

# **Food Irradiation Research and Technology**

*EDITORS*

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# Chapter 16

## A FUTURE UNCERTAIN: FOOD IRRADIATION FROM A LEGAL PERSPECTIVE

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### **Introduction**

Food irradiation is not a new technology; its effectiveness in killing microbes in food has been known for more than 80 years.<sup>1</sup> It is estimated that 500,000 tons of food are irradiated each year around the world.<sup>2</sup> Yet, in the United States, the GAO reports that the amount of food irradiated each year represents a “tiny fraction of the total amount of food consumed.” This is so despite the fact that the CDC estimates that irradiating meat and poultry could prevent nearly a million cases of foodborne illness, 8,500 hospitalizations, more than 6,000 catastrophic illnesses, and 350 deaths in the United States each year.<sup>3</sup>

There are numerous and conflicting factors that could explain why the food industry has not adopted irradiation as a preventive technology. These factors include technical feasibility, the high capital costs of irradiation equipment, the reluctance to be a first-mover in a competitive, low-profit-margin industry, a market limited by consumer concerns, and a wide variety of other economic disincentives for safety-related process innovation.<sup>4</sup>

Viewed from a legal perspective, which is to say the perspective of an attorney practicing in this area, the industry’s failure to adopt irradiation technology, or to widely use irradiated products, is more difficult to explain. Indeed, to the plaintiff attorneys who handle the majority of food product cases filed each year, the extremely limited use of irradiation in the food industry is extremely puzzling.<sup>5</sup>

Food irradiation has the capacity to substantially reduce not only the risk of lost sales that result from an outbreak or recall but also the lawsuits that inevitably follow. The filing of these lawsuits is nearly always accompanied by significant and sustained media attention, most of it negative. Moreover, during the course of litigation, news about the outbreak continues to come out, often depressing sales and the company's stock price. For example, in the year that litigation arising from a *Salmonella* outbreak linked to a Chicago-area restaurant was pending, the value of the company's outstanding shares fell by sixteen percent, for a loss of a half billion dollars.<sup>6</sup>

Given that there is rarely, if ever, an effective legal defense against an outbreak-related foodborne illness claim, one might reasonably assume that manufacturers and restaurant owners would adopt food irradiation, or the use of irradiated food, as a means of reducing their lawsuit-related risk exposure. But that has certainly not occurred.

Nonetheless, when viewing the issue of food irradiation from a legal perspective, three preliminary conclusions can be reached. First, the widespread adoption of irradiation technology is unlikely to occur based on legal incentives in the absence of a regulatory mandate or customer demand for a safer product linked to a specific acceptance of irradiation. Second, a legal duty to irradiate already exists with regard to susceptible populations, and the legal consequences associated with the breach of this duty may turn out to be the primary driver of greater consumer acceptance of irradiated food products. Third, the question of whether food irradiation poses any long-term safety risk to the consumer raises the possibility of future legal liability that acts as a further disincentive to the adoption of the technology.

### **Liability for the Manufacture of a Defective Food Product**

There is a commonly held misconception in the food industry. That misconception is that liability for a product-related injury requires proof of negligence.<sup>7</sup> As a result, it is assumed that if a person injured by a product wants to sue to recover damages, she must be able to present evidence that the product was defective because the manufacturer failed to use reasonable care in making it. It is further assumed that if a person cannot come up with such evidence, or if the manufacturer can prove it acted as carefully as possible, the lawsuit will fail. These assumptions, however, represent wishful thinking on the part of food industry.

The rule that governs the right to recover for product-related injury is decidedly stricter than is often assumed. Indeed, the rule is called strict

liability for a reason; it is liability without regard to fault. And, at present, some form of strict liability exists in all 50 states.<sup>8</sup>

### ***The Origins of Strict Liability in Tainted Food Cases***

The rule of strict liability has its roots in the judicial creation of a legal remedy for people injured by unsafe food.<sup>9</sup> The seminal case is a 1913 decision by the Washington Supreme Court, *Mazetti v. Armour & Company*.<sup>10</sup> It has been called "one of the most important cases in the development of early twentieth century product law in the United States."<sup>11</sup> The case involved canned tongue that had somehow gone foul, causing the person who ate it to become quite sick. In holding that the injured person could sue the manufacturer, even though it had no contractual relationship with it, the court recognized that there exists in law an implied warranty (or promise) that all food sold is fit for consumption, and that, when it is not, the manufacturer is liable for the injury so caused.

This new rule was said by the court to be necessary due to the "modern method of preparing food for use by the consumer, and the more general and ever increasing use of prepared food products." The rule was also premised on what it called "the demands of social justice."

The law was being forced to catch up with the rise of mass production and broader distribution of consumer products. A new relationship between producer and user was emerging, and the courts were being called upon to grapple with the socio-legal implications.<sup>12</sup> Whereas previously a person might grow his own food, or buy food from someone with whom he had a personal relationship in a face-to-face dealing, now packaged food came from myriad sources with nothing to identify the maker except brand names. For this reason, brand names came to be trusted as guarantees of consistent product quality—so much so that even now consumers prefer branded over nonbranded products because they reduce concerns about product quality.<sup>13</sup>

### ***The Modern Rule of Strict Liability***

The modern rule of strict liability was first announced by a court in 1963 in a case that involved a defective power tool. The case was *Greenman v. Yuba Power Products*, and it did away with the legal fiction that a manufacturer's liability for injury was based on the implied promise that the product was safe to use.<sup>14</sup> Writing for the California Supreme Court, Chief Justice Roger Traynor, widely considered a father of product liability law, stated that it was "clear that the liability is not one governed by the law of contract warranties but by the law of strict liability in tort."

Under this new rule of strict liability, to hold a manufacturer liable, a person injured while using a product need show only that: (1) the product was defective; (2) it was used as intended; and (3) the defect caused the injury. The care used in the manufacture of the product is irrelevant to the determination of liability. The only issue in a product liability case is the defectiveness of the product, not the manufacturer's conduct in somehow allowing the defect to come into existence. As a result, proof of negligence is not required to recover damages in a product defect case. And although strict liability has given rise to controversy in other contexts, there has been little if any when applied to food.<sup>15</sup>

### ***Defining Products and Defects***

There are three kinds of product defects that give rise to strict liability: manufacturing defects, design defects, and marketing claims. Food injury claims primarily involve manufacturing defects, the most straightforward and uncontroversial of product claims. As one commentator has aptly pointed out, when talking about a manufacturing defect, the need for a definition is not obvious. For decades, both courts and commentators considered the meaning of the "manufacturing defect" concept so self-evident as to be self-defining.<sup>16</sup>

The inquiry into whether a product is defective closely coincides with common sense. A product is defective for not being used how it was supposed to be. Put in more strictly legal terms, the product is not reasonably safe in construction because, as one state legislature has defined it, "the product deviated in some material way from the design specifications or performance standards of the manufacturer, or deviated in some material way from otherwise identical units of the same product line."<sup>17</sup> This is in marked contrast to design and marketing defect cases in which the defective products are said to be "generically dangerous," because every product unit designed and marketed in the same way shares the same risk potential.<sup>18</sup> The risks associated with an entire product line are, as a result, potentially charged to the manufacturer.<sup>19</sup>

### ***Proving the Existence of a Defect in Food***

Just as it is commonly assumed that proof of negligence is required to establish liability for a product-related injury, so it is equally commonly assumed that proving the existence of a defect is difficult in food cases.<sup>20</sup> This assumption might seem reasonable, at first glance, because food products are typically destroyed—that is, eaten or discarded—and thus

direct evidence of the defect rarely exists. Fortunately for the injured person, direct evidence is not required to prove the existence of a product defect, or precisely how or why the product failed.

In manufacturing defect cases the fact of product malfunction, and resulting injury, is by itself enough to give rise to a presumption of negligence and thus liability in most states. This is sometimes referred to as the malfunction doctrine.<sup>21</sup> Its fundamental premise is the high correlation between the existence of a defect and a failure of some kind in the manufacturing process.<sup>22</sup> This makes the issue of negligence not worth the cost and uncertainties of trying to prove. Thus, in the case of a manufacturing defect, it is simply not a useful exercise to ask whether the defect could have been prevented; the existence of the defect is by itself sufficient to impose liability.

For cases involving unsafe food, it is nearly always a manufacturing defect at issue, especially when pathogens such as *E. coli* O157:H7, *Salmonella*, or hepatitis A are involved. And although it is true that a manufacturer is not liable for a product-related injury unless the product is both defective and unsafe, in food cases this is a distinction without a difference. Food that is unsafe because it is unfit to eat is by definition defective. For that reason, it is rare to have a defendant in a food contamination case dispute liability unless there is a serious question of causation, or some other product-related problem of proof.<sup>23</sup> Moreover, because only cases with problems of proof, or uncertain damages, tend to go to trial, this would explain the low win percentage for plaintiffs who go to trial, and the relatively small damage awards for those cases the plaintiffs do win.<sup>24</sup> In short, unless a defendant acts irrationally, defective food cases nearly always settle.

### **Strict Liability Creates Few If Any Legal Incentives in Favor of Food Irradiation**

The rationales supporting the rule of strict liability are hotly debated.<sup>25</sup> That is, except when it comes to food cases. As noted by one group that exhaustively studied the topic:

Although the doctrine of strict liability (or recovery without proof of fault on the part of the seller) is controversial in some contexts, it has not elicited any substantial outcry with respect to food-related harms.<sup>26</sup>

One reason for this lack of controversy is the primacy the public gives to food safety, particularly when it comes to microbial contamination. In

one study, the number one food safety concern cited was the risk of contamination by bacteria or other microorganisms.<sup>27</sup>

Another reason for the lack of controversy is that manufacturers have near-exclusive access to the information needed for the effective control of product hazards. Strict liability is therefore intended to motivate manufacturers to use the information to reduce the occurrence of product-related accidents.<sup>28</sup> In addition to the information advantage they possess over consumers, manufacturers also get to make a deliberate choice about the level of investment in production quality and control processes.<sup>29</sup> Certainly, many of these choices are dictated by regulatory regimes such as those that require USDA-inspected meat-processing facilities to adopt HACCP plans.<sup>30</sup> But even so, the details of such plans, including the technologies used, remain solely in the control of the manufacturer. As a result, the fact that a plant is federally inspected and its HACCP plan required as a matter of regulatory law provides no legal defense to a strict liability claim, despite the meat industry's continuing arguments to the contrary.<sup>31</sup>

Consequently, when it comes to food irradiation it is reasonable to ask why the continued prevalence of foodborne illness outbreaks has not given rise to the greater adoption of this technology. The USDA's Economic Research Service has looked at the issue from an economic perspective without finding any one answer.<sup>32</sup> It has also looked at incentives to food safety from the perspective of product liability, concluding in part that a lack of information about the true costs of food-related litigation prevented anything but educated guesses.<sup>33</sup> A national committee on ensuring safe food concluded the same thing.<sup>34</sup>

From the perspective of the attorneys who have handled the majority of food defect cases over the last several years, it appears that resistance to irradiation and other innovative preventive technologies is in part the result of a kind of corporate denial of risk. Time after time it seems that only the benefit of hindsight motivates companies to act, even when the risk was foreseen and preventable. For example, something as simple as the scheduled replacement of water heaters would likely have been enough to prevent the *Salmonella* outbreak at a Chicago-area restaurant closed when sales did not recover. But the investment in this policy change did not occur until after the outbreak happened, too late for those injured in it.

Improvements accomplished after an accident are something that the law has long taken into account. For example, evidence of "subsequent remedial measures" is not admissible at trial "to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction."<sup>35</sup> The reasons for the Rule are many,

but the most notable and widely accepted one rests on a social policy of encouraging people to take, or at least not discouraging them from taking, steps that advance safety.<sup>36</sup>

Although the doctrine of strict liability is supposed to create a similar kind of encouragement of improved product safety, it is not at all clear that the doctrine has had that effect in the food industry. Recall that the great reforms of the early twentieth century were prompted in large part by Upton Sinclair's throwing open the doors of the slaughterhouse and showing the public what really went on inside there.<sup>37</sup> With the rise of strict liability and its easing of the burden of proof on the issue of product defect, the focus is no longer on how the manufacturer acted. And although this is a good thing for those injured by defective products, because it nearly guarantees them a recovery that they might not otherwise have received, it remains open to question whether strict liability might be more disincentive than incentive when it comes to the adoption of expensive preventive technologies.

On the other hand, as expertise in food-related litigation continues to be concentrated in one or two law firms, there may yet be a tipping point that results in the availability of new information that would allow the more thorough and accurate analyses that most agree are necessary to ensure improved food safety. The number of confidential settlements may decrease as attorneys representing plaintiffs refuse to agree to them. More and better cases may start going to trial with verdicts becoming part of the public records. And as discussed further below, plaintiffs may begin to increasingly seek punitive damage awards for which there is no insurance coverage available, thus causing greater economic harm to companies who fail to adopt available food safety innovations.

In sum, although legal liability may in the short term be a relatively weak incentive to proactive improvement in food safety, its potential remains largely untapped. Therefore, as with so many things, time will tell.

### **A Possible Existing Legal Duty to Use Irradiated Food: The Challenge of Highly Susceptible Populations**

We know that not all segments of the population are equally at risk for infection with a foodborne pathogen. Organisms that a healthy immune system might otherwise fight off pose a greater risk to someone whose immune system is impaired. Consequently, one major identified factor contributing to the emergence of foodborne disease in the United States is a significant annual increase in the proportion of the population with decreased or impaired immune function.<sup>38</sup> The members of these so-



called "highly susceptible populations" include the elderly, preschool age children, persons with AIDS or infected with the HIV virus, and anyone else immunocompromised as a result of chronic disease, chemotherapy, or organ-transplantation.<sup>39</sup> Because it is clear that the size of the highly susceptible population is certain to grow, the food industry has no choice but to take this increasing risk into account when making decisions about what, if any, additional steps to take to prevent a parallel increase in the incidence of foodborne illness attributable to its product. Failing to take action is likely to otherwise result in a potentially significant increase in litigation.

***Negligence: Failing to Avoid a Known and Avoidable Risk***

Negligence is the failure to exercise ordinary care. What defines ordinary care is in most cases knowledge of the risk. Actual knowledge is not required, however. The law attributes to one who acts both what is known and what should be known or have been discovered. In other words, ignorance is no defense where the facts known *or available* would have alerted a reasonable person to the likelihood of danger.

When dealing with a strict liability claim involving a manufacturing defect, we know that proof of negligence is not required. This does not mean, though, that there is no fault; it means only that the plaintiff need not prove fault to hold the manufacturer liable for her damages. And because a manufacturer cannot be held liable more than once and so provide an injured person with a kind of double-recovery, proving the elements of negligence, in addition to the elements of strict liability, gains nothing. That said, there are times when proof of negligence is necessary, as in when the entity being sued is not a manufacturer, and strict liability does not apply.

Say, for example, you are a resident of an assisted-living facility and, as part of the services provided for a monthly fee, you have access to a dining room where three meals per day are served. The meals are prepared on-site by employees of the facility. One morning you are given eggs benedict with hollandaise sauce made from unpasteurized shell eggs. You eat the meal, are infected with *Salmonella*, and after a lingering, painful illness, you die. Assuming that the owner of the facility is not deemed a manufacturer, and the deadly breakfast not a product, then a case for negligence would need to be made. And given these facts, it would be an easy case to make.

The risk associated with the use of unpasteurized eggs in food establishments that serve a highly susceptible population is by now well established and understood. The publication of the 2001 FDA Food Code gave

this standard of care the equivalent of the force of law. Even in jurisdictions that do not adopt the standard, an establishment failing to follow the standard would likely find its conduct impossible to justify if such failing caused injury or death. The risk was known and the means to avoid it was available at little cost relative to the harm.

Because the use of pasteurized fruit juice and eggs with highly susceptible populations is now essentially mandatory, it is not surprising that the use of irradiated food in therapeutic diets fed to immunocompromised patients in health care facilities is one area in which we see greater acceptance of such products.<sup>40</sup> What is surprising, however, is that people who are at increased risk of foodborne illness do not themselves seem more willing to buy irradiated products.<sup>41</sup>

When the use of pasteurized and irradiated food products in a therapeutic setting is admitted to be a legal (and arguably ethical) no-brainer, the question then arises why these products are not used in every setting where there is a high likelihood of there being consumers who are members of highly susceptible populations? That was a question faced by the FDA as it considered whether to make mandatory the safe egg handling and preparation practices in its 2001 Model Food for all retail establishments that serve a highly susceptible population.<sup>42</sup> But as several of the comments submitted on the proposed rule pointed out, it does not make a lot of sense to protect highly susceptible populations in one setting, but not another, when their presence, as a general matter, is equally foreseeable given their numbers.

### ***The Eggshell Plaintiff: Irradiation, Liability, and Susceptible Populations***

Some might argue that it is unfair to hold a company liable for the full extent of a person's injuries when the largest part of those injuries can be attributed to the fact that the person was immunocompromised or otherwise in frail condition. This argument has no support in the law, however.

In the first year of law school one of the truisms that all students learn is that the defendant takes the plaintiff as she comes. This is referred to as the eggshell or thin-skulled plaintiff rule, and it holds that a defendant is liable for all injuries caused by its negligent conduct, even when it has the misfortune of having a plaintiff particularly susceptible to severe injuries or even death.

There are also cases in which there exists a relatively small group of people with outsized and, arguably, unpredictable reactions to the exposure to, or use of, a product otherwise safely used by millions of others.

In these cases the question sometime becomes whether the product is, in fact, defective. Latex gloves are one example of a product that was found by a jury to be defective even though they contained no impurities and were dangerous only as a result of an allergic reaction by the user.<sup>43</sup> Although noting that there is not usually recovery when the reaction to the product is "idiosyncratic" and "extremely rare," in this case the court found that such a rule does not act as an innate bar to recovery in every allergic reaction case. Instead, the question of defectiveness would have to be determined on a case-by-case basis considering the magnitude of danger necessary to render a product dangerous to an extent beyond which would be contemplated by the ordinary consumer.

Such an evaluation done with regard to the use of irradiated food with susceptible populations would seem to result in but one conclusion: a nonirradiated product when intended for consumption by a susceptible person is an unreasonably dangerous product. Therefore, once more we are driven to the conclusion that failure to use an irradiated food product when it is reasonably likely that the failure will result in injury or death constitutes negligence.

### ***The Prospect of Punitive Damages As a Stronger Incentive***

The circumstances that apply to a negligence claim may also apply to a claim for punitive damages. Also known as exemplary damages, these claims are typically premised on conduct that represents a "conscious and knowing disregard" or a "conscious indifference" to a known safety risk.<sup>44</sup> Although many have argued that punitive damages are inconsistent with strict liability and its focus on the product, not conduct, this argument has not gained wide acceptance in the courts. This is because the conduct proved in punitive damage cases is of a nature easily deemed outrageous and thus worth both punishing and deterring. The injured person is therefore entitled to a kind of windfall award of damages, above what is needed for compensation, as an inducement to bring "malefactors to justice."<sup>45</sup>

Punitive damages are most often awarded in product cases in which there is evidence that a company deliberately chose to expose consumers to serious risks against which they have no good way to defend. This would typically be instances in which the defect is not obvious. Combine this with evidence of a strong profit motive and you have a case in which punitive damages are likely to be upheld, although not in every case.

In the case of irradiated food, there seems little question that the failure to use it in a therapeutic setting would constitute a conscious disregard of a known risk, because we know that irradiation can eliminate mi-

crobial pathogens from ready-to-eat food products, fresh vegetables, meat, and poultry.<sup>46</sup> We also know that immunocompromised people are at greater risk for infection with a foodborne disease, as well as at greater risk for more serious injury or death as a result of the infection.<sup>47</sup> Combine such knowledge with evidence that irradiation adds only pennies per pound to the cost of food and it is likely that most juries would have no difficulty awarding punitive damages against, for example, the operator of a nursing home that chose to use a cheaper, but demonstrably more dangerous, nonirradiated product.

The size of punitive damage awards is notoriously difficult to predict, and often rests on jury outrages as much as anything else. For example, in 2002, a jury in Nevada awarded five guests of the Reno Hilton \$22,000 for the injuries suffered as a result of outbreak-related norovirus infections.<sup>48</sup> The plaintiffs had argued that an award of punitive damages was justified because the hotel had acted in outrageous fashion by not having a paid sick-leave policy and knowingly allowing sick workers to keep working. The jury obviously agreed because it awarded the plaintiffs \$25.2 million in punitive damages.

Given the enormity of the risk and its unpredictability, the prospect of a punitive damages award should act as a strong incentive for the use of irradiated food where the establishment serves highly susceptible populations. Although such an award has not yet occurred, its occurrence is probably, again, just a matter of time. And when it does occur, whatever institutional resistance to the use of irradiated food still exists is likely to disappear at a rapid pace. This then might also spur others in the food industry to revise their own risk assessments, especially in light of the increasing numbers of immunocompromised persons in all settings.

### **The Possibility of Liability Arising from Irradiated Foods**

There is no question that the irradiation of food remains a controversial topic, and the primary source of the controversy is concern over the long-term health effects of consuming irradiated food. This controversy is stoked by organizations such as Public Citizen and Center for Food Safety, which actively oppose FDA and other agency efforts to allow increased use of irradiation in the manufacture of foods.<sup>49</sup> These groups argue that official governmental reviews have “whitewashed” the potentially serious public health concerns that will become more serious if a larger portion of the food supply is irradiated. Some even speak of a looming “epidemic of cancer” attributable to the chemical byproducts created by irradiation in meat.

Not surprisingly, this vocal opposition to food irradiation does not appear to represent the views of a majority of consumers.<sup>50</sup> Opinion surveys and consumer research consistently show that people will purchase irradiated food, and that acceptance increases markedly when potential purchasers are knowledgeable about both the process and food safety risks it prevents. Nonetheless, the perception of far greater resistance than might actually exist appears to have undercut the willingness of manufacturers to market irradiated food products on anything but a small-scale or test basis. This has prompted two leading public health officials to blame the public health community for being silent for so long on the issue, and to question "why the food industry has not stepped into the vacuum created by this lack of leadership from public health," especially when "[f]aced with the liability of marketing hazardous foods."<sup>51</sup>

There are two probable and complementary answers to this question. First, the food industry appears unwilling to be frank about the risks posed by its products as a means of educating the consumer about the need for irradiation. To talk about the significant public health benefits that would derive from irradiation of meat and poultry, the industry would require the food industry to talk about the illness and death presently caused by its products, something that it is understandably reluctant to do. Second, the food industry apparently prefers to move beyond the controversy by moving beyond the use of the term "irradiation" altogether. By using the term "cold pasteurization," the industry hopes that the already accepted technology of pasteurization will act as a proxy for acceptance of irradiation under a new name.

Some might call this a "bait-and-switch" tactic, but it is better characterized as a simple attempt to avoid the question of the long-term safety of eating irradiated food. Trying to gain acceptance with a name change, rather than forthrightly defending both the safety of irradiation and, more important, the need for it, plays into the hands of those who are accusing the government and the food industry of trying to whitewash the dangers. It is not enough to criticize opponents of food irradiation solely by way of an analogy to earlier, and unfounded, objections to milk pasteurization.<sup>52</sup> For even if this analogy appears by all evidence to be apt, it is not a complete rebuttal. Moreover, the history of litigation is replete with products once deemed safe that turned out years and even decades later to have been dangerous. Consider, for example, asbestos.

Asbestos was widely used and considered safe before being linked to massive numbers of illness and deaths caused by long-term exposure to the product.<sup>53</sup> The resulting litigation pushed most asbestos manufacturers into bankruptcy or out of existence. And this litigation, which started in earnest in 1973 with a federal court decision finding asbestos manu-

facturers strictly liable to workers injured as a result of exposure to their products, is still going on today.

The food industry is no doubt mindful, just as the public is, of the doubts being expressed about the safety of food irradiation. Therefore, irradiated food will likely continue to be used primarily as ingredients in products that require a higher level of safety or quality assurance, because no label informing the consumer of such use is required. Other than that, most companies will be content to wait and see, waiting on a substantial increase in consumer acceptance and allowing others in the food industry to become first adopters.

## Conclusion

The law has been aptly characterized as a "choosing system, in which the individuals can find out, in general terms at least, the costs they have to pay if they act in certain ways."<sup>54</sup> In the case of the food industry and irradiation, such costs will continue to be difficult to predict, and most often found out after the fact. In the absence of a regulatory mandate, such as that which occurred with the pasteurization of milk, the use of irradiation in the manufacture of food is likely to remain dependent on consumer acceptance and demand. The sole exception will be food products intended for consumption by highly susceptible populations where safety and liability risks are high, and resistance is minimal or nonexistent. Of course, if subsequent research demonstrates that irradiation is not as safe as it presently seems, then adoption and use of the technology will come to a swift halt, and a wave of litigation possibly like that seen with asbestos may result.

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3. Tauxe at p. 519, *supra* at Note 1.
4. For an excellent discussion of the economics of food safety innovation, see E. Golan, *et al.*, Food Safety Innovation in the United States: Evidence from the Meat Industry, Economic Research Service/USDA, AER No. 831 available online at [www.ers.usda.gov/Publications/aer831/](http://www.ers.usda.gov/Publications/aer831/). For a related discussion focusing on equipment costs and consumer concerns, see P. Frenzen *et al.*, *Consumer Acceptance of Irradiated Meat and Poultry in the United States*, Jnl. Food Prot. 64(12); 2020-2026, and specifically

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5. The author is a principal in Marler Clark, a law firm that for the last seven years handled most of the more prominent foodborne illness cases in the United States. For a partial list of cases, see [www.marlerclark.com/foodlitigation.htm](http://www.marlerclark.com/foodlitigation.htm)
  6. Barry Michaels, Ph.D. Personal correspondence, 2005.
  7. Personal observations of the author and his partners at Marler Clark. As presenters on legal issues at up to twenty industry-sponsored or related conferences and meetings per year, we have been frequently confronted, especially during question-and-answer periods, by persons expressing shock that their company could be sued for a product-related injury despite their ability to prove that they took every possible precaution.
  8. *Restatement (Third) of Torts: Product Liability* 1 (1998). Not all states, however, call it strict liability. For example, in Michigan, such liability is still treated as a form of implied warranty. See, e.g., *Vincent v. Allen Bradley Co.*, 95 Mich. App. 426, 291 N.W. 2d 1 (1986) (holding that a breach of implied warranty is established on proof of injury caused by a defect in the product, attributable to the manufacturer, that made the product not reasonably fit for its intended use).
  9. D.G. Owen, *Manufacturing Defects*, 53 S.C. L. Rev. 851 (Summer 2002). For a concise but thorough overview of product liability law as it applies to food, see pp. 884-904.
  10. 135 Pac. 633 (Wash. 1913).
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  12. For an interesting, if somewhat overly philosophical and at times impenetrable, discussion of the relationships we can have with products, see A. Bernstein, *How Can a Product Be Liable*, 45 Duke L.J. 1 (October, 1995).
  13. Golan at p. 6, *supra* at Note 4.
  14. 377 P.2d 897 (Cal. 1963). Justice Traynor's decision in *Greenman v. Yuba Power Products* anticipated the inclusion of the rule in the Restatement (Second) of Torts, the American Law Institute's exhaustive survey of the common law. The rule was set forth at Section 402A, leading to strict liability being often referred to as "Section 402A liability."
  15. Committee to Ensure Safe Food from Product to Consumption. Ensuring Safe Food from Production to Consumption, at 33, National Academy Press, 1998 (hereinafter *Safe Food Committee*). The exception to this is for the most part confined to cases involving raw meat products in which the industry's position continues to be that it is the consumer's responsibility to make raw meat safe to eat. To its credit, the USDA has rejected the meat industry's position on consumer responsibility, stating that "[b]ecause industry has the means to reduce the risk or eliminate the hazard, consumers should not be expected to assume all responsibility for preventing foodborne illness associated with *E. coli* O157:H7." See "Recent Developments Regarding Beef Products Containing *E. coli* O157:H7," FSIS Docket No. 99-060N65, Fed. Reg. 6881, at 6884 (Feb. 11, 2000).
  16. Owen at p. 865, and 894, *supra* at Note 9.
  17. Revised Code of Washington, 7.72.030(2)(a) (defining one standard of strict liability for a product manufacturer).
  18. The term was coined by Professors James A. Henderson, Jr., and Aaron D. Twerski in *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. Rev. 265, 272 (1990) (stating that "after years of frustration, many courts have finally abandoned the search and declared that, for all intents and purposes, strict liability, as applied to generically dangerous product cases, was simply negligence by another name").

19. W. Kip Vicusi, *Wading Through the Muddle of Risk-Utility Analysis*, 39 Am. U.L. Rev. 573, 574 (Spring 1990).
20. See, e.g., S. Lassiter, *From Hoof to Hamburger: The Fiction of a Safe Meat Supply*, 33 Willamette L. Rev. 411, at 418 (1997), where the author argues, incorrectly, that "monetary awards are low because of the limited success in establishing a breach in the meat producer's duty to produce meat that is safe for human consumption."
21. Owen at p. 877-874, *supra* at Note 9. This doctrine is usually understood as a variation on the doctrine of *res ipsa loquitur*, which means "the thing speaks for itself".
22. G. Schwarz, *New Products, Old Products, Evolving Law, Retroactive Law*, 58 N.Y.U. L. Rev. 796, 810 (1983).
23. Owen at pp. 855-856 and fn. 27, *supra* at Note 9. The food cases at Marler Clark have consistently borne this out. See, e.g., *Almquist v. Finley School District*, 57 P.3d 1191 (2002) (conceding E. coli O157:H7 in a school lunch taco meat would make it defective but denying that the taco meat was the cause of the outbreak in question).
24. J.C. Buzby *et al.*, Product Liability and Microbial Foodborne Illness, Economic Research Service/USDA, AER-799, at pp. 13-23 (noting that, of 175 foodborne illness lawsuits that went to verdict from 1988-1997, only 31.4% were won by plaintiffs, and the median damage award was \$25,560).
25. Bernstein at pp. 5-6 and footnotes 14-16, *supra* at Note 12 (noting how the subject had become "overtly politicized" and citing the range of opinions among commentators). See also J. Henderson, *Why Negligence Dominates Tort*, 50 UCLA L. Rev. 377, 394 (December 2002) (noting that "American torts scholarship divides along several lines of fundamental disagreement" when it comes to defending strict liability over negligence and their competing rationales).
26. Safe Food Committee at p. 33, *supra* at Note 15.
27. C. Bruhn, *Consumer Concerns: Motivating to Action*, EID 3(4):511-515 (Oct-Dec 1997).
28. Madden and Owen on Products Liability, vol. 1, § 5.2, 3d Ed. 2000. This rationale was the one most often emphasized by Chief Justice Traynor in those early cases holding in favor of strict product liability. *Greenman v. Yuba Prods., Inc.*, 377 P.2d 897 (Cal. 1962); *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 440 (Cal. 1964) (Traynor, J., concurring); see also Roger W. Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 Tenn. L. Rev. 363 (1965).
29. Owen at p. 855, *supra* at Note 9.
30. 9 C.F.R. § 417.2(a)(1).
31. See *Kriefall v. Excel Corp.*, 265 N.W.2d 476 (Wis. App. 2003) (arguing, ultimately unsuccessfully, that the USDA's interpretation of the Federal Meat Inspection Act pre-empted state product liability law on what constitutes a defective meat product).
32. Golan at pp. *iv-vi*, *supra* at Note 4.
33. J.C. Buzby *et al.*, Product Liability and Microbial Foodborne Illness, Economic Research Service/USDA, AER-799, at p. *iv*.
34. Safe Food Committee at p. 83, *supra* at Note 15.
35. FED.R.EVID. 407.
36. FED.R.EVID. 407, Advisory Committee Notes to 1972 Proposed Rules (citing Falknor, *Extrinsic Policies Affecting Admissibility*, 10 Rutgers L. Rev. 574, 590 (1956)).
37. The Jungle, 1906.
38. S.F. Alterkruse, M.L. Cohen and D.L. Swerdlow, *Emerging Foodborne Diseases*, EID, 3(3); 285-293.
39. *Id.*; see also S.R. Crutchfield, *et al.*, An Economic Assessment of Food Safety Regulations: The New Approach to Meat and Poultry Inspection, ERS/AER No. 755, July



- 1997, pp. 4-5. For the definition of the term "highly susceptible population" see 2001 FDA Food Code 1-201.10(B)(4).
40. E.E. DeRuiter & J. Dwyer, *Consumer Acceptance of Irradiated Food: Dawn of a New Era?* Food Serv. Tech. 2(2), June 2002.
  41. Frenzen at pp. 2020-2026, *supra* Note 4.
  42. 69 Fed. Reg. 56,825 (Sept. 22, 2004).
  43. *Green v. Smith & Nephew AHP, Inc.*, 629 N.W.2d 727 (Wis. 2001).
  44. See, generally Marshall Shapo, *The Law of Product Liability*, Vol. 2, Chap. 29, 3d ed. 1994.
  45. Owen, *Punitive Damages in Products Liability Litigation*, 74 Mich. L. Rev. 1257, 1278 (1976).
  46. Tauxe at pp. 518-519, *supra* Note 3; GAO Report at pp. 14-16, *supra* Note 2.
  47. Alterkruse at p. 288, *supra* Note 36. See also J. Buzby, *Older Adults at Risk of Complications from Microbial Foodborne Illness*, Food Review 25(2): 30-35.
  48. K. Ching, *Jury Awards Hotel Guests \$25 million for Illness*, Reno Gazette Journal, May 20, 2002.
  49. See, e.g., Public Comment, FDA Docket No. 99F-5321, dated May 14, 2001, available online at [www.centerforfoodsafety.org/pubs/CommentsFDARefrigeratedMeat5.14.2001.pdf](http://www.centerforfoodsafety.org/pubs/CommentsFDARefrigeratedMeat5.14.2001.pdf). Well over one hundred groups are listed on the Public Citizen Web site as being opposed to irradiated food.
  50. Frenzen, *supra* at Note 4; Bruhn, *supra* at Note 26.
  51. M. Osterholm and M. Potter, *Irradiation Pasteurization of Solid Foods: Taking Food Safety to the Next Level*, EID, 3(4): 575-577.
  52. See, e.g. Tauxe at p. 516, *supra* at Note 3.
  53. Asbestos Litigation Costs and Compensation: An Interim Report, RAND Institute for Civil Justice (2002) available online at [www.rand.org/publications/DB/DB397/](http://www.rand.org/publications/DB/DB397/).
  54. H.L.A. Hart, "Legal Responsibility and Excuses," in *Punishment and Responsibility* 28, 44 (1968).