellosis</u></b>	<i>Shigella</i> (facultative) BACTERIA	1-7 days 1-3 days	Indefinite
<b><u>Listeriosis</u></b>	<i>Listeria monocytogenes</i> BACTERIA	2 days – 3 weeks 4-21 days	Indefinite; high fatality in the immuno-compromised
<b><u>Staphylococcus</u></b>	<i>Staphylococcus aureus</i> BACTERIA	1-6 hours 2-4 hours	1-2 days
<b><u>Clostridium perfringens</u></b>	<i>Clostridium perfringens</i> BACTERIA	8-22 hours 10 hours	24 hours
<b><u>Bacillus cereus</u></b>	<i>Bacillus cereus</i> BACTERIA	½ - 5 hours; 8-16 hours ½ -5 hrs; 12 hrs	6-24 hours; 12 hours
<b><u>Campylobacter</u></b>	<i>Campylobacter jejuni</i> BACTERIA	2-5 days	5-7 days 3-5 days
<b><u>E. coli 0157:H7</u></b>	<i>Escherichia coli</i> BACTERIA	2-5 days	5-10 days 2-5 days
<b><u>Botulism</u></b>	<i>Clostridium botulinum</i> BACTERIA	12-36 hours; 72 or more hours	Several days – year 18-36 hours
<b><u>Viral Gastroenteritis</u></b>	Snow Mountain, calicivirus virus	24-48 hours	24-60 hours 36 hours
<b><u>Hepatitis A</u></b>	Hepatitis A VIRUS	7-50 days	Several weeks to months 25-30 days
<b><u>Norovirusn infection</u></b>	Noro Virus	12-96 hours	1-2 days

Establishment of an incubation period may permit a defendant to wholly rebut a plaintiff's claim. In *Anderson v. Piccadilly Cafeteria, Inc.*, Anderson filed suit against Piccadilly Cafeteria, Inc., alleging that a salad purchased at Piccadilly Cafeteria, Inc. caused her to suffer severe vomiting and diarrhea. Ms. Anderson stated that her symptoms began within fifteen minutes of eating the salad. Defendants put forth evidence demonstrating “that the incubation period for food bacteria is at least one hour, usually much longer.”<sup>45</sup> Accordingly, plaintiff abandoned the claim that the food was adulterated, instead arguing that she suffered a “vagal response” to the salad, a claim with which the appellate court dispatched. Other plaintiffs’ claims have been similarly disproven based on evidence regarding the incubation period.<sup>46</sup>

<sup>45</sup> *Anderson v. Piccadilly Cafeteria, Inc.*, 804 So. 2d 75, 77 (La. App. 2001).

<sup>46</sup> *Denaro v. 99 Restaurant, Inc.*, 2002 WL 31546120 at \*2 (M.A. App. Div. 2002); *See Klapper, supra* note 4, p. 35.

If the ISDH has not yet obtained a stool sample, counsel may wish to consider contacting the claimant directly about providing a stool sample for independent testing.<sup>47</sup> In making that determination, counsel will need to evaluate a competing consideration – that some evidence indicates that juries return lower verdicts where the plaintiff is unable to attribute his injuries to a particular pathogen.<sup>48</sup> Thus, it is possible that lack of testing, and thus a lack of identification of the pathogen, may result in a lower verdict. As identification of the pathogen, however, may wholly eliminate a client’s product, it will, in most cases, still be advisable to arrange for testing. In some circumstances, however, it will be impossible to obtain a proper stool sample as the claimant’s symptoms subsided long before counsel was notified of the claim. In those situations, it is all the more important to obtain a food history, discussed herein, as soon as practicable.

If possible, counsel should also obtain a sample of the food that allegedly gave rise to the claimant’s illness. If a pathogen is identified in the stool sample, the food sample can be tested for that pathogen. If no sample is identified, it is possible that the food sample can still be tested for any evidence of contamination.

#### b. Obtaining Necessary Information

The fact that many people assume, often incorrectly, that a foodborne illness was caused by the last meal consumed before the onset of symptoms, means that counsel will want to obtain a “food history” from the claimant as soon as possible. Days or weeks after the illness, when the health department is investigating the source – or, worse, months or years later when the deposition occurs – the claimant will no doubt remember the last meal she ate before becoming ill, as she likely already associates that meal with her illness. What she likely will not remember is the food she ate in the days leading up to becoming ill or the restaurants she visited during that span – information that may identify the actual source of the illness. Thus, in order to ensure that a client will have the opportunity to show an alternate source for the illness, particularly when multiple claimants are involved, it is critical that a “food history” be obtained from the claimant as soon as possible. Oregon publishes a sample questionnaire that offers an excellent guide on the type of information needed.<sup>49</sup> The questionnaire seeks to identify what treatment the claimant has received and what types of samples, if any, have been taken.<sup>50</sup> It also seeks information on the foods consumed by the claimant, including at which restaurants or stores the claimant purchased the food.<sup>51</sup>

The questionnaire may also help to identify the precise incubation period of the illness, which may rule out the client’s products. In addition, counsel may consult with the ISDH. If the department has not yet gathered the information, counsel may contact the claimant to schedule an interview to gather the information. Obviously, if the claimant is already represented by counsel, the questionnaire should be sent to opposing counsel for discussion with the claimant.

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<sup>47</sup> If the claimant has used antibiotics near the time of the sample, the sample may reveal a false negative. See Marler, Presentation at the 2005 Defense Research Institute Conference on Food Liability Litigation, Separating the Chaff from the Wheat: How to Determine the Strength of a Foodborne Illness Claim.

<sup>48</sup> Jean C. Buzby, et al, *Product Liability and Microbial Foodborne Illness*, Report from the United States Department of Agriculture. This 2001 study analyzed verdicts in 175 foodborne illness cases from 1988-1997. In those cases “where the alleged illness came from a specified pathogen, plaintiffs won 41.7 percent of the time, and received an average award of \$82,333. In cases where the illness was caused by an unspecified pathogen, however, plaintiffs prevailed only 22 percent of the time and received average awards of only \$4,554.”

<sup>49</sup> <http://www.oregon.gov/DHS/ph/acd/outbreak/shotgun.doc>; Minnesota’s Department of Health also publishes a questionnaire, which is available at [http://www.co.washington.mn.us/client\\_files/documents/phe/ENV/ENV-MDH06G1sum.pdf](http://www.co.washington.mn.us/client_files/documents/phe/ENV/ENV-MDH06G1sum.pdf), p.185.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

Counsel may also want to evaluate the plaintiff's behavior as a source of comparative fault. Many people stricken with foodborne illness overlook their own role in the illness – i.e. the manner in which food was prepared or stored in the home. A study revealed that 1.5% of the persons studied drank raw milk, 1.9% ate raw shellfish, 19% ate runny eggs, and 30% preferred pink hamburger. Only 93% responded that they “almost always washed their hands after handling raw meat or poultry,” and that they “almost always washed their cutting board after cutting raw chicken.”<sup>52</sup> Accordingly, either at the informal discovery or formal discovery stage, counsel should gather information on how claimant, or the person in claimant's household responsible for food preparation, handled food as that information may reveal another possible cause of the claimant's injuries.

c. Gathering Necessary Documents from Client

Upon notice of the claim, counsel should immediately encourage the client to begin marshalling all documentation regarding the purchase, preparation, sale, or distribution of the product at issue. In particular, counsel should seek to gather the following types of documents: all contracts with vendors or distributors related to the product; all invoices for the purchase of the product by the client and the sale of the product to any consumers, including any records showing the method of transporting the product to the client or to a sales point; any indemnification agreements related to the product; and any records documenting the preparation or storage of the product.

It is possible that these documents will enable counsel to eliminate the client's product as a source of the illness – perhaps the client did not sell products to the location at issue or did not sell products during the relevant time period.<sup>53</sup> Even if the documents do not provide such a clear cut defense, and they most often will not, they will ensure that documents necessary to defend the client are not lost or destroyed.

Counsel should also consider reviewing any contracts pertaining to the product. Do the contracts indicate which party will bear the responsibility of tracing the product in the event of an outbreak – i.e. is the distributor responsible for notifying all stores to which it sold contaminated peanut butter? If so, counsel may contact the responsible party to ask that they conduct the necessary investigation to trace the product. Counsel may also review the invoices to see if those documents support or contradict the claimant's story regarding the purchase of the product. For instance, if the claimant asserts that he got sick from a product purchased from a particular store, verify that the client's products were in fact sold to that store (and at such a time that the product would not have expired prior to sale). Counsel should also identify any companies that transported the product to the client. If the product requires maintenance of a certain temperature to avoid spoiling, identify whether the transporting company has any records indicating the proper temperature was maintained. If not, consider adding the transporting company as a cross-defendant. To the extent the client has any indemnification agreements concerning the product, and the indemnification runs in the client's favor, counsel should notify the indemnifying party of the claim.

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<sup>52</sup> Shiferaw B, et al, *Prevalence of High-Risk Food Consumption and Food-Handling Practices among Adults: A Multistate Survey, 1996 to 1997*, FoodNet Publication. With respect to the types of food consumed, as such as raw milk or runny eggs, the study was based on what the participants had eaten in the five days before the study.

<sup>53</sup> Shawn K. Stevens, *Uncovering the Truth in Foodborne Illness Litigation: Defending Liability and Damages*, DRI Food Liability Seminar (May 2008), p. 50.

Finally, counsel may examine all records regarding the preparation or storage of the product. A client with detailed records may be able to show that no contamination occurred, by presenting circumstantial evidence on how difficult it would be for contamination to occur given the client's precautions.<sup>54</sup> For instance, Pepsi-Cola once exposed a hoax where people claimed to have discovered syringes in Pepsi cans, by showing the canning process and demonstrating that it was impossible for someone to contaminate a can with a syringe.<sup>55</sup> Similarly, if a company can show the lengths to which it goes to ensure proper preparation and storage, it may be able to show that contamination was either impossible or, at least, highly improbable.

Finally, the client's insurer should be put on notice, to ensure that any claims for coverage are preserved.<sup>56</sup>

## 2. Litigation Strategy

If the matter does proceed to litigation, counsel must evaluate whether the claims are preempted and what types of experts or consultants are needed to defend the claim and protect the client from harm to the brand or company name.

Some claims against the food industry may be preempted by federal law. One example of preemption is the express preemption provision in the Federal Meat Inspection Act, which provides, in part, that states may not impose requirements "in addition to, or different from those" under the Act regarding the "premises, facilities and operations of any establishment" where meat is inspected by the USDA/FSIS.<sup>57</sup> Further, states are prohibited from imposing "[m]arking, labeling, packaging, or ingredient requirements in addition to, or different than, those imposed by the FMIA."<sup>58</sup> In interpreting an express preemption provision from another statute, the Supreme Court explained that

*the phrase "no requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules. As we noted in another context, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."*<sup>59</sup>

Accordingly, statutes barring states from imposing any "requirements" on a particular issue not only bar the state from passing laws or regulations on the issue, but may also bar common-law claims.<sup>60</sup> Thus, counsel may want to evaluate which statutes govern the product at issue and then

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<sup>54</sup> See *Id.*, p. 49-50.

<sup>55</sup> Laura Zinn and Mary Beth Regan, *The Right Moves, Baby*, Business Week, July 5, 1993.

<sup>56</sup> This article does not address the insurance coverage issues arising in a foodborne illness claim, such as whether foodborne illness claims constitute "bodily injury," or whether a insured is covered for claims made by downstream parties affected by the contaminated product.

<sup>57</sup> 21 U.S.C. §678.

<sup>58</sup> *Id.*

<sup>59</sup> *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992).

<sup>60</sup> See *Cohen v. McDonald's Corp.*, 808 N.E.2d 1 (Ill. App. Ct. 2004)(holding plaintiff's claims about nutritional information provided by McDonald's were preempted by the NLEA.)

determine if that statute contains any preemption provisions and the applicability of any such provisions to the claims at issue.

As the matter nears trial, counsel can also evaluate whether to hire a media consultant to aid the client with responding to, and even influencing, media coverage. In smaller cases, and particularly those with only one claimant, such a consultant may not be necessary. In instances, however, with several claimants, it may be wise to hire a consultant to help the company convey a clear message that the company's products are safe if such a statement is supported by the initial investigation. While counsel will, understandably, be focused on prevailing at trial – such a victory will be hollow if the company's brand suffers irreparable harm during the period of litigation. A media consultant can help counsel identify how the litigation strategy may impact the client's brand and counsel can then discuss such concerns with the client. Just as the media consultant can help counsel spot potential issues, counsel can guide the media consultant about how certain statements to the media may impact the ongoing litigation.

Also, counsel will want to be aware that the client may value certain business concerns more than a particular litigation strategy. For instance, a client may have viable cross-claim against a vendor but elect not to pursue it as doing so would jeopardize a long-standing relationship that cannot be easily repaired or replaced.

Further, when a case reaches the jury, counsel should consider evaluating the “CSI-effect” – “a purported phenomenon whereby high-tech, forensic science dramatized in television crime dramas theoretically promotes unrealistic expectations among jurors of how conclusively forensic evidence determines...causation or liability.”<sup>61</sup> A jury consultant, Tara Trask, has explained that “the lack of forensic scientific evidence, even if it was simply overlooked, it never existed or is otherwise irrelevant, may in the end cause many jurors to disbelieve a legitimate claim or defense.”<sup>62</sup> Accordingly, in addition to “artfully teaching the science of food safety, a food liability attorney should always: (1) anticipate what scientific or forensic evidence jurors might independently believe “should” be available; and (2) if the evidence is not accessible (or, does not exist), be sure to explain why.”<sup>63</sup> Accordingly, if the client does not have a sample of the food that gave rise to the claim, counsel should explain the reasons to the jury. Further, if no samples were collected from the claimant at the time of the claimant's illness – such as a stool sample – that must also be explained to the jury. Failing to explain the absence of this evidence, the understandable reasons for its absence (for instance, all the food was eaten or leftovers were disposed of), may cause one or more jurors to conclude that the evidence existed but was not offered because it was unfavorable. Further, in a class-action or serious injury matter, it may make sense to retain a jury consultant who can help identify potential “CSI effect” issues.

#### D. Claims Related to Misbranding or Inaccurate Labeling

Food companies may be subject not only to foodborne illness claims but to claims related to labeling as well. In particular, counsel should be aware of the potential risks a client faces when it makes a nutrient content claim or a health claim on the label. FDA regulations indicate that “an expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., ‘low sodium’ or ‘contains 100 calories.’”<sup>64</sup> Further, phrases such as

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<sup>61</sup> Tara Trask, *The “CSI Effect”: Popular Culture's Effect on Civil Juries*, DRI Food Liability Seminar (May 2008).

<sup>62</sup> Shawn Stevens, *Anticipating Juror Perceptions and the “CSI Effect” in Complex Food-borne Illness Lawsuits*, Gass Weber Mullins LLC, available at <http://www.defendingfoodsafety.com/tags/food-poisoning-litigation-and/>, last accessed on May 14, 2009.

<sup>63</sup> *Id.*

<sup>64</sup> 21 CFR 101.13(b)(1).

“high in oat bran,” or those that suggest that the product “may be useful in maintaining healthy dietary practices,” such as “healthy, contains 3 grams (g) of fat” are “implied nutrient content claim[s].”<sup>65</sup> The FDA has defined a health claim as “any claim made on the label or in labeling of a food...that expressly or by implication, including ‘third party’ references, written statements (e.g., a brand name including a term such as “heart”), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition.”<sup>66</sup>

The FDA recently posted a letter to General Mills, Inc., taking issue with certain health claims made on Cheerios packaging and on General Mills’ website.<sup>67</sup> The FDA has posted a letter taking issue with claims on Cheerios that “Cheerios is .... clinically proven to lower cholesterol. A clinical study showed that eating two 1.5 cup servings daily of Cheerios cereal reduced bad cholesterol when eaten as part of a diet low in saturated fat and cholesterol.”<sup>68</sup> The FDA does permit health claims “linking soluble fiber from whole-grain oats with a lower risk of coronary heart disease, and also to include – as part of that statement – a note about lowering total and LDL cholesterol levels.”<sup>69</sup> The FDA contends, however, that the Cheerios’ label “inappropriately separates the heart disease and cholesterol claims.”<sup>70</sup> The FDA gave General Mills 15 to correct the matter. In response, General Mills issued a statement that the science supporting its claims is “not in question,” and that it looks forward to discussing the matter with the FDA.<sup>71</sup>

The Federal Trade Commission (“FTC”) regulates the related subject of food advertising, in particular whether the advertising is misleading.<sup>72</sup> Thus, if a company makes an assertion about the health effects of a food and that assertion is either incorrect or misleading, the FTC may file a complaint, alleging deceptive trade practices.<sup>73</sup> For example, in June 1987, Kraft, Inc. (“Kraft”) published an advertisement that implied that Kraft Singles had as much calcium as a five ounce glass of milk and that their product had more calcium than other cheese products.<sup>74</sup> Both implications were untrue.<sup>75</sup> The FTC entered an order requiring Kraft to cease and desist from making these claims about “any product that is a cheese, related cheese product, imitation cheese, or substitute cheese.”<sup>76</sup> Kraft filed suit seeking to overturn the order, but its appeal was denied.<sup>77</sup>

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<sup>65</sup> *Id.* at 101.13(b)(2).

<sup>66</sup> 21 CFR 101.14(a)(1). Both nutrient content claims and health claims are heavily regulated by the FDA and this article, as an overview of potential litigation affecting members of the food industry, cannot provide an exhaustive treatment of the subject. Thus, counsel with clients considering use of nutrient content or health claims may wish to review 21 CFR 101.12 and 21 CFR 101 in its entirety.

<sup>67</sup> Miranda Hitti, *FDA Warns Cheerios on Health Claims, FDA Calls Cheerios ‘Misbranded’ Because of Health Claim Rules; General Mills Stands by its Science*, WebMD Health News, May 13, 2009, available at <http://www.webmd.com/food-recipes/news/20090513/fda-warns-on-cheerios-health-claims>.

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> *Id.* at 38. Further, in Indiana, a food is considered misbranded if it contains a “false or misleading representation with respect to another food or a drug, device, or cosmetic.” 410 IAC 7-5-1(a).

<sup>73</sup> See *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7<sup>th</sup> Cir. 1992).

<sup>74</sup> *Id.*; *Federal Appeals Court Upholds FTC Ruling that Kraft Misrepresented Calcium Content of Individual Cheese Slices*, FTC Press Release, August 10, 1992.

<sup>75</sup> *Id.*

<sup>76</sup> *Id.* at 315.

<sup>77</sup> *Id.* at 327.

The FTC is not the only party cracking down on inaccurate or misleading labels. Consumers have mounted quite an attack of their own – and their attacks often prove costly.

One area of growing litigation is class-action litigation directed at a correlation between food companies and obesity. McDonald’s Corporation was sued by a class of plaintiffs claiming (1) that the company misled consumers to believe that the company’s food was nutritious, (2) that McDonald’s failed to disclose that some additives made the food less healthy, and (3) that McDonald’s implied that nutritional information was available when it, in fact, was not.<sup>78</sup> They also alleged that “as a result, plaintiffs have developed ‘obesity, diabetes, coronary heart disease, high blood pressure, elevated cholesterol intake, related cancers, and/or other detrimental and adverse health effects.’”<sup>79</sup> McDonald’s filed three motions to dismiss the plaintiff’s allegations, all of which were ultimately denied.<sup>80</sup> Today, some three years after the court denied McDonald’s third motion to dismiss – and no doubt countless hours of attorney time later - the court is evaluating whether to certify the class.<sup>81</sup>

Other plaintiffs have learned from the progeny of decisions in the *Pelman* case and have taken other food companies to task in class actions based on similar claims that the companies misrepresented that their products were healthy.<sup>82</sup> A recent example of such a case is *Lockwood v. Conagra Foods, Inc.*<sup>83</sup> In *Lockwood*, the plaintiff claimed the defendant engaged in “misleading conduct by advertising its ‘Healthy Choice’ pasta sauce as ‘all natural’ when in fact it includes ‘high fructose corn syrup.’”<sup>84</sup> Conagra moved to dismiss, arguing that plaintiff’s claims were preempted by the provisions of the National Labeling and Education Act (“NLEA”).<sup>85</sup> The NLEA provides that a state may not impose “labeling requirements for artificial flavors, colors or preservatives,” unless they are identical to the FDA’s requirements.<sup>86</sup> The *Lockwood* court denied Conagra’s Motion to Dismiss, noting that plaintiff did not allege that Conagra’s product contained “artificial flavoring, coloring or a chemical preservative,” instead plaintiff alleged that “‘high fructose corn syrup’ is not produced by a natural process and therefore the pasta is not ‘all natural.’”<sup>87</sup> Another court faced a similar claim – there the plaintiff claimed Snapple’s use of the phrase “all natural” was misleading because the product contained high fructose corn syrup – and that court reached a different conclusion.<sup>88</sup> The *Holk* court held that while the NLEA did not preempt the claims, implied preemption existed under the Food

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<sup>78</sup> *Pelman v. McDonald’s Corporation*, 396 F.3d 508, 510 (2<sup>nd</sup> Cir. 2005)(*Pelman III*). The *Pelman* case has given rise to numerous decisions, including, but not limited to: *Pelman v. McDonald’s Corporation*, 237 F. Supp. 2d 512 (S.D.N.Y. 2003)(*Pelman I*); *Pelman v. McDonald’s Corporation*, 2003 U.S. LEXIS 15202 (S.D.N.Y. 2003)(*Pelman II*); *Pelman v. McDonald’s Corporation*, 452 F. Supp. 2d 320, 322 (S.D.N.Y. 2006).

<sup>79</sup> *Id.*

<sup>80</sup> *See Id.*

<sup>81</sup> *See* March 27, 2009 Order, Docket No. 136 in *Pelman v. McDonald’s Corporation*, 1:02-cv-07821-SHS.

<sup>82</sup> *Mills v. Giant of Maryland, LLC*, 441 F. Supp. 2d 104, 105-06 (D.D.C. 2006); *Williams v. Gerber Products Co.*, 523 F.3d 934, 936-37 (9<sup>th</sup> Cir. 2008)(claiming packaging for fruit snacks were deceptive “because the product contained no fruit juice from any of the fruits pictured on the packaging and because the only juice contained in the product was white grape juice from concentrate).

<sup>83</sup> 2009 U.S. Dist. LEXIS 10064 (N.D. Cal. 2009).

<sup>84</sup> *Lockwood v. Conagra Foods, Inc.*, 2009 U.S. Dist. LEXIS 10064 (N.D. Cal. 2009).

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *Id.* The court also compared the plaintiff’s Complaint to various other express preemption provisions of the NLEA, each time holding plaintiff’s claims were not preempted. The *Lockwood* court also noted that the NLEA did not result in implied preemption of all state law regarding labeling, as the statute explicitly stated what it did preempt and contained a “savings clause” stating that “the NLEA ‘shall not be construed to preempt any provision of State law, unless such provision is expressly prohibited under’ 21 U.S.C. §343-1(a).” *Id.*

<sup>88</sup> *Holk v. Snapple Beverage Corp.*, 574 F. Supp. 2d 447 (D. N.J. 2008).

## E. Other Agencies and Regulations Affecting the Food Industry

Both federal and state agencies regulate food, including matters related to both labeling and food safety.

### 1. Regulation by Federal Government

The Food and Drug Administration (“FDA”) regulates approximately seventy-eight percent of “the domestic and imported foods sold in interstate commerce.”<sup>90</sup> The Food Safety Inspection Service (“FSIS”), an agency falling under the United States Department of Agriculture (“USDA”), regulates the remainder.<sup>91</sup> FSIS is charged, specifically, with regulating meat, poultry, and shell egg products.<sup>92</sup>

While the FDA and FSIS are the primary agencies overseeing the food industry, several other agencies touch the industry as well. For instance, the Center for Disease Control (“CDC”) collects and tracks data on various illnesses, including foodborne illnesses. In fact, the CDC investigates outbreaks of foodborne illness and monitors the effectiveness of measures aimed at combating such outbreaks.<sup>93</sup> The CDC also helps “state and local epidemiologists (and state health laboratories) identify and prevent food-borne illness and other outbreaks.”<sup>94</sup> The Environmental Protection Agency (“EPA”) touches on the food industry because it regulates certain pesticides and “establishes tolerances for residues on various food commodities and animal feed.”<sup>95</sup> Also, as already noted, the FTC regulates the advertising of food.

### 2. Regulation by Indiana

States may also each regulate the food industry. Indiana has taken advantage of that opportunity, imposing its own requirements for the labeling of food.<sup>96</sup> In particular, Indiana - like most states - requires a food manufacturer to provide the “quantity of food in the package,” which must be expressed “in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure...”<sup>97</sup> Further, Indiana has passed numerous regulations pertaining to the safe handling of food in restaurants and other establishments that serve food to the public.<sup>98</sup>

As already noted, many states are becoming very active with regard to the food industry. Oregon recently passed legislation imposing civil fines, as high as \$10,000, for companies that sell adulterated food.<sup>99</sup> Georgia passed a bill requiring companies to report, within twenty-four

<sup>89</sup> *Id.*; The Lockwood court criticized the Holk decision, stating the latter court “did not consider how the FDCA preemption provisions added by the NLEA affect the implied preemption analysis.” *See supra*, note 82.

<sup>90</sup> *Id. supra*, note 49 at p. 37.

<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> *Id.* Other agencies that regulate the food industry, although to a lesser degree, are the Animal and Plant Health Inspection Service; Grain Inspection, Packers, and Stockyards Administration; Agricultural Marketing Service; and National Marine Fisheries Service.

<sup>96</sup> *See* 418 IAC 7-5-1.

<sup>97</sup> 418 IAC 7-5-1(F)(2).

<sup>98</sup> *See* 410 IAC 7-21.

<sup>99</sup> *See* Zhang, *supra* note 7.

hours, any test results revealing tainted food.<sup>100</sup> Indiana has not yet introduced measures this strong. It has, however, recently considered legislation regarding nutritional information in restaurants.<sup>101</sup> House Bill 1207 was not passed in the last session, although it is likely that a similar measure may be introduced again next session. If it had passed, however, the bill would have required any restaurant with twenty or more locations in Indiana to provide certain nutritional information on their menus for “each item or unit of food” – namely “total calories, total fat and grams, total saturated fat and grams, total trans fat and grams, total cholesterol and grams, total sodium and milligrams, total carbohydrates and grams, total fiber and grams, total sugar and grams, total protein and grams.”<sup>102</sup> The information concerning calories and carbohydrates is required to be “made available to consumers in a manner that allows consumers to consider the information when selecting an item or unit of food for consumption, including presenting the information on the printed and posted menu of the food establishment.”<sup>103</sup> The other information required by the statute can be provided on a separate document made available to the customers.<sup>104</sup> At this time, the bill has been referred to the Committee on Commerce and Public Policy and Interstate Cooperation of the Senate.

While House Bill 1207 has not yet resulted in legislation, it should be noted that other states have passed similar legislation and that the legislation has raised particular concerns for the food industry – and their counsel. For instance, what methods must the restaurant use to calculate the nutritional content of its foods? May it rely on nutritional software, which calculates nutritional information based on ingredients, or must the restaurant have each menu item tested by a laboratory?<sup>105</sup> Also, will the legislation give rise to a private right of action if the restaurant fails to provide the required information or if it provides inaccurate information?<sup>106</sup> In addition, what is a restaurant’s liability for variation in the preparation or serving of dishes?<sup>107</sup> “As one restaurateur said, ‘[i]f you’re working by hand and making pasta, putting in cream and tossing in things as you go, it’s probably fairly close, but there are going to be variances because it’s not prepackaged ... Even if you’re cutting a meatloaf, if the specifications [sic] on the meatloaf is 12 ounces and (instead) cuts 13 ounces, it’s going to be off by 6 to 8 percent.’”<sup>108</sup> These questions are no longer merely rhetorical – Applebees was hit with a \$5 million lawsuit “after an independent lab found more calories and fat in a menu item than the chain’s nutritional information claimed.”<sup>109</sup> In fact, more than one lawsuit has been filed against Applebee’s

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<sup>100</sup> *Id.*

<sup>101</sup> A recent study reveals that consumers armed with nutritional information may “moderate” their eating habits; Howlett, et al, *Coming to a Restaurant Near You? Potential Consumer Responses to Nutrition Information Disclosure on Menus*, Journal of Consumer Research, 2009; *People Will Make Healthier Choices if Restaurants Provide Nutritional Data, Study Finds*, Science Daily, April 6, 2009.

<sup>102</sup> House Bill 1207, 116<sup>th</sup> Gen. Assem. (Ind. 2009); New York passed similar legislation, which was upheld despite challenges by the New York Restaurant Association. *N.Y. Restaurant Association v. New York Board of Health*, 556 F. 3d 114, 117-18 (2<sup>nd</sup> Cir. 2009). In particular, the Second Circuit explained that “the NLEA *does not* regulate nutrition information labeling on restaurant food, and states and localities are free to adopt their own rules.” *Id.* at 120, 123. A state may not, however, regulate use of nutrition “claims,” such as “heart healthy.” *Id.* at 123-24.

<sup>103</sup> House Bill 1207, 116<sup>th</sup> Gen. Assem. (Ind. 2009).

<sup>104</sup> *Id.*

<sup>105</sup> Kenneth Odza, *Nitty-Gritty on Menu Labeling Requirements and What Can Be Done to Stem Consumer Litigation*, November 12, 2008, <http://www.foodliabilitylaw.com/2008/11/articles/food-litigation-tips/nittygritty-on-menu-labeling-regulations-and-what-can-be-done-to-stem-consumer-litigation/>.

<sup>106</sup> *Id.*

<sup>107</sup> *Id.*

<sup>108</sup> *Id.*; citing Rebekah Denn, *Local Chains Affected by Labeling Law Ready Their Nutritional Data*, Seattle Post Intelligence, November 11, 2008.

<sup>109</sup> *Id.*

regarding this issue.<sup>110</sup> The situation faced by Applebees is a bit unique – as that chain worked with Weight Watchers to market certain portions of the Applebees menu as more nutritional fare, providing not only nutritional information but also the “points” information from the Weight Watchers program. The lawsuits, however, underscore the fact that when restaurants provide nutritional information – consumers expect it to be accurate and some consumers will, inevitably, seek to hold the restaurant liable when it is not. While the legislature may ultimately specify that the Indiana law creates no private right of action, or the Indiana courts may interpret the law in this manner, the fact remains that the legislation may pose a risk of liability to restaurant owners that is not immediately clear on the face of the act.

Even if such a bill passes, restaurants that do not have twenty locations within the state will not be required to comply with the proposed statute. Those restaurants may feel compelled to voluntarily comply, however, if they compete with restaurants affected by the law. Restaurants considering voluntary compliance with the nutritional information requirement should consider the risks outlined above – as the decision to offer nutritional information may lead to liability for inaccuracies in the reporting of the information. Further, any restaurant that voluntarily complies with the legislation, if such legislation ever passes, should consider expressly noting the variability in the preparation of the food and risk of error in that information.<sup>111</sup>

## CONCLUSION

Recent developments demonstrate that the food industry is under increasing scrutiny that is unlikely to ebb in the near future. This dynamic and uncertain time for the food industry presents a unique opportunity for counsel to serve their clients with a thorough understanding of the challenges faced by the industry and to provide guidance designed to reduce, and handle, claims faced by the industry, whether they are related to foodborne illness or labeling. While Indiana law in this area is relatively underdeveloped, the onset of increased food-related litigation seems as unavoidable as the human need to eat. Armed with an understanding of how to prevent and defend claims, knowledge regarding the underlying laws and regulations, and with lessons learned in other litigation, Indiana defense practitioners can be prepared to respond when Indiana plaintiffs inevitably begin to ask “was it something I ate?”

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<sup>110</sup> Meg Marco, *Lawsuits Claim Applebees Weight Watchers Food has Too Much Fat*, *The Consumerist*, October 10, 2008, available at <http://consumerist.com/5061748/>.

<sup>111</sup> See *supra* note 103.