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Keep Away From Mouth: How The American System Of Food Regulation Is Killing Us

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Keep Away from Mouth: How the American System of Food Regulation Is Killing Us

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They are trying to save their souls—and who but a fool could fail to see that all that is the matter with their souls is that they have not been able to get a decent existence for their bodies?¹

I. INTRODUCTION

Food is not a luxury; indeed, it is not even an option. Yet our food may very well be killing us: Food-borne illness is responsible for up to 9000 deaths annually in the United States² and obesity-related deaths

* Articles and Comments Editor, *University of Miami Law Review*; J.D. Candidate 2011, University of Miami School of Law; B.A. 2006, Harvard University. This comment is dedicated to the countless people who have touched my life and helped me get to this juncture in ways big and small, but especially BDS, whose steadfast support and confidence in me has made so much of the last three years possible; SMM, whose level of commitment to my success defies description, and who somehow always knows when to be a mother and when to be a friend; BLM, who inspires me to be a little better each day than I was the day before; SEM, who always makes me laugh; and RTS and ARZ, without whose loyalty, humor, and senses of adventure I would have thrown in the towel long ago. Special thanks to Prof. Stephen Diamond for being a sounding board throughout the writing process and for unwittingly pushing me to challenge my preconceived notions of the world; and Mrs. Barbara Bell for never letting me rest on my laurels.

1. UPTON SINCLAIR, *THE JUNGLE* 237 (Barnes & Noble Books 2003) (1906).

2. PAUL S. MEAD ET. AL., *CTRS. FOR DISEASE CONTROL & PREVENTION, FOOD-RELATED ILLNESS AND DEATH IN THE UNITED STATES* (1999), available at <http://www.cdc.gov/ncidod/eid/vol5no5/pdf/mead.pdf>. Although there have been no reported deaths associated with the recent outbreak of salmonella in eggs produced in Iowa, 1813 illnesses have been linked to the incident.

toll 400,000 annually³—not including the uncounted deaths caused by illnesses such as diabetes and heart disease, which are often directly related to diet. The advent of gourmet food stores and the so-called “organic” food movement may have lulled us into a false sense of security—while it might be chic to say one eats “organic” food, is “organic” really “safe”? For that matter, what does “organic” even mean?

In truth, organic food can be unsafe. Organic lettuce or spinach, commonly grown in soil to which manure has been added, can contain *E. coli* bacteria, which can cause hemorrhagic colitis, acute kidney failure, and even death. . . . Ironically, eating organic food may expose people to more, not fewer risks from [*E. coli*]. Outbreaks of *E. coli* O157:H7 stem not only from bad beef, but also from fresh fruit juices, raw milk, lettuce, and minimally processed produce.⁴

Doesn't the very concept of “natural” food markets or “whole” foods imply that the mainstream food supply is somehow unnatural or not whole? A major criticism of the organic food movement is that only wealthy people can afford to purchase good, clean, “healthy” produce and meat that the movement purports to provide.⁵ As Americans, have we created a society of food classism, where lower-income individuals are forced to eat food that can, and probably will, kill them? In an era when health care reform is the hot topic on everyone's lips, a vicious cycle is being ignored: our health care system is severely taxed as every year we become a less healthy nation, plagued by obesity and all its related diseases, as well as food-borne epidemics that are literally “fed”

Investigation Update: Multistate Outbreak of Human Salmonella Enteritidis Infections Associated with Shell Eggs, CENTERS FOR DISEASE CONTROL & PREVENTION (Dec. 2, 2010) [hereinafter *Investigation Update*], <http://www.cdc.gov/salmonella/enteritidis/>.

3. Ali. H. Mokdad et al., *Actual Causes of Death in the United States, 2000*, 291 JAMA 1238–45 (2005), available at http://jama.ama-assn.org/cgi/content/abstract/291/10/1238?ijkey=5e2afe40d9c5948c92575e7b7285bbcd4ca95ac8&keytype2=tf_ipsecsha; see also NEAL D. FORTIN, *FOOD REGULATION: LAW, SCIENCE, POLICY, AND PRACTICE* 199–200 (2009) (“[T]he USDA . . . estimated the medical costs and losses in productivity of five major foodborne pathogens at between \$5.6 billion and \$9.4 billion. However, this estimate does not include hepatitis A virus and other significant pathogens Further these aggregate estimates of cost do not include the loss of food (i.e., recall and destruction), lost production, lost sales, or pain and suffering. The aggregate estimates also do not encompass foodborne illness that is too mild to require medical treatment Finally, none of the aggregate estimates includes the costs of the chronic sequelae of foodborne illness. . . . In this light, even the highest estimate, \$164 billion per year for direct medical costs, may be far below the total burden of foodborne illness.”)

4. GREGORY E. PENCE, *DESIGNER FOOD: MUTANT HARVEST OR BREADBASKET OF THE WORLD?* 1–2 (2001).

5. Bryan Walsh, *The Real Cost of Cheap Food: America's Food Crisis and How to Fix It*, TIME, Aug. 31, 2009, at 31, 33. Buying “organic” or “sustainable” food can cost as much as double what “conventional” food costs. With just one dollar a consumer can buy 1200 calories of potato chips, or just 170–250 calories of fresh fruits and vegetables. *Id.*

by our food infrastructure.⁶ Why not work to make Americans healthier *before* they need to make use of the health care system? Just like any day in the life of most Americans, that goal begins and ends with food. If we define negligence as the “failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation”⁷ and culpable negligence as “negligent conduct that, while not intentional, involves a *disregard of the consequences likely to result from one’s actions*,”⁸ then aren’t food producers, and the government, liable to us?

This comment argues that the way in which Americans regulate the food supply is fundamentally flawed, allowing consumers to become sick, and in some cases die, from what they eat. The genetic modification of food, the new frontier of biotechnology, is destined to follow in conventional food’s footsteps. Part II examines the way in which we think about the food we eat and explores the ways in which our food is making us sick. Part III traces food safety regulation from its origins and looks critically at the current statutory and administrative scheme. Part IV analyzes the way in which food safety has been litigated and can be litigated in the future, making an argument for applying strict liability to food cases. Finally, Part V explores a recent federal regulatory change and looks briefly at the Minnesota state public health system in an effort to find ways in which the federal system of food safety regulation can be improved, while maintaining the importance of keeping the judicial system open to food safety litigants.

II. SETTING THE SCENE

A. *The Problem with Our Food*

To understand the legal ramifications of food safety, one should first examine the impact it has on our lives. In reality, ancient Man was largely an herbivore—and stood at a meager four feet tall.⁹ As the species evolved and acquired the ability to hunt, diets included much more meat, changing the quantity and quality of caloric intake. Brain size and body size exploded, and Man moved farther away from the equator, necessitating further dependence on meat and higher caloric intakes.¹⁰ The human obsession with food was born. Fast forward to the Industrial

6. See *id.* at 32. Obesity-related illness adds \$147 billion a year to Americans’ medical bills. *Id.*

7. BLACK’S LAW DICTIONARY 479 (3d ed. 2006).

8. *Id.* at 480 (emphasis added).

9. PAUL ROBERTS, THE END OF FOOD 5–6 (2008).

10. *Id.* at 6–7.

Revolution: Mechanization equates food with a factory product.¹¹ Globalism, made possible by a new network of railroads and shipping routes, made a new global system of food production possible.¹² The United States was at the forefront of production, seemingly “born to superabundance.”¹³ As global populations grew, so too did the demand for food, leading to the rise of the kind of “low-cost, high-volume agriculture” embodied by food industry giants, such as Nestlé:

[J]ust as farmers have been trapped in a cycle of overproduction, companies like Nestlé must sell more and more convenience, by way of a steady stream of new and improved products that is becoming very difficult to sustain. Beyond the enormous material costs of so much processing and packaging, the sale of convenience depends not only on increasingly aggressive promotional strategies (advertising junk food in schools, for example, or selling baby formula to Third World mothers) but on *the continued decline in consumers' ability to prepare, or even understand, their own food*. If human beings are indeed inherently “conservative when it comes to food,” the success of companies like Nestlé marks one of the most radical and potentially troubling developments in the story of food economy.¹⁴

Enter the biggest factor in changing the way we as a society think of food: a fundamental post-World War II change in consumer demand. The rise of the two-income household and the resulting consumer time shortage forced companies to produce more “ready-to-eat” food that could be manufactured and then prepared quickly and cheaply.¹⁵ This is only one example of the birth of the, perhaps uniquely, American culture of “instant gratification,” but one that would change the most fundamental of human characteristics—the way we eat and, more importantly, *what* we eat.

In fact, in the modern food business, *most* traditional food practices, and most traditional foods, just don’t work. As production has become almost entirely automated, with vegetables diced, meats ground, batters mixed, doughs extruded, and ready-to-serve dinners assembled all by computer-controlled robots at rates of thousands of units per minute, the food itself has had to be amended, often significantly, in order to tolerate the process.¹⁶

It is at this point that the issue gets more complicated. Food is frozen, thawed, canned, and dehydrated. A battery of additions or amendments are made in order to make the food last longer on the shelf of the

11. *Id.* at 32.

12. *Id.* at 17.

13. *Id.*

14. *Id.* at 31 (emphasis added).

15. *Id.* at 35.

16. *Id.* at 45 (citations omitted).

supermarket or pantry. A new brand of industry personnel called “food engineers” discovered chemical upon chemical combination that could be added to food to meet this growing consumer demand while increasing company profit. Of course, these various chemical processes change the nature of the food product by doing just that—changing the nature of the food, thereby taking out color, flavor, and sometimes texture. So naturally, the food engineers went back to work finding more chemical processes that could be used to reverse what the initial chemical processes took out.¹⁷ These advances have “allowed companies to dramatically simplify what was once a very complex process . . . and thus gain a considerable measure of control over costs.”¹⁸ But at what “costs” to consumers? A compound called diacetyl was used for years to create the “butter” in microwave popcorn until it was taken off the market as a “possible” cause of lung disease.¹⁹ Tetracycline, a common antibiotic, was discovered as a “growth factor” for chicken, turkey, beef, and pork.²⁰ But isn’t it possible that daily human consumption of residual amounts of antibiotics will create a population resistance?²¹

The problem is not merely limited to “processed” foods in the traditional sense: canned, frozen, ready-made products. A recent magazine article painted the grim picture:

Somewhere in Iowa, a pig is being raised in a confined pen, packed in so tightly with other swine that their curly tails have been chopped off so they won’t bite one another. To prevent him from getting sick in such close quarters, he is dosed with antibiotics. The waste produced by the pig and his thousands of pen mates on the factory farm where they live goes into manure lagoons that blanket neighboring communities with air pollution and a stomach-churning stench. He’s fed on . . . corn that was grown with . . . millions of tons of chemical fertilizer.²²

While Americans surely know that much of their food comes from farms, the idea of the “farm” is a rather abstract one. Consumers are often content to stroll down the aisles of mega supermarkets, blindly picking up products without ever inquiring where they came from. Most shoppers “do not know what farms, or what kind of farms [their food

17. *Id.* at 45–46.

18. *Id.* at 47.

19. *Id.* (citations omitted).

20. *Id.* at 4.

21. See *Antibiotic Resistance Questions and Answers*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/getsmart/antibiotic-use/antibiotic-resistance-faqs.html> (last updated June 30, 2009); see also William M. Sage & David A. Hyman, *Combating Antimicrobial Resistance: Regulatory Strategies and Institutional Capacity*, 84 TUL. L. REV. 781, 784, 790 (2010).

22. Walsh, *supra* note 5, at 31.

comes from], or where the farms are . . . or how farming today bears little resemblance to farming as practiced a hundred years ago.”²³ Heavy reliance on fertilizers has become necessary as a result of severe soil erosion, but these fertilizers often contain poisonous heavy metals. Pesticide residues linger on the produce we purchase, leading to cumulative effects on health. Gigantic, near-perfect specimens of produce can be seen almost everywhere and are the result of genetic manipulation of the crop for the purposes of creating desirable characteristics, such as insect resistance (while incidentally destroying flavor and texture).²⁴ Cattle and pigs are overproduced and herded into gigantic pens, fattened with pesticide- and fertilizer-rich grain, injected with antibiotics, and then slaughtered, creating 130 times more waste than humans. Oceans have been over-fished to such an extent that only ten percent of large, commonly eaten fish are left, forcing the birth of an unsustainable fish farming industry.²⁵ These facts, however, are not readily apparent in the supermarket aisle, leaving consumers effectively in the dark about what they put into their own bodies. “Someone has to tell us whether the packaged meat we see originated as an anemic calf (veal), an obese steer (hamburger), an obese hog (pork sausage), or a grotesquely large-breasted turkey (bologna).”²⁶

B. *The Role of Food Producers*

Thus far it would seem clear that the American food system is broken. Yet it is just these kinds of advances that have permitted agribusiness to substantially decrease global hunger in the face of a soaring population. Furthermore, political and economic tensions make solving the problems of food safety regulation less than simple. These tensions are embodied in a piece of omnibus legislation that is pushed through Congress every five to seven years, commonly known as the “Farm Bill.”²⁷ The Bill addresses two main issues: (1) low-income food stamp programs and (2) commodity crop incentives. The latter has as its goal the promotion of stability for farmers in an inherently unstable, “insecure and tempestuous” profession; however, it has become the basis for the extraordinary surplus production of certain commodities, most nota-

23. HARVEY BLATT, *AMERICA’S FOOD: WHAT YOU DON’T KNOW ABOUT WHAT YOU EAT*, at vii (2008).

24. *Id.* at viii.

25. *Id.* at ix.

26. *Id.*

27. DANIEL IMHOFF, *FOOD FIGHT: THE CITIZEN’S GUIDE TO A FOOD AND FARM BILL* 22 (2007).

bly corn.²⁸ This surplus has helped fuel the alarming dietary crisis Americans now face, wherein one-third of the population is considered “medically obese” and two-thirds are at least thirty pounds overweight.²⁹ The Farm Bill is always riddled with political tensions, requiring no less than nine congressional committees and subcommittees to agree before the Bill passes muster.³⁰ Yet interestingly, it is the incentives for commodity crop production that appear to be “untouchable,” as producers are able to successfully lobby for more money at the expense of such programs as beginning farmer supports and farm-to-school distribution arrangements.³¹ This creates a system of “flat funding” that creates an uphill lobbying battle for constituents other than commodity producers who want to get their share of the legislation funds.³² Therein lies the fight over what food sits on every American’s dinner table nightly: the political fight between the major mega-farms, dominated by corn and meat producers, and everyone else. In an effort to guarantee themselves an almost never-ending supply of cheap commodity crops that can then be sold for almost any purpose, industry giants like Cargill and Archer Daniels Midland virtually “writ[e] the Farm Bills.”³³ Not only does this make it almost impossible for smaller farmers to succeed unless they work for such giants, it floods our food supply with corn-based products, such as high-fructose corn syrup, that are virtually inescapable and that directly contribute to serious health threats such as diabetes and obesity. Add to these domestic tensions a fundamental distrust by Europeans of all things American, most notably food imports, and what seems like a simple and basic human necessity becomes an even more complex global industry.³⁴

From an economic perspective, farmers are faced with what economists call differentiation. Unlike cars, clothes, or other market products, food products are all basically the same: A cucumber is a cucumber and a steak is a steak. It is almost impossible for a farmer to distinguish, or differentiate, his product from a competing farmer’s. The only way to guarantee his market share without decreasing his profit margin is to find a way to lower his price by lowering his operating costs, drawing consumers to buy more of his product than his competitor’s.³⁵ Lowering

28. *Id.* at 22–23. Interestingly, it is just this type of surplus that led to the farm crisis of the Great Depression. *See id.* at 34.

29. *Id.* at 23 (“Driven by government subsidized corn sweeteners, saturated fats, and food additives, this dietary crisis disproportionately affects children, people of color, and the poor.”)

30. *Id.* at 26.

31. *Id.* at 27.

32. *Id.* at 29.

33. *Id.* at 39.

34. *See generally* PENCE, *supra* note 4, at 9–26; *see also* discussion *infra* at pp. 227–29.

35. ROBERTS, *supra* note 9, at 36.

costs can take the form of decreasing contract prices with participating farmers, working with a minimal labor force, or keeping minimal safety standards. No matter how it manifests itself, it amounts to cutting corners with your food. Processed food manufacturers face the opposite problem: They attempt to add to the cost of their product enough to raise their price and profit margin but not enough to make the product too expensive and unable to compete in the marketplace. Out of the money paid for a box of cereal, for example, the cereal company still enjoys a gross profit margin of approximately 44 percent, even after the supermarket cut and basic costs. These companies differentiate their products through heavy promotion and branding, often inducing consumers to buy into an image. As a result, not only are more and more food manufacturers entering the processed (i.e., unhealthy and largely corn-based) market, but more and more consumers choose to buy processed foods over fresh foods.³⁶

In light of these tensions, it becomes clear that the food industry, and in particular the arena of food safety, must be regulated. In fact, food safety regulation finds its roots in the Roman Empire and early Judeo-Christian civilizations. As the various countries of Europe emerged from the ruins of the Roman Empire, food safety laws were adopted and molded to the needs of individual nations.³⁷

By the nineteenth century, the dangers of chemical contamination of food became known. As a result of this new public health threat, new scientific knowledge and understanding of food chemistry emerged and created a professional discipline for food safety. As the century progressed, the regulation of food safety and food purity, based on the analysis of chemical and food composition, provided the basis for modern food sciences and food safety regulation. At the end of the nineteenth century, new technologies for food preservation and conservation were developed in response to international food trade and growing consumer demand for processed food.³⁸

The twentieth century brought exponential technological advances in food storage and food production methods, while also heralding an explosion of food safety concerns, such as food-borne illnesses. Additionally, the rise of a more global food industry demanded a more complex system of food safety regulation that could apply across national borders.³⁹

36. *Id.* at 37–39.

37. Reba A. Carruth, *Socio-Economic Foundations of Food Safety Regulation*, in *GLOBAL GOVERNANCE OF FOOD AND AGRICULTURE INDUSTRIES: TRANSATLANTIC REGULATORY HARMONIZATION AND MULTILATERAL POLICY COOPERATION FOR FOOD SAFETY* 3, 4 (Reba A. Carruth ed., 2006).

38. *Id.*

39. *Id.* at 5.

C. *The American Obesity Epidemic*

Finally, it is impossible to consider the American food system and its corresponding regulation without delving into the alarming prevalence of obesity in the United States population. The scientific and medical communities define obesity as a body mass index of 30 or greater, which can be calculated from a person's weight and height. Body mass index is a "reasonable indicator" of the kind of weight that leads to health problems. "Obesity is a major risk factor for cardiovascular disease . . . cancer, and type 2 diabetes[;]"⁴⁰ obesity-related deaths toll a staggering 400,000 annually.⁴¹ Perhaps even more troubling, obesity is more prevalent among Hispanic and black non-Hispanic communities,⁴² providing a correlation between socioeconomic status and, ultimately, health.⁴³ Childhood obesity is on the rise as well, with a staggering 14.6 percent of low-income preschool-age children considered obese in 2008.⁴⁴ Childhood obesity in particular results in an increased burden on the U.S. economy, including increased healthcare costs, time lost from work and school, and future lack of productivity due to health problems.⁴⁵ While genetics can certainly play a part in making one obese,⁴⁶ it would seem clear that what one chooses to eat has at least something to do with it. But is it all just a matter of personal responsibility? That may have been the tobacco industry's argument—it's the individual who chooses to smoke, not the company that forces him to—and while a higher degree of consumer responsibility must be demanded, the solutions to this crisis are far from being that simple.⁴⁷

40. *U.S. Obesity Trends*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/obesity/data/trends.html> (last updated Sept. 1, 2010).

41. See Mokdad, *supra* note 3.

42. *U.S. Obesity Trends*, *supra* note 40.

43. See generally Census 2000 Fact Sheet for Black Population, U.S. CENSUS BUREAU, <http://factfinder.census.gov> (follow "Fact Sheet" hyperlink; then follow "Fact Sheet for a Race, Ethnic, or Ancestry Group" hyperlink; then select "Black alone;" then follow "Go" hyperlink) (last visited Jan. 2, 2011); Census 2000 Fact Sheet for Hispanic Population, U.S. CENSUS BUREAU, <http://factfinder.census.gov> (follow "Fact Sheet" hyperlink; then follow "Fact Sheet for a Race, Ethnic, or Ancestry Group" hyperlink; then select "Hispanic or Latino of any race;" then follow "Go" hyperlink) (last visited Jan. 2, 2011). As of 2000 the median income of both groups was well below that of the total U.S. population, barely half in the case of black families. *Overweight and Obesity: Causes and Consequences*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/obesity/causes/index.html> (last updated Dec. 7, 2009).

44. *Obesity Prevalence Among Low-Income, Preschool-Aged Children 1998–2008*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/obesity/childhood/lowincome.html> (last updated Mar. 16, 2010).

45. See Joan R. Rothenberg, *In Search of the Silver Bullet: Regulatory Models to Address Childhood Obesity*, 65 *FOOD DRUG L.J.* 185 (2010).

46. See sources cited *supra* note 43.

47. See HANK CARDELLO, *STUFFED: AN INSIDER'S LOOK AT WHO'S (REALLY) MAKING AMERICA FAT*, at xiv (2009).

So who is making America fat? As Hank Cardello notes, “[p]ointing the fickle finger of fat responsibility at any one group is ultimately futile and will do little to solve the problem.”⁴⁸ Food executives certainly play their part; despite the fact that they provide a product that is essential to sustaining life, food companies are still for-profit businesses. Ultimately, these executives need the consumer to buy as much of their product as possible in order to fulfill the omnipresent “bottom line.”⁴⁹ The more they sell, the greater the company’s profit and their own bonuses. In order to do this, food executives have become adept at following the trends of consumer demand—and we consumers don’t always want what’s best for us. Instead, we want more bang for our buck.⁵⁰ The true “bottom line” is that what’s holistically best for the consuming population has almost nothing to do with the decisions food executives make about their products, whereas “coerc[ing]” and “manipulat[ing]” consumers into buying as much food as possible takes center stage.⁵¹ Cardello explains:

The executive mantra [is] bigger packages, bigger servings, and more of everything per container. In the process, portion size got dangerously out of hand. We went from “buy one, get one free,” to “buy it by the dozens and save.” Unfortunately, this also dictated *how much* we ate. We began to crave oversized entrees and 20-ounce Mountain Dews, and the packaged goods companies were more than willing to oblige, ignoring the inherent risks behind a nation fueled by processed foods and gallons of soda.⁵²

Restaurant executives engage in similar tactics. In order to increase profits, restaurants drastically increase the size of the portions they serve. The increase in ingredient cost is nominal, but the potential profits soar. The effect on patrons’ health doesn’t even enter into the equation—it’s a question of survival.⁵³ Then again, consumers make it easy:

America eats out more than ever before. This is a recent—meaning approximately the last half[-]century—cultural concept, fomented in part by our endlessly busy lifestyles. Mom and Dad are working and they’re exhausted after picking the kids up from after-school activities, so they don’t have time to cook. And authorities agree, the more you rely on someone else to cook your food, the less you know what’s in it Mostly, the time-pressed consumer eats high-calorie, low-nutrition fare.⁵⁴

48. *Id.*

49. *See id.* at 17–18.

50. *Id.* at 18.

51. *Id.* at 14.

52. *Id.* at 19.

53. *Id.* at 24.

54. *Id.* at 25.

The advent of the “combo” meal made matters worse: Now consumers don’t even have to think about what they’re eating, and they justify that lack of thought as saving a few hard-earned pennies.⁵⁵ Are restaurants merely responding to customers’ needs, or are customers justifying their bad habits as literally just eating what they’re fed?

Okay, so instead of visiting one of these chain restaurants that fool you into eating more food of lesser quality, you choose to go to the grocery store and prepare food at home; surely, this will allow you greater control over what you actually eat and virtually guarantees that you will eat “better,” right? Wrong. “Because there is so much pressure on the bottom line, [supermarkets] look to cut costs and extract the maximum promotional dollars from the producer companies.”⁵⁶ Essentially, supermarkets have ultimate control over the placement of food throughout the store, and they make sure that the food you see the most is the food they have the greatest profit margin on. That means food that is cheaper to produce (full of chemical fillers and cheap corn products) and food made by companies that can afford to pay for the lucrative real estate: end-of-aisle displays and eye-level shelf space.⁵⁷ Supermarkets strategically place “power” foods, such as meat, eggs, and milk, all the way in the back of the store in order to ensure that you have to walk through the aisles to get what they know you won’t leave without, encouraging you to be attracted by impulse buys that are well-placed to catch your eye.⁵⁸ Of course, the overly sweetened children’s cereals can be found two shelves from the bottom, at perfect child eye level.⁵⁹ The organic food movement, spearheaded by high-end supermarkets, such as Whole Foods, have “lured [us] into a false feeling of comfort and security [from] thinking that everything in the store is good for you.”⁶⁰ After all, it’s more expensive so it *must* be better. This may very well be at least partially true of the largely (but not entirely) pesticide- and preservative-free produce and meat, but the packaged goods are of the same high-calorie, over-sized variety as any mainstream supermarket.⁶¹ While it is certainly a step in the right direction, organic food producers are still for-profit businesses and still have a bottom line to which to answer, making them just as vulnerable to the less-than-honorable motives we

55. *Id.* at 26 (“Sure, there’s a small price break . . . [b]ut the average check goes up, because the combo meal encourages the customer to buy more.”).

56. *Id.* at 21.

57. *Id.* at 33–35 (“They *need* you to keep buying the 70-percent-margin boxes of sugar-laced Frosted Flakes . . . because they’re staples for the quarterly shareholder reports.”) (emphasis added).

58. *Id.* at 32.

59. *Id.* at 34.

60. *Id.* at 43.

61. *Id.* at 45.

might find abhorrent in traditional food producers.⁶²

The food industry is already heavily regulated. Yet sufficient loopholes exist to allow the types of abuses discussed above to be pervasive. One of the only lawsuits yet to be filed in tort on the subject of obesity was dismissed for failure to state a claim upon which relief may be sought.⁶³ The plaintiffs were a class of infants and minors who had consumed McDonald's products and alleged that as a result "such consumption [had] been a significant or substantial factor in the development of their obesity, diabetes, coronary heart disease, high blood pressure, elevated cholesterol intake, and/or other detrimental and adverse health effects and/or diseases."⁶⁴ The complaint alleged that the plaintiffs had been misled through false advertising into believing that McDonald's food products were nutritious, that McDonald's failed adequately to disclose the true nutritious value (or lack thereof) of its food, and that the company engaged in unfair and deceptive acts and practices through such advertising campaigns.⁶⁵ The trial judge cited three main reasons why such a claim could not proceed:

First, if traditional rules are followed, plaintiffs would have to show that their obesity was caused by food, not by failure to exercise, other lifestyle choices, or genetics. Second, plaintiffs would have to show that a particular defendant's food caused this harm Finally . . . there will have to be a major change in the definition of what constitutes a "product defect" for liability to ensue.⁶⁶

Significantly, however, on appeal the circuit court found that, while these factors were indeed relevant to this type of claim, the information was properly the subject of discovery and not grounds for dismissal.⁶⁷ This clearly left the door open for potential subsequent litigation in an effort to force food producers to take responsibility for the quality of the food they "push" onto consumers. Several other lawsuits in the obesity context, all based on alleged misrepresentations, have settled out of court.⁶⁸ The idea behind this type of litigation, sometimes called "regulation through litigation," is that the threat of litigation and massive risks of liability will force behavioral change among the relevant class of defendants. While there must always remain an avenue open to liti-

62. *Id.* at 47.

63. *Pelman v. McDonald's Corp.*, No. 02 Civ. 7821, 2003 WL 22052778 (S.D.N.Y. Sept. 3, 2003).

64. *Id.* at *1.

65. *Id.* at *2.

66. VICTOR E. SCHWARTZ & PHIL S. GOLDBERG, *CLOSING THE FOOD COURT: WHY LEGISLATIVE ACTION IS NEEDED TO CURB OBESITY LAWSUITS* 9 (2004).

67. *Pelman v. McDonald's Corp.*, 396 F.3d 508, 511-12 (2d Cir. 2005). The case was remanded for further proceedings, but no disposition is currently available.

68. SCHWARTZ & GOLDBERG, *supra* note 66, at 11.

gants—foreclosing the right of a litigant to vindicate his or her right in a court of law would be tantamount to denying such a right exists—it can be argued that such a process is designed to settle disputes between parties, and not to establish public policy.⁶⁹ A fundamental change in legislative regulation, through the authority of relative agencies and otherwise, must be effectuated.

D. *Genetically Modified Food*

The common understanding of biotechnology is that it refers to the science of modifying deoxyribonucleic acid (“DNA”) and other genetic material of an organism in order to change its essential traits. Genetic engineering is the process of using biotechnology modification of recombinant deoxyribonucleic acid (“rDNA”), also called gene splicing, to produce desirable traits in organisms. Finally, the term “genetically modified” is the way genetically engineered food is more commonly referred to—“[t]he term ‘genetically engineered’ more precisely indicates that humans have directly engineered the DNA. In the broadest sense, all food crops have been genetically modified by humans using conventional cultivation and propagation techniques.”⁷⁰ Genetically modified food is fundamentally different than the so-called “hybrid” food that we have been eating for decades. Genetic modification techniques relevant to the scope of this comment allow “scientists the ability to isolate genes and to introduce new traits into foods without simultaneously introducing many other undesirable traits, as may occur with traditional breeding[,] . . . [and] enable the transfer of traits from bacteria or animals into plants.”⁷¹ The major rationale for developing genetically engineered food is that it affords the ability to increase crop yields by changing the genetic makeup of the crop to resist herbicides and pests.⁷² Yet risks have been recognized:

[T]he use of biotechnology has also raised concerns about its potential risks to the environment and people. For example, some people fear that common plant pests could develop resistance to the introduced pesticides in GM crops that were supposed to combat them. Further some fear that crops modified to be tolerant to herbicides could foster the evolution of “super weeds.” Finally, some fear that

69. *Id.* at 2.

70. FORTIN, *supra* note 3, at 413.

71. *Genetically Engineered Foods: Hearing Before the Subcomm. on Basic Research of the H. Comm. on Science*, (1999) (statement of James H. Maryanski, Ph.D., Biotechnology Coordinator, Center for Food Safety and Applied Nutrition, Food and Drug Administration) [hereinafter *Hearing*], available at <http://www.fda.gov/NewsEvents/Testimony/ucm115032.htm>.

72. U.S. GEN. ACCOUNTING OFFICE, GAO-02-566, GENETICALLY MODIFIED FOODS: EXPERTS VIEW REGIMEN OF SAFETY TESTS AS ADEQUATE, BUT FDA’S EVALUATION PROCESS COULD BE ENHANCED (2002) [hereinafter GEN. ACCOUNTING OFFICE REPORT].

scientists might unknowingly create or enhance a food allergen or toxin.⁷³

Despite the inherent risks, genetically modified food can have a positive effect on the world's food supply. By making crops more resistant to bacteria, food manufacturers can essentially produce larger quantities of food. This important contribution cannot be ignored in a global climate where as much as 75 percent of the population in some countries is undernourished.⁷⁴

III. HOW AMERICANS REGULATE FOOD

A. *The History of Food Safety Regulation*

As introduced above, the American food industry is already heavily regulated. As early as the fourth century, ancient Roman writers discussed the problem of food adulteration, and laws were put in place to punish transgressions with condemnation to the mines or even exile.⁷⁵ Later, trade guilds banded together to impose stringent food safety regulations purely as a means of strengthening the economy of the food industry, recognizing that providing a "purer" product could give a competitive edge. In the New World, colonial-era food regulation was almost exclusively the province of local and state governments, with no unified federal presence in the industry at all. Finally, in the late 1880s Congress began taking action against adulterated food, passing first a ban on adulterated tea and later the so-called "oleo-margarine statute," both designed to protect producers from the competition of adulterated products that could be sold at lower prices with larger profit margins.⁷⁶ As scientific progress allowed for new ways to produce adulterated food, so too did it allow for its detection.⁷⁷

We face a new situation in history. Ingenuity, striking hands with cunning trickery, compounds a substance to counterfeit an article of food. It is made to look like something it is not; to taste and smell like something it is not; to sell like something it is not, and so deceive the purchaser.⁷⁸

As food became a product of the factory, the demand for regulation grew. Dr. Harvey Wiley's leadership of the U.S. Bureau of Chemistry

73. *Id.*

74. Food and Agriculture Organization of the United Nations, Prevalence of Undernourishment in Total Population (Sept. 13, 2010), <http://www.fao.org/economic/ess/food-security-statistics/en/>.

75. FORTIN, *supra* note 3, at 4.

76. *Id.*

77. *Id.* at 4–5.

78. *Id.* at 5. This kind of adulteration was particularly prevalent in the "oleo-margarine" industry where adulterated butter and fats were colored to look like real butter. *Id.*

and his use of the crude but highly publicized “Poison Squad” to increase awareness of the potential hazards of adulterated food helped garner public support for food safety regulation.⁷⁹

The cry for reform finally hit its peak in the first decade of the twentieth century, largely thanks to a new wave of sensationalist journalism and the publication of Upton Sinclair’s *The Jungle*, both of which exposed in gruesome detail the unsanitary practices of the meat-packing industry. In response, Congress passed the Pure Food and Drug Act⁸⁰ and the Meat Inspection Act⁸¹ in 1906, adding regulatory functions to the U.S. Bureau of Chemistry (the precursor to the present-day Food and Drug Administration) and requiring inspection of all “cattle, sheep, swine, goats, and horses” during the slaughtering process.⁸² Although it did not take long for calls for expansion and strengthening of the statutes to begin, change would not come until more than 107 people died, including many children, from taking a form of sulfanilamide, a form of the antibiotic sulfa that had been doctored with harmful taste additives. The manufacturer had not performed any safety tests on the product before making it available to the public because none were required.⁸³ This catastrophic mistake set up a pattern that would continue in American food safety—if it hasn’t killed enough people yet, it doesn’t need to be regulated. As a result, Congress passed the Food, Drug, and Cosmetic Act (“FD&C Act”) in 1938, which mostly increased regulation over drugs, cosmetics, and therapeutic devices in response to the sulfanilamide disaster. However, among other subsidiary regulations, it did require that “safe tolerances be set for *unavoidable poisonous substances* in food.”⁸⁴ A dangerous precedent had been set; there was now federal recognition and acceptance of food that was less than pure. After all, a “safe tolerance” still means that the food contains poison. What may be a “safe” amount for a full-grown man may not be so safe for a three-year-old child. The use of the word “unavoidable” sends a clear message to the food industry: We expect to have poison in our food, and that’s okay. Furthermore, such acceptance implies that some degree of impurity, *even if it makes us sick from time to time*, is federally sanctioned.

In the face of this linguistic loophole, food laws continued to be enacted and amended as Congress struggled to react to outbreaks of ill-

79. *Id.*

80. Pure Food and Drug Act, ch. 3915, 34 Stat. 768 (1906) (repealed 1938).

81. Federal Meat Inspection Act, ch. 2907, 34 Stat. 1260 (1906) (current version at 21 U.S.C. § 601 (2006)).

82. *Id.*

83. FORTIN, *supra* note 3, at 6.

84. *Id.* at 7 (emphasis added).

ness and other breaches that were fully permissible under the initial regulatory scheme.⁸⁵ The Food Additives Amendment of 1958 demanded “evaluation” of food additives to determine safety.⁸⁶ The Delaney Clause⁸⁷ implicitly required testing of food substances on laboratory animals and banned any such substance that was found to cause cancer in test subjects. The Color Additive Amendment of 1960 required safety of all color additives in food, drugs, and cosmetics⁸⁸—a concept we now take for granted. A rash of botulism outbreaks resulting from canned foods sparked passage of the Low-Acid Food Processing Regulations of 1973.⁸⁹ Cyanide-induced deaths from Tylenol resulted in the (now ubiquitous) requirements of the Tamper-Resistant Packaging Regulations of 1982.⁹⁰ A year later, Congress made such tampering a federal crime by enacting the Federal Anti-Tampering Act.⁹¹

The last two decades of the twentieth century saw a marked paradox: The “health nut” wave spurred companies to increasingly market foods purported to “fulfill health concerns” while the food industry continued to make (dangerous) strides in food processing on a national, rather than a local, level.⁹² In a seemingly revolutionary step in the right direction, in 1990 Congress required all packaged foods to be labeled with nutritional information, and for that information to conform to Food and Drug Administration terms, by enacting the Nutritional Labeling and Education Act.⁹³ It is against this backdrop of after-the-fact regulation—legislation in response to major food safety breaches, as opposed to in anticipation thereof—that we now turn to who, exactly, regulates our food.⁹⁴

B. *The Current State of Affairs*

The majority of direct federal oversight for food regulation in the United States comes from the Food and Drug Administration (“FDA”) and the United States Department of Agriculture (“USDA”). These two

85. See generally *id.* at 6–8.

86. Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (current version at 21 U.S.C. § 331) (2006)).

87. *Id.*

88. Color Additive Amendment of 1960, Pub. L. No. 86-618, 74 Stat. 397 (current version at 21 U.S.C. § 331 (2006)).

89. 21 C.F.R. § 108.35 (1977).

90. 21 C.F.R. § 700.25 (1982).

91. Federal Anti-Tampering Act, Pub. L. No. 98-127, 97 Stat. 831 (1983) (current version at 18 U.S.C. § 1365 (2006)).

92. FORTIN, *supra* note 3, at 7–8.

93. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (current version at 21 U.S.C. § 343-1 (2006)).

94. See generally INTERNATIONAL FOOD LAW 539–614 (Jocelyn Kellam & Elizabeth Toni Guarino eds. 2000).

agencies, however, share some portion of that role with other agencies, such as the Environmental Protection Agency (“EPA”), the Federal Trade Commission (“FTC”), and the Alcohol and Tobacco Tax and Trade Bureau (“TTB”).⁹⁵ The FDA has jurisdiction over both imported and domestic food, except meat and poultry, bottled water, and wine with less than seven percent alcohol content.⁹⁶ This agency performs a variety of functions, including inspecting food production sites, analyzing food samples for safety, establishing safety guidelines for food producers (and, ostensibly, enforcing them), requiring safety recalls of products, and working with foreign governments to ensure safety of imports.⁹⁷ Critically, the Centers for Disease Control and Prevention (“CDC”) typically only get involved once an “official” food-borne disease outbreak is reported.⁹⁸ It also has primary responsibility for maintaining a “nationwide system of food[-borne] disease surveillance” but does not necessarily work with other agencies, such as the FDA, to prevent such outbreaks.⁹⁹

The USDA is primarily responsible for conducting inspections of all domestic and imported meat and poultry, including any related products (i.e., processed or frozen foods containing meat and poultry).¹⁰⁰ It is also responsible for regulating processed egg products—as opposed to fresh eggs, which fall under the FDA’s jurisdiction.¹⁰¹ The USDA’s jurisdiction is derived largely from the Federal Meat Inspection Act,¹⁰² the Poultry Products Inspection Act,¹⁰³ and the Egg Products Inspection Act,¹⁰⁴ all of which vest in the agency the responsibility to inspect animals for disease before and after slaughter, inspect slaughter and processing locations and, like the FDA, establish and enforce guidelines for the safety of these types of products.¹⁰⁵

The EPA has primary responsibility over drinking water¹⁰⁶—bot-

95. FORTIN, *supra* note 3, at 23.

96. See scattered sections of 21 C.F.R. See also FORTIN, *supra* note 3, at 24.

97. FORTIN, *supra* note 3, at 24.

98. *Id.*

99. *Id.*

100. *Id.* at 25.

101. *Id.*

102. 21 U.S.C. §§ 601–625 (2006).

103. 21 U.S.C. §§ 451–472 (2006).

104. 21 U.S.C. §§ 1031–1056 (2006).

105. FORTIN, *supra* note 3, at 25; see also Brett T. Schwemer and Jolyda O. Swaim, *Food: Meat and Poultry Inspection*, in *FOOD AND DRUG LAW AND REGULATION* 127, 130–46 (David G. Adams et al., eds., Food and Drug Law Institute 2008).

106. FORTIN, *supra* note 3, at 25.

tled water is regulated by the FDA¹⁰⁷—and pesticide safety,¹⁰⁸ which is largely enacted in the form of setting tolerance levels for pesticide residues in foods.¹⁰⁹ This responsibility necessarily requires cooperation with the FDA and the USDA in order to regulate pesticide runoff and contamination of food animal drinking water. The National Marine Fisheries Service (“NMFS”) inspects and certifies fish and seafood products, but significantly this is done through a voluntary, paid service.¹¹⁰ However, the NMFS also inspects fishing vessels, plants, and retail facilities, but only for federal sanitation standards, not for product safety.¹¹¹ The TTB (formerly the Bureau of Alcohol, Tobacco, and Firearms) regulates alcoholic beverages (except the category of wine that is under the FDA’s jurisdiction), including labeling and adulteration.¹¹² The United States Customs Service works with various other aforementioned regulatory agencies to inspect all incoming and outgoing food products according to U.S. law.¹¹³ The FTC is charged with enforcing federal laws prohibiting unfair, deceptive, or fraudulent practices, which most often are found in the area of food advertising.¹¹⁴ Finally, the United States Department of Justice (“DOJ”) has jurisdiction over any individual or company for alleged violations of food safety laws and can seize by court order unsafe food products that have not yet entered the marketplace.¹¹⁵ Additionally, much of this delegated responsibility becomes further delegated to state and local governments, which often have more manpower and more financial resources to perform these regulatory tasks. This non-exhaustive list of federal agencies that have a hand in ensuring that the food we eat every day is “safe” highlights the “haphazard patchwork” nature of food safety regulation. In the same way that legislation is enacted as a reaction to safety issues as they arise, so, too, is agency power delegated.¹¹⁶ The result is that when an outbreak occurs, it is often not clear which agency had responsibility over the precise safety issue that caused it, and it is rarely possible to identify a clear point in the regulation and inspection process that led to the prob-

107. *Id.* at 24.

108. Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. No. 92-516, 86 Stat. 973 (1972) (current version at 7 U.S.C. § 136 (2006)).

109. *Id.*; see also discussion *supra* p. 215–16. These types of linguistic loopholes continued to be pervasive in our food safety schemes. *Id.*

110. FORTIN, *supra* note 3, at 26.

111. *Id.*

112. *Id.*

113. *Id.*

114. *Id.* at 27

115. *Id.*

116. *Id.* at 28.

lem. The patchwork merely allows agencies to point the finger at each other and results in yet more patchwork legislation and delegation.

In addition to the Food, Drug, and Cosmetic Act¹¹⁷—and its seemingly never-ending slew of amendments¹¹⁸—and the Federal Meat Inspection Act,¹¹⁹ there are two other major pieces of federal legislation noteworthy to this discussion. The Food Quality Protection Act of 1996¹²⁰

mandates a single, health-based standard for all pesticides in all foods; provides special protections for infants and children; expedites approval of safer pesticides; and creates incentives for the development and maintenance of effective crop protection tools for American farmers. It also requires periodic re-evaluation of pesticide registrations and tolerances to ensure that the scientific data supporting pesticide registrations will remain up to date in the future.¹²¹

Significantly, the FDA Modernization Act of 1997 eliminated the FDA's requirement of agency pre-market approval for most packaging and substances that might come into contact with food.¹²² Instead, it implements a system of self-regulation whereby the manufacturer determines whether the product is safe and then simply notifies the agency of its intent to use the substance. The FDA then has 120 days to object, and the product enters the marketplace.¹²³ A critical question raised by this new system of self-regulation is whether the FDA can reasonably determine if an objection is necessary simply by notice, as opposed to the inspection and testing the agency would have done under the old system. If one analogizes to the system of self-regulation of the American banking system implemented in the last decade of the twentieth century, can the American public reasonably believe that a food manufacturer would blow the whistle on one of its own unsafe products if the FDA has no power to inspect or test it for itself?

C. *Legislative Flaws*

Although an exhaustive discussion of the many facets of, and definitions contained in, the Food, Drug, and Cosmetic Act would be superfluous to this discussion, it is important to highlight that the Act

117. Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.).

118. See discussion *supra* p. 216.

119. Federal Meat Inspection Act, Pub. L. No. 90-201, 81 Stat. 584 (1967) (current version at 21 U.S.C. § 601) (2006)).

120. Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489.

121. FORTIN, *supra* note 3, at 31.

122. Food and Drug Administration (FDA) Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296.

123. *Id.*

provides specific food classifications from which is derived agency jurisdiction over different products.¹²⁴ In addition, the Act provides specific definitions for the terms “food” and “food additive,” which become important in analyzing whether a given product or substance is regulated at all. These definitions are:

The term “food” means

- (1) articles used for food or drink for man or other animals
- (2) chewing gum, and
- (3) articles used for components of any other such article.¹²⁵

The term “food additive” means *any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any food . . . if such substance is not generally recognized . . . as having been adequately shown . . . to be safe under the conditions of its intended use . . .*¹²⁶

These definitions highlight the importance of determining a product’s or substance’s “intended use” in order to properly classify it.¹²⁷ Also important to note is that a substance only comes under the definition of “food additive” if it is reasonably expected to become a component of a food product. This implicitly and glaringly opens the door for substances not so intended, but present anyway, to be unregulated as falling outside the strictly circumscribed definition. In contrast, the definition for “food” is completely devoid of any reference to intent. However, “a court may consider the intended use of the product in considering whether it is a food.”¹²⁸

As our civilization continues to become increasingly global, so, too, does our food supply. Changes in the nature and volume of imports have completely overwhelmed the FDA and made it increasingly harder to regulate.¹²⁹ The United States is receiving more and more raw materials

124. FORTIN, *supra* note 3, at 39.

125. 21 U.S.C. § 321(f) (2006).

126. 21 U.S.C. § 321(s) (2006) (emphasis added). It is important to note that this definition does not include pesticides or color additives.

127. See *United States v. Cal’s Tupelo Blossom U.S. Fancy Pure Honey*, 344 F.2d 288 (6th Cir. 1965) (finding honey to be classified as a drug because of the company’s therapeutic claims); *United States v. Sterling Vinegar & Honey*, 338 F.2d 157 (2d Cir. 1964) (finding vinegar and honey to be classified as a drug because of the company’s therapeutic claims); *United States v. Hohensee*, 243 F.2d 367 (3d Cir. 1957) (finding tea to be classified as a drug because of the company’s therapeutic claims); *United States v. 500 Plastic Bottles*, Civ. No. 88-1482-FR, 1989 WL 131257 (D. Or. Oct. 23, 1989) (finding water to be classified as a drug because of the company’s therapeutic claims).

128. FORTIN, *supra* note 3, at 46.

129. Kelly Chen & Rosa Dunnegan-Mallat, *H.R. 3610, The Food and Drug Import Safety Act of 2007*, 42 INT’L LAW. 1339, 1340 (2008). FDA-regulated imports have increased almost ten-fold since 1993. *Id.*

from countries with little or no regulatory scheme in place.¹³⁰ This trend has led to a surge of new risks, including “food-borne diseases not previously identified[,] . . . dangerous industrial compounds, and carcinogenic drugs in food imports.”¹³¹ The FDA’s limitations in dealing with this flood of potentially dangerous imports can be traced to two factors: a growth of responsibility without a commensurate growth in budget and an inherently reactive, versus proactive, system.¹³² As a result, the proposed Food and Drug Import Safety Act sought to amend the FD&C Act to solve at least part of these problems by increasing funding for import inspections, restricting ports of entry for food to cities where there are preexisting FDA laboratories, establishing country-of-origin labeling requirements for imported products, and increasing fines for violations.¹³³

Of significant interest to this discussion is section 10 of the Act, which would provide the FDA with recall authority “if there is a reasonable probability that a food could ‘cause serious, adverse health consequences or death.’”¹³⁴ The first obvious point of discussion regarding this language is that it continues the long-standing “probability” decision calculus in determining what we, as consumers, are allowed to eat.¹³⁵ Even if there is a *possibility* that the product will “cause serious, adverse health consequences or death,” the product would still pass FDA muster so long as the subjective “reasonable probability” standard is not met.¹³⁶ The second issue glaringly highlighted by this language is the current lack of authority to recall products: “Presently, ‘FDA may not unilaterally order a recall *even of a product that is life threatening*.’”¹³⁷ Yet, not surprisingly, “[t]he food industry agrees that the current voluntary recall program works well.”¹³⁸ Data indicates, however, that consumers believe that the government should be able to recall products, a sentiment echoed by such interest groups as the Center for Science in the Public Interest.¹³⁹ Despite the reactive system of our federal regulatory scheme, and despite widely publicized outbreaks of disease here and

130. *Id.*

131. *Id.*

132. *Id.* at 1340–41.

133. *Id.* at 1343–47.

134. *Id.* at 1347 (quoting H.R. 3610, 110th Cong. § 10 (2007)).

135. See discussion *supra* p. 22.

136. Chen & Dunnegan-Mallat, *supra* note 129, at 1347–48.

137. *Id.* at 1348 (emphasis added) (citations omitted). The recent massive Iowa egg recall highlights this flaw; it was not until two producers voluntarily recalled their products that public attention was drawn to the severe salmonella outbreak. See Investigation Update, *supra* note 2.

138. Chen & Dunnegan-Mallat, *supra* note 129, at 1347.

139. *Id.*

abroad,¹⁴⁰ there is still a legislative reluctance to grant ultimate recall authority. In the wake of these public disasters, doesn't this exhibit a disregard for the consequences likely to result from such reluctance?¹⁴¹ The Act was never passed, dying at the conclusion of the 110th Congress.¹⁴²

Although the issues surrounding nutritional labeling of food are beyond the scope of this comment,¹⁴³ it is noteworthy to include a brief discussion of the regulation of so-called *trans* fats. *Trans* fatty acids can be found in hydrogenated vegetable oil, a key ingredient in the staples of American diets: "margarine, commercial cakes and cookies, doughnuts, potato chips, crackers, popcorn, nondairy creamers, whipped toppings, gravy mixes, cake mixes, frozen French fries and pizzas, fish sticks, and virtually all fried foods, unless you fry them yourself in unhydrogenated oils."¹⁴⁴ More than a decade ago, a professor at the Harvard School of Public Health estimated that 30,000 deaths from heart disease per year could be attributed to the use of hydrogenated oils and the resulting *trans* fats, characterizing it as "the biggest food processing disaster in U.S. history."¹⁴⁵ In fact, the FDA itself concluded that "*trans* fat is even more harmful than saturated fat."¹⁴⁶ The Center for Science in Public Interest argues that these types of oils are "absolutely unnecessary in the food supply" and eliminating them "is probably the single easiest, fastest, cheapest way to save tens of thousands of lives each year."¹⁴⁷ Yet despite these warnings, and despite an admission from an FDA advisory panel itself, the agency declined to ban *trans* fat from processed foods

140. See, e.g., *Recall Expands to More Than Half a Billion Eggs*, MSNB.COM (Aug. 20, 2010, 6:57 PM), http://www.msnbc.msn.com/id/38741401/ns/health-food_safety; see also Investigation Update, *supra* note 2.

141. See BLACK'S LAW DICTIONARY, *supra* note 7; see also Chen & Dunnegan-Mallat, *supra* note 129, at 1349 ("Under section fourteen . . . a label would be required for those meat, poultry, or seafood products with carbon monoxide . . .") (emphasis added). Instead of prohibiting the use of carbon monoxide to preserve the color of the food product (implying that the product isn't fresh enough to maintain color on its own), the Act merely requires that the consumer be informed of its presence. *Id.*

142. H.R. 3610 [110th]: Food and Drug Import Safety Act of 2007, <http://www.govtrack.us/congress/bill.xpd?bill=h110-3610> (last visited Apr. 27, 2010). A new piece of legislation that purports to grant the FDA more authority to order recalls was introduced in the wake of the Iowa salmonella outbreak. As of this writing, the bill has been passed in the Senate, but it is still not clear whether it will be enacted or what the final wording will be. Bill Tomson, *Food-Safety Bill Clears Senate*, WSJ.COM, Nov. 17, 2010, http://online.wsj.com/article_email/SB1000142405274870464860457562062373347294-lMyQjAxMTAwMDEwNzExNDcyWj.html.

143. See Mel Drozen & Eve Pelonis, *Food Labeling*, in FOOD AND DRUG LAW AND REGULATION 77-101 (David G. Adams et al. eds., 2008), for information on the basic labeling requirements of the Food, Drug, and Cosmetic Act, and the Fair Packaging and Labeling Act.

144. FORTIN, *supra* note 3, at 112 (internal citations omitted).

145. *Id.* (internal citations omitted).

146. *Id.* (internal citations omitted).

147. *Id.* at 112-13.

altogether, opting instead to require that all packaged foods include a label advising consumers of the amount of *trans* fat in one serving of the product. However, *trans* fat does not have to be listed at all if the product contains less than half a gram of total fat per serving and the packaging makes no claims about fat content.¹⁴⁸ In other words, the FDA, in full knowledge of the consequences of ingesting the *trans* fats that are ubiquitous in the processed food staples of American diets, disregarded the consequences likely to result from allowing them to remain in the food supply,¹⁴⁹ performing a “conscious . . . omission” without regard for such likely consequences.¹⁵⁰

“Congress has opined that a determination of safety may be situational and, as a result, can often be assessed against a background of social and economic values, depending on the nature of the food and the nature of the risk.”¹⁵¹ In other words, safety is not an absolute. This is nowhere better illustrated than by examining the Food, Drug, and Cosmetic Act itself:

Any poisonous or deleterious substances added to any food, *except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice*, shall be deemed to be unsafe . . . ; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health [S]uch food shall not . . . be considered to be adulterated within the meaning of . . . this title. In determining the quantity of such added substance to be tolerated . . . the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided¹⁵²

The Act conveniently provides statutory authority for the FDA knowingly to allow substances considered poisonous or deleterious to enter the food supply if it’s “unavoidable.”¹⁵³ However, the Act is devoid of any definition of what “unavoidable” means in this context, or who decides whether the additional substance is truly unavoidable. In fact, food that contains such substances in quantities below the stated tolerance is not even considered adulterated. This loophole provides an

148. *Id.* at 113.

149. See BLACK’S LAW DICTIONARY, *supra* note 7, at 480.

150. *Id.* Gross negligence is defined as “[a] conscious, voluntary act or omission in reckless disregard of a legal duty and of the consequences to another party, who may typically recover exemplary damages.” *Id.* In this context, the legal duty arises from the statutory grant of authority to the FDA to regulate the safety of domestic food products.

151. Fred H. Degnan, *Food Safety*, in FOOD AND DRUG LAW AND REGULATION, *supra* note 143, at 17, 27.

152. 21 U.S.C. § 346 (2006) (emphasis added).

153. *Id.*; see also 21 C.F.R. § 109.3 (2010).

opportunity for food manufacturers to claim that additions are unavoidable and necessary for the production of their product without repercussion. Under this standard, a manufacturer can ostensibly claim that the inclusion of hydrogenated vegetable oil is "necessary" because the only substitute would be a saturated fat. Significantly, the FDA's interpretation of the standard may evade judicial review; as long as a court is convinced that the standard is "sufficiently rational," it will not substitute its own interpretation of the statutory language for the agency's.¹⁵⁴

Pesticide residue is governed by section 408 of the FD&C Act, which provides that the burden of proof of safety lies with the pesticide manufacturer, not with the FDA, to prove safety or lack thereof.¹⁵⁵ Although the FDA is charged with regulating "poisonous" substances, the EPA is the agency empowered to set tolerances for pesticide residues on produce and regulate the safety of chemicals in food, once again providing statutory authority for the presence of some chemicals on produce.¹⁵⁶ As with the discussion above regarding the presence of added substances in adulterated food, there is no statutory standard for what constitutes a sufficient amount of pesticide to be "deleterious" to human health. As Fortin notes:

The FD&C Act contains no provision that explicitly provides a regulatory mechanism for substances that become constituents of food through environmental contamination. Many of these substances, such as mercury, PCBs, aflatoxin, and PBBs, can pose serious risk to public health. In part because the FD&C Act did not authorize FDA to set tolerances for these contaminants, FDA began to set informal section 406 "actions levels" . . . [which] are the highest level of contamination that will not trigger FDA enforcement action.¹⁵⁷

As previously discussed, the Delaney Clause of the FD&C Act established a zero tolerance standard for the presence of carcinogenic pesticides on food products.¹⁵⁸ After decades of being largely ignored by the FDA and spurred by the controversial new technologies that allowed the industry to more easily detect residues,¹⁵⁹ Congress replaced the clause with the more lenient Food Quality Protection Act in 1996, providing in part:

154. See, e.g., *Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 981 (1986).

155. 21 U.S.C. § 346a (2006).

156. FORTIN, *supra* note 3, at 212; see also Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. No. 92-516, 86 Stat. 973 (1972) (current version at 7 U.S.C. § 136 (2006)) and 21 U.S.C. § 346a (2006).

157. FORTIN, *supra* note 3, at 214.

158. Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (current version at 21 U.S.C. § 331 (2006)).

159. Congress began whittling away at the Clause by exempting saccharin from its restrictions. FORTIN, *supra* note 3, at 221.

As used in this section, the term “safe,” with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.¹⁶⁰

Alarming, if the residue is deemed “necessary” to avoid a “significant disruption” of the food supply, the tolerance passes muster under the new statutory scheme.¹⁶¹

It is important to note that the FD&C Act’s statutory grant of authority to the FDA is extremely broad, yet the agency’s budget has never been set commensurate with the responsibilities granted to it under the Act.¹⁶² Furthermore, courts have regularly upheld the FDA’s discretion to *decline* to take regulatory action against violations that it deems are not “flagrant” enough to warrant the expenditure of resources.¹⁶³ To make matters more complicated, the FDA does not have sole discretion in choosing to bring enforcement actions, but must instead cooperate with the Department of Justice.¹⁶⁴ In order to exercise its power to seize products and move for injunctions, the agency’s attorneys must send requests to Department of Justice attorneys, who can decline to litigate if they so choose.¹⁶⁵ Furthermore, the agency is often forced to litigate the issue of jurisdiction since section 331 of the Act requires the “introduction into interstate commerce” of the product to trigger jurisdiction.¹⁶⁶ Therefore, administrative enforcement most often comes in the form of FDA warning letters, which are arguably largely ineffective.¹⁶⁷ Recalls are voluntary, and manufacturers are not required to report them, though the FDA requests to be notified.¹⁶⁸ Moreover, the FDA can recommend a recall to a manufacturer, which then has discretion as to whether to recall the product; if the product is not recalled, the FDA must commence the costly litigation to seize the product.¹⁶⁹ Also, it is interesting

160. 21 U.S.C. § 346a(b)(2)(A)(ii) (2006).

161. 21 U.S.C. § 346a(b)(2)(B)(iii)(II) (2006).

162. FORTIN, *supra* note 3, at 498.

163. *Id.*; *see also, e.g.*, Heckler v. Chaney, 470 U.S. 821 (1985) (holding that the FDA’s discretion in enforcement actions are not subject to judicial review); Nat’l Milk Producers Fed’n v. Harris, 653 F.2d 339 (8th Cir. 1981).

164. FORTIN, *supra* note 3, at 498

165. *Id.*

166. *Id.* at 499. This hurdle, however, is often overcome by use of a rebuttable presumption, codified in 21 U.S.C. § 379a, that all FDA-regulated products have moved in interstate commerce. *Id.* at 503.

167. *Id.* at 504–05.

168. *See* Iowa egg scare, *supra* notes 137, 140.

169. FORTIN, *supra* note 3, at 510–11. The few exceptions to the FDA’s lack of authority to order a recall do not apply to food, but do apply to infant formula *only* if it lacks the required

to note that the FDA voluntarily declines to inspect or regulate restaurant sanitation, which is delegated to state and local governments but does not fall under the umbrella category of federal food safety.¹⁷⁰

D. *Genetically Modified Food and European Tensions*

Primary responsibility for regulating genetic engineering of plants to promote resistance to insects, bacteria, and viruses lies with the Environmental Protection Agency. However, under its statutory authority to regulate “adulterated food,” or rather to ensure that the food supply remains “unadulterated,” the FDA established a policy on genetically modified food in 1992: In much the same way as conventional food is regulated, “FDA relies on companies developing GM foods to *voluntarily notify the agency before marketing the foods*.”¹⁷¹ Such notification triggers a two-part process at the end of which the company provides the FDA with an internally produced safety assessment. Pursuant to the information in that assessment, the agency then grants (or denies) the company permission to market the product.¹⁷² Genetically engineered food, or food products that contain genetically modified ingredients, are not required to be so labeled because the FDA “does not consider the methods used to develop [genetic modification] . . . to be ‘material’ within the meaning of ‘misleading’ in section 201(n) [of the] Food, Drug, and Cosmetic Act”; nor does the agency automatically require pre-market approval based on the sole fact of genetic modification.¹⁷³ The agency’s position is that genetically modified food does not differ in any significant or meaningful way from conventional food and does not present any different or substantial safety risks.¹⁷⁴ Through an approach called substantial equivalence, the FDA compares the attributes of new genetically modified products to those of conventional products; if they are “substantially equivalent,” they are treated in the same way. Critically, the FDA does not consider the actual process used to create the new product because it presumes that the process has no bearing on the

nutrients or is otherwise misbranded, but not necessarily if it is dangerous. *Id.* Other remedies, rarely invoked in the context of food, include debarment (a total prohibition from importing products) and import detentions. *Id.* at 511–12. Additionally, criminal prosecutions under strict liability can be filed. *Id.* at 524–25; *see also* United States v. Park, 421 U.S. 658 (1975) (holding the CEO of a supermarket chain responsible for causing food adulteration regardless of whether he had actual knowledge of the unsanitary conditions in the company’s warehouses). The Department of Justice may further indict violators under other provisions of title 18, such as willful misconduct. FORTIN, *supra* note 3, at 533–34.

170. FORTIN, *supra* note 3, at 503.

171. *Id.*

172. *Id.*

173. *Id.* at 415. However, labeling may be required if the genetic modification significantly changes what the consumer might expect the food to be. *See Hearing, supra* note 71.

174. FORTIN, *supra* note 3, at 416; *see also* GEN. ACCOUNTING OFFICE REPORT, *supra* note 72.

issue of safety.¹⁷⁵

[T]he available tests do not guarantee absolute safety of GM foods, but *comparable safety*. There is no assurance that even conventional foods are completely safe . . . Because they have been consumed for many years, though, conventional foods are used as the standard for comparison in assessing the safety of GM foods[.]¹⁷⁶

Some biotechnology experts argue that the agency's evaluation process has inherent flaws and could be improved. Importantly, the agency should independently verify the individual companies' test data regarding genetically modified products; additionally, the communication between the agency and the consuming public should be more open and clear.¹⁷⁷ The agency itself admits that the current regulatory scheme for genetically modified food allows for the possibility that material that has not been expressly regulated might "inadvertently enter the food supply" before the FDA can approve it.¹⁷⁸ Cross-pollination from field tests to commercial fields results in the presence of unregulated material in the food supply.¹⁷⁹ This means that the agency knows, or should know, of the dangers inherent in the current system and of the reasonable possibility that an untested, unregulated food product could make consumers sick. The possibility, of course, also exists that this same food product will *not* make consumers sick, but the important point to note is that neither the FDA, the food manufacturers, nor the consuming public knows which possibility will prevail. Allowing this loophole with full knowledge of the potential consequences is gambling with our health—practically by definition culpable negligence to which strict liability attaches.¹⁸⁰

In comparison, Europeans view genetically modified food with great caution.¹⁸¹ This attitude is largely derived from a history fraught with atrocities in the name of genetic science. As a result, the Green

175. FORTIN, *supra* note 3, at 416.

176. GEN. ACCOUNTING OFFICE REPORT, *supra* note 72.

177. *Id.*; see also Jørgen Schlundt, *Governance of Biotechnology: Emerging Regulation of GM Crops and Livestock in Global Food Industries and Food Systems*, in GLOBAL GOVERNANCE OF FOOD AND AGRICULTURE INDUSTRIES 359 (Reba A. Carruth ed., 2006).

178. FORTIN, *supra* note 3, at 422.

179. *Id.* at 423.

180. See discussion *supra* p. 203.

181. A comprehensive review of European attitudes toward food and the resulting regulatory schemes is beyond the scope of this comment; however, in the context of genetically modified food a brief discussion of the intersection between European and American food markets is useful. Furthermore, Japan has instituted a "zero tolerance" policy for genetically modified food products, which it deems to be "contaminants." R. Michael Roberts, *Genetically Modified Organisms for Agricultural Food Production: The Extent of the Art and the State of the Science*, in LABELING GENETICALLY MODIFIED FOOD: THE PHILOSOPHICAL AND LEGAL DEBATE 10, 14 (Paul Weirich ed., 2007).

Parties of Europe, working largely with Greenpeace International, have fought for a “better-safe-than-sorry” policy.¹⁸² Instead of viewing the lack of conclusive evidence, largely due to the lack of scientific study, of any adverse effects of genetic modification as proof that no such effects exist, European advocates champion the idea that it’s better to wait for such evidence before allowing products into the food supply. Since the United States has declined to follow Europe’s lead, the European Commission banned food imports containing genetically modified material unless they are so labeled.¹⁸³ To make matters worse, Europeans have largely lost trust in American food companies since the fatal outbreak of “mad cow disease” coincided perfectly with the beginning of genetically modified products being “slipped” into the American food supply as well as American food products exported to Europe. This “quick switch” method only served to heighten European fears about food safety, allowing deep-seated historical mistrust and fundamental cultural differences to resurface.¹⁸⁴

Genetically modified food symbolizes the clash between American and European cultures. It symbolizes European resistance to encroaching American cultural hegemony over the planet. But while Europeans can do little about American military might, or space exploration, or finance, they know what they like to bring into their kitchen. They know how they like to eat and where. They know they don’t want McCafés to replace the real ones, and they know they don’t want the American model of fast food to become the norm in Europe.¹⁸⁵

The final compromise—referred to as the precautionary principle—allows countries to ban imports of genetically modified food from the United States merely based on concerns of the *potential* dangers of the product.¹⁸⁶ This now leaves Americans alone in their tolerance of the traditional reactive system; since no evidence excluding the possibility of danger exists, genetically modified food remains in our food supply. Consider, however, that there was once a time when there was no “evidence” of contracting *E.coli* from eating a hamburger, but in hindsight it would be foolish to extrapolate from that lack of evidence that the possibility did not exist.

The American judiciary, the traditional forum for vindicating American rights when the executive and legislative branches have failed

182. PENCE, *supra* note 4, at 9.

183. *Id.*

184. *Id.* at 10. “Americans eat garbage food, they’re fat, and they don’t know how to eat properly.” *Id.* at 9 (internal citations omitted).

185. *Id.* at 24.

186. *Id.* at 22.

to do so, could arguably become a proving ground for opponents of genetic modification to highlight the failures of the current regulatory scheme. In theory, the federal judiciary has the power to shape regulatory policy and grant relief through remedies such as damages and injunctions.¹⁸⁷ Yet fundamental notions of separation of powers prohibit the judiciary from doing much more than what the statutory scheme currently in place allows it to do. Further, it cannot act at all unless presented with a ripe “case” or “controversy.”¹⁸⁸ Most importantly, in light of the comparative lack of litigation in proportion to food-related illness and death in the context of traditional food, coupled with the regulatory loopholes already in place, it is illogical to assume that the federal judiciary will be able to overcome these same inherent hurdles in the realm of genetically modified food.

IV. FOOD SAFETY LITIGATION

A. *Public Litigation*

Litigation due to failures of the American food safety regulation system is not as prevalent as might initially be expected.

[I]n the area of foodborne illness, the vast majority of injuries never reach trial. Foodborne pathogen determination requires expensive investigation and laboratory testing. The chance of finding the causative agent (and responsible party) is slight. Fewer than one in ten thousand foodborne illness cases are litigated and even fewer are paid compensation. For every million acute foodborne illnesses, approximately [ten] to [forty-five] torts ensue. Put another way, out of 76 million serious foodborne illness cases annually in the United States, roughly 75,996,000 victims lack recourse to tort remedies.¹⁸⁹

Much of the litigation that does occur involves condemnation proceedings pursuant to the authority of the FDA, in concert with the Department of Justice, under the FD&C Act. Seizures, authorized in section 334 of the FD&C Act,¹⁹⁰ require fewer resources than injunctions and criminal prosecutions and can often be effectuated fairly quickly. However, it still requires that the FDA district recommend a seizure action to FDA headquarters, where the recommendation goes through multiple levels of review before final legal review by the Office of General Counsel. If the recommendation passes review, it is then transmitted back to the FDA district, which then must seek Department of Justice approval

187. Blake Denton, *Regulating the Regulators: The Increased Role for the Federal Judiciary in Monitoring the Debate over Genetically Modified Crops*, 25 UCLA J. ENVTL. L. & POL'Y 333, 369 (2007).

188. U.S. CONST. art. III, § 2.

189. FORTIN, *supra* note 3, at 606.

190. 21 U.S.C. § 334 (2006).

pursuant to which the U.S. Attorney files a complaint on behalf of the agency.¹⁹¹ Seizure and condemnation proceedings, still generally restricted to only the most flagrant of violations despite their relative “ease,” do not proceed in tort and do not end with damages judgments. Instead, defendants found guilty of violating the Act usually face recalls and condemnation of the product, or in very severe cases refusal to provide inspection services for producers found to be unfit to be in business, though this usually requires a finding of multiple violations.¹⁹² In such proceedings, the government bears the burden of proof of adulteration, subject to the language loopholes inherent in the statutory scheme discussed above.¹⁹³ However, food manufacturers, and the chief corporate officer if named individually, have the ability to assert affirmative defenses in such suits—for example, that he or she was powerless to prevent the violation of which the company is accused.¹⁹⁴ The defense seems grounded in, and indeed approved by, the statutory language of inevitable contamination. For example, a defendant charged with adulteration is able to argue that he exercised “extraordinary care” and yet still could not prevent violations of the Act; such a defense would then place an additional burden on the government to overcome evidence of extraordinary care beyond a reasonable doubt.¹⁹⁵

Food sold by restaurants is governed almost entirely outside the realm of the FD&C Act, regulated instead by the implied warranty of merchantability of the Uniform Commercial Code.¹⁹⁶ Essentially, because the serving of food is a sale, a warranty that the food is wholesome and fit for consumption attaches;¹⁹⁷ the test for whether food is fit for consumption includes not only freedom from foreign or deleterious substances, but also freedom from any substance not reasonably to be expected by the consumer in the food served.¹⁹⁸ Accordingly, restaurant patrons who find spiders in their soup or get sick after eating spoiled food may sue under breach of warranty following Uniform Commercial Code standards, but have no recourse under food safety regulation.¹⁹⁹

191. FORTIN, *supra* note 3, at 514.

192. 21 U.S.C. § 671 (2006).

193. 35A AM. JUR. 2D *Food* § 72 (2010).

194. *Id.*

195. *United States v. New Eng. Grocers Supply Co.*, 488 F. Supp. 230 (D. Mass. 1980).

196. U.C.C. § 2-314 (2003).

197. *See, e.g.,* *Wachtel v. Rosol*, 271 A.2d 84 (Conn. 1970); *Hochberg v. O'Donnell's Rest., Inc.*, 272 A.2d 846 (D.C. 1971); *Ray v. Deas*, 144 S.E.2d 468 (Ga. Ct. App. 1965); *Koster v. Scotch Assocs.*, 640 A.2d 1225 (N.J. Super. Ct. Law Div. 1993); *Levy v. Paul*, 147 S.E.2d 722 (Va. 1966).

198. *See, e.g.,* *Hochberg*, 272 A.2d at 848-49.

199. *Compare* 63 AM. JUR. 2D *Products Liability* § 716 (2009) (discussing *Wernick v. Bob Ware's Food Shops, Inc.*, 27 Mass. App. Dec. 19 (finding breach of warranty by the presence of a date pit in a muffin)) *with* *Webster v. Blue Ship Tea Room, Inc.*, 198 N.E.2d 309 (Mass. 1964)

B. *Private Litigation*

Private suits brought against food providers or manufacturers generally claim negligence in the contexts of a breach of duty of care, not dissimilar from products liability tort litigation, strict liability, and breach of warranty.

Products liability theories provide three main causes of action in which liability might apply to a manufacturer or distributor of an FDA-regulated product plus a fourth related theory of liability: (1) strict liability, (2) breach of implied warranty, (3) negligence, and (4) misrepresentation or nondisclosure. . . . Misrepresentation or nondisclosure causes of action may arise with FDA-regulated products either from the premise that the manufacturer concealed material information from the FDA during the agency's review, or from allegation of misrepresentation or nondisclosure to the consumer. Of these causes of action, strict liability and breach of implied warranty are the primary theories of recovery.²⁰⁰

Courts are fairly divided as to what may constitute *prima facie* evidence of negligence in such cases: Georgia, Iowa, Louisiana, New York, and New Jersey have found that illness or injury following ingestion establishes a *prima facie* case,²⁰¹ while Alabama, Colorado, Illinois, Massachusetts, Mississippi, North Carolina, Tennessee, and Washington have not.²⁰² Interestingly, California courts have found both ways.²⁰³ Logically, however, the burden of proof shifts to the defendant wherever the same asserts an affirmative defense, such as tampering.²⁰⁴ In the current absence of effective regulation, "private . . . litigation can influence food policy, leading to changes in the conduct of food manufacturers . . ." ²⁰⁵

(finding no breach of warranty by the presence of fish bones in New England fish chowder that became lodged in plaintiff's throat); *see also* U.C.C. § 2-314 (2001).

200. FORTIN, *supra* note 3, at 607.

201. *See* H.J. Heinz Co. v. Fortson, 8 S.E.2d 443 (Ga. Ct. App. 1940); Davis v. Van Camp Packing Co., 176 N.W. 382 (Iowa 1920); Doyle v. Fuerst & Kraemer, Ltd., 56 So. 906 (La. 1911); Wilson v. Coca-Cola Bottling Co., 65 A.2d 630 (N.J. Super. Ct. App. Div. 1949); Rosenbusch v. Ambrosia Milk Corp., 168 N.Y.S. 505 (App. Div. 1917).

202. *See* McCarley v. Wood Drugs, Inc., 153 So. 446 (Ala. 1934); China Doll Rest., Inc. v. MacDonald, 180 A.2d 503 (D.C. 1962); Warren v. Coca-Cola Bottling Co., 519 N.E.2d 1197 (Ill. App. Ct. 1988); Crocker v. Balt. Dairy Lunch Co., 100 N.E. 1078 (Mass. 1913); Goodwin v. Misticos, 42 So. 2d 397 (Miss. 1949) (en banc); Lamb v. Boyles, 135 S.E. 464 (N.C. 1926); Bell v. Bowers Stores, Inc., 3 Tenn. App. 590 (Ct. App. 1926); Geisness v. Scow Bay Packing Co., 132 P.2d 740 (Wash. 1942).

203. *Compare* Reese v. Smith, 70 P.2d 933 (Cal. 1937) (finding evidence insufficient to establish *prima facie* case of negligence where plaintiff was diagnosed with botulism after eating pork sausage found to contain maggots) with Dougherty v. Lee, 168 P.2d 54 (Cal. Ct. App. 1946) (finding evidence sufficient to establish *prima facie* case of negligence where plaintiff's cows had no access to food but defendant's hay and died within twenty-four hours after eating it).

204. *See, e.g.,* Wallace v. Coca-Cola Bottling Plants, Inc., 269 A.2d 117 (Me. 1970).

205. Rothenberg, *supra* note 45, at 186. At least one lawsuit has already been filed in connection with the salmonella outbreak leading to a massive egg recall by producers in Iowa.

1. IMPLIED WARRANTY

One theory under which plaintiffs may bring food safety claims is implied warranty. The Uniform Commercial Code provides three alternatives for states to choose from in determining who may benefit from such a warranty.²⁰⁶ The first alternative protects anyone pertaining to the family or household of the buyer or any guest in the home of the buyer provided that it is reasonable to expect that such person would use, consume, or be affected by the product in question.²⁰⁷ The second and third alternatives protect anyone at all who “may reasonably be expected to use, consume, or be affected by the goods and who is injured by breach of the warranty.”²⁰⁸ The sole difference between the two latter alternatives is in the omission of the word “natural” to qualify “person” in the third alternative; consequently the third alternative provides that, “a seller may not exclude or limit the operation of this section with respect to injury to the person of an individual to whom the warranty extends.”²⁰⁹ For purposes of food safety litigation, therefore, an express or implied warranty regarding the safety or wholesomeness of a food product extends beyond the immediate buyer that enters into a contract with the seller, depending on a particular state’s choice of statutory alternative.²¹⁰

The concept of an implied warranty on the part of a food producer or seller is not a new one. In the early 1900s, courts recognized that the common law implies a warranty of wholesomeness on a retail sale of food.²¹¹ This rule of implied warranty “has its ethical basis in the reasonable presumption that the vendor, if a regular retail dealer, and *especially if he be also the manufacturer*, has the better means of knowledge of the character of the food which he offers for sale.”²¹² The Supreme Court of Washington held that public policy demanded a finding of breach of implied warranty in a case where the plaintiff purchased dried beef prepared and sold by the defendant and soon after became violently ill, suffering permanent damage to his digestive system.²¹³ This demand is due to the fact that “the consequences resulting from the purchase of an unsound article may be so serious and may prove so disastrous to the

See *Wright County Egg Recall: Lawyer for Salmonella Investigation and Lawsuit*, PRITZKER OLSEN, P.A., <http://www.pritzkerlaw.com/salmonella/wright-county-egg-salmonella.html> (last visited Jan. 2, 2011).

206. U.C.C. § 2-318 (2008).

207. *Id.*

208. *Id.*

209. *Id.*

210. See also U.C.C. §§ 2-313A(1) to B(1) (2003).

211. *Flessner v. Carstens Packing Co.*, 160 P. 14, 16 (Wash. 1916).

212. *Id.* at 17 (emphasis added).

213. *Id.* at 14–15.

health and life of the consumer.”²¹⁴ Similarly, Iowa courts have found that privity of contract is not a necessary condition to finding a canned food manufacturer in breach of implied warranty of wholesomeness.²¹⁵ Significantly, however, the Iowa Supreme Court found no express warranty where a can of pork and beans had a label stating that the meat had been federally inspected and was sanitary.²¹⁶ Nevertheless, the plaintiff, who had suffered ptomaine poisoning, was granted a new trial because the proof of injury was sufficient to allow a jury to decide whether the manufacturer had breached the implied warranty of wholesomeness.²¹⁷ Not only does such an implied warranty extend to the “immediate buyer,”²¹⁸ such as a grocer, but also extends to the “ultimate consumer” who purchases the product from the grocer.²¹⁹ One Ohio court found a bakery company in breach of implied warranty after a consumer purchased a cake from a retail grocer and was injured as a result of a needle he ingested while eating it.²²⁰ Interestingly, the court also recognized that the mental suffering of the plaintiff could properly be considered by the jury in determining damages.²²¹

In contrast, a North Carolina court found no liability under breach of implied warranty where the plaintiff did not purchase the defective soft drink in question directly from the bottler, but from a lunch room.²²² Even though the court recognized that manufacturers of food—and bottlers of beverages—have a high duty of care to the consumer and impliedly warrant that their products are fit for human consumption, it declined to find such a warranty beyond the parties to the contract for sale.²²³ Furthermore, a Louisiana court declined to impose liability on a seller where no evidence was presented to show that the product defect was known or should have been known²²⁴—juxtaposing negligence analysis onto an action for breach of implied warranty. That court effectively foreclosed any claim under a theory of implied warranty and placed the burden on the plaintiff to prove that the food was deleterious

214. *Id.* at 17.

215. *Davis v. Van Camp Packing Co.*, 176 N.W. 382 (Iowa 1920).

216. *Id.* at 387.

217. *Id.* at 392.

218. *See* U.C.C. § 2-318 (2008).

219. *Ward Baking Co. v. Trizzino*, 161 N.E. 557, 559 (Ohio Ct. App. 1928). This theory seems to foreshadow the later statutorily enacted alternatives regarding the scope of implied warranty. *See* U.C.C. § 2-318 (2008).

220. *Trizzino*, 161 N.E. at 558.

221. *Id.* at 560.

222. *Terry v. Double Cola Bottling Co., Inc.*, 138 S.E.2d 753, 754 (N.C. 1964) (action for injuries due to the presence of a green fly in a soft drink).

223. *Id.* at 753.

224. *McCauley v. Manda Bros. Provisions Co., Inc.*, 202 So. 2d 492, 497 (La. Ct. App. 1967).

and that his illness resulted therefrom;²²⁵ the plaintiff had suffered an acute attack of gastroenteritis approximately two hours after consuming a hot sausage sandwich.²²⁶ Significantly, under the court's analysis liability would not be foreclosed under a theory of negligence, nor would the plaintiff be unable to bring a warranty claim against the manufacturer of the sandwich.

2. STRICT LIABILITY

A *prima facie* case of strict liability can be established by proof that the defendant was engaged in the business of selling the offending product, the product consumed was defective *and* "unreasonably" dangerous, the defective and dangerous nature of the product was already present when it left the defendant's control, and consumption of the product caused the plaintiff physical harm.²²⁷ No contractual relationship need be proved, nor does the plaintiff have to establish that the defendant failed to exercise *all* possible care.²²⁸ What, exactly, constitutes an "unreasonable" amount of danger? This implies once again that there is a level of danger inherent in defective food that is generally acceptable and not subject to tort liability. "Unreasonably dangerous" can be construed to mean "dangerous to an extent beyond that which would be contemplated by the ordinary consumer"²²⁹ Assumption of risk is a viable defense to strict liability in this context,²³⁰ allowing producers to wiggle out of claims by, for example, labeling their product with information such as *trans* fat content or risk of foreign objects or substances (like olive pits).²³¹ Indeed, since much of this labeling is statutorily mandated, isn't our regulatory scheme virtually giving producers an implicit way out of liability?

In the strict liability context, food litigation can be successfully analogized to other forms of products liability litigation. Despite the fact that food is explicitly excluded from the Consumer Product Safety Act,²³² there is increasing recognition of liability in that context. The

225. *Id.* at 495-96. It was significant for the court that the product had been prepackaged but not sealed. *Id.* at 494.

226. *Id.* at 493.

227. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

228. *Cause of Action for Physical Harm Caused by Eating or Drinking Dangerous or Contaminated Food or Beverage*, 4 CAUSES OF ACTION 787 (2010).

229. RESTATEMENT (SECOND) OF TORTS § 402A cmt. i (1965); *see also* *Matthews v. Campbell Soup Co.*, 380 F. Supp. 1061, 1065 (S.D. Tex. 1974).

230. FORTIN, *supra* note 3, at 607.

231. *See, e.g.*, *Kolarik v. Cory Int'l Corp.*, 721 N.W.2d 159 (Iowa 2006) (holding that use of the words "minced pimento stuffed" on jar label could not be construed as express warranty that olives had been pitted).

232. 15 U.S.C. § 2052(a)(5)(I) (2006); *see also* *Abernathy v. Schenly Indus., Inc.*, 420 F.Supp.

Third Restatement of Torts indicates:

One engaged in the business of selling or otherwise distributing food products who sells or distributes a food product that is defective . . . is subject to liability for harm to persons or property caused by the defect. . . . [A] harm-causing ingredient of the food product constitutes a defect *if a reasonable consumer would not expect the food product to contain that ingredient*.²³³

This view, though contrary to the broad Consumer Product Safety Act, explicitly recognizes that liability for harm caused by defects in food products can and should be determined under the same rules as non-food products.²³⁴ Liability for breaches of food safety under a products liability analysis does contain an inherent problem—unlike other types of “products,” food products “do not have specific product designs that may be used as a basis for determining whether the offending product ingredient constitutes a departure from design” to which liability may attach.²³⁵ Most relevant to analyzing food safety problems under the FD&C Act, a product’s noncompliance with a product safety statute renders the product “defective” for purposes of products liability claims,²³⁶ but a product’s compliance with the same type of statute or administrative regulation “is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation”²³⁷ Therefore, a presumption is created that allows food producers to escape liability through one of the many loopholes inherent in the current statutory scheme.²³⁸ In essence, “[w]hen a court concludes that the defendant is not liable by reason of having complied with a safety design or warnings statute or regulation, it is deciding that the product in question is not defective as a matter of the law of that state.”²³⁹ Courts, not surprisingly, are divided on how much weight compliance with a relevant statute should be given.²⁴⁰ Significantly,

1 (W.D.N.C. 1976) (precluding a suit for wrongful death from acute ethanol poisoning because alcoholic beverage is “food” within the meaning of the Consumer Product Safety Act).

233. RESTATEMENT (THIRD) TORTS: PRODS. LIAB. § 7 (1998) (emphasis added).

234. *Id.* cmt. a.

235. *Id.* cmt. b.

236. *Id.* § 4(a).

237. *Id.* § 4(b). However, such compliance does not preclude the finding of a product defect. *Id.*

238. See discussion *supra* pp. 215–16, 220–26.

239. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 4 cmt. e (1998) (“Thus, most product safety statutes or regulations establish a floor of safety below which product sellers fall only at their peril, but they leave open the question of whether a higher standard of product safety should be applied.”).

240. See, e.g., *Miller v. Lee Apparel Co., Inc.* 881 P.2d 576 (Kan. App. 1994) (finding a presumption of nondefectiveness in the event of compliance with safety regulations); *Sim v. Washex Mach. Corp.*, 932 S.W.2d 559 (Tex. App. 1995) (holding that compliance with government regulations is “strong evidence” of a lack of defect); *Lubbock Mfg. Co. v. Perez*, 591

such analysis has not been undertaken in the specific context of food safety. However, the attention given to similar analysis—governed by the *same statute*—is significantly greater in the context of drug safety.²⁴¹

It is illustrative to examine traditional products liability cases to see the analogy to food safety. Generally, a plaintiff claiming strict products liability must prove that the product was unsafe for its “intended user.”²⁴² “A product will be deemed defective only if it left the supplier’s control lacking any element necessary to make it safe for its *intended use* or possessing any feature that renders it unsafe for the *intended use*.”²⁴³ Most importantly, the privity-of-contract analysis sometimes used in implied warranty cases, as well as the foreseeability and reasonableness concepts of negligence, have no place in a products liability case based on strict liability.²⁴⁴ The Pennsylvania Supreme Court, in *Phillips v. Cricket Lighters*, ultimately declined to find strict liability against a manufacturer and distributors of disposable butane cigarette lighters based on a design defect; although the lighters did not have any sort of child-resistant features, the court held that the two-year-old child who had started a fire with the lighter was not an intended user of the product.²⁴⁵ The court did, however, find that under a theory of negligence summary judgment was precluded because an issue of fact remained as to whether the manufacturer owed a duty of care to equip the lighters with child-resistant features.²⁴⁶ This would seem paradoxical since such a duty analysis essentially would require the jury to determine whether use by a two-year-old child is reasonably foreseeable, which in essence becomes an analysis of whether a two-year-old child *might* be an intended user (despite the fact that the manufacturer may not actively *intend* for the child to use the lighter). The court emphasized, however, the need to keep strict liability and negligence concepts separate when determining liability, stating that “[s]trict liability focuses solely on the product, and is divorced from the conduct of the manufacturer.”²⁴⁷ The fact that the court’s refusal to extend liability turned on

S.W.2d 907, 914 (Tex. Civ. App. 1979) (finding that a pre-approved package insert warning did not relieve the drug company of its obligation to properly warn consumers); Wash. State Physicians Ins. Exch. & Assoc. v. Fisons Corp., 858 P.2d 1054, 1069 (Wash. 1993) (finding that evidence of compliance with FDA regulations does not automatically relieve a drug manufacturer of liability).

241. See, e.g., RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (1998).

242. *Phillips v. Cricket Lighters*, 841 A.2d 1000, 1005 (Pa. 2003).

243. *Id.* (internal quotations omitted); see also text *supra* p. 220 (discussing FD&C Act “intended use” analysis).

244. *Phillips*, 841 A.2d at 1005–06.

245. *Id.* at 1007–08.

246. *Id.* at 1009–10.

247. *Id.* at 1007.

whether a two-year-old child can be properly considered an intended user of a butane lighter is significant to the analysis of food safety litigation. Where can a court draw the line between which consumers are “intended users” of certain food products and which are not? This once again brings attention to a statutory flaw—the FD&C Act grants the FDA authority to work with food producers to set tolerances of, essentially, product defects. Yet the human body tolerance of poisonous and deleterious substances varies by age, weight, and gender. Every consumer must be considered an “intended user” of food. This presents one of the strongest arguments for continuing to extend the requisite duty of care of food producers to the highest level—if a food producers’ “intended user” is essentially every American citizen, the standard to which they are held must be significantly higher than traditional product manufacturers.

Recent cases have emphasized that the policy rationale behind imposing such strict liability on manufacturers of “defective products” is that “where a manufacturer places a defective and unreasonably dangerous product into the stream of commerce, the manufacturer, not the injured consumer, should bear the costs of the risks posed by the product.”²⁴⁸ Since foreseeability of risk plays no part in the analysis, a manufacturer can be found liable regardless of whether there was any knowledge, or possibility of knowledge, of the risk of harm its product presented to consumers.²⁴⁹ The plaintiff, therefore, need only prove that the product was defective and unreasonably dangerous.²⁵⁰ Significantly, recent court decisions have focused on the Second Restatement of Torts’ consumer-contemplation test for determining whether a product is unreasonably dangerous, holding that a product can be found defective and unreasonably dangerous *solely* based on consumer expectations of the product.²⁵¹ This standard is entirely consumer-centric, defining “defect” as a condition not contemplated by the ultimate consumer and “unreasonably dangerous” as dangerous to an extent beyond that which would be contemplated by the ordinary consumer.²⁵² The Supreme Court of Wisconsin explained in *Green v. Smith & Nephew AHP, Inc.*:

This does not mean, however, that to prevail on a strict products liability claim, an injured consumer must prove that the product at issue is potentially dangerous to every consumer. Because product defects

248. *Green v. Smith & Nephew AHP, Inc.*, 629 N.W.2d 727, 752 (Wis. 2001).

249. *Id.* at 750–51.

250. *Id.* at 752.

251. *Id.* at 741–42. The court explicitly found the consumer-contemplation test to be appropriate in cases involving complex products. *Id.* at 742. The way in which our food is produced can only be described as complex. See discussion *supra* pp. 206–08.

252. *Id.* at 752–53.

vary, the magnitude of danger necessary to render a product dangerous to an extent beyond that which would be contemplated by the ordinary consumer—i.e., unreasonably dangerous—must be evaluated on a case-by-case basis.²⁵³

The *Green* court rejected the older “danger-utility” test approach, which found a product to be defective as designed “if, but only if, the magnitude of the danger outweighs the utility of the product.”²⁵⁴

The court found the manufacturer of latex gloves strictly liable for injuries resulting from an allergic reaction exclusively on the grounds that the gloves were unreasonably dangerous because the ordinary consumer would not be aware that they could cause an allergic reaction in five to seventeen percent of consumers.²⁵⁵ The gloves in question had harmful proteins that naturally occur in the latex, but the manufacturer could have significantly reduced the protein levels by changing the manufacturing process.²⁵⁶ In the *Green* case, the allergic reaction disproportionately affected members of the plaintiff’s profession,²⁵⁷ whereas food safety breakdowns affect every single consumer. Significantly, “[i]f the average consumer would reasonably anticipate the dangerous condition of the product and fully appreciate the attendant risk of injury, it would not be unreasonably dangerous and defective.”²⁵⁸ No reasonable consumer would wear latex gloves that he or she knew would lead to a severe allergic reaction; no reasonable consumer would eat food that he or she knew would make them sick or obese. Because we rely exclusively on food producers and retail grocers for our food supply, a higher duty of care attaches and we cannot “fully appreciate the attendant risks” involved; consumers have a reasonable expectation that their food will not make them sick, either in the long term or short term, making a virtually iron-clad case for imposing strict liability on food producers who place deleterious products into the stream of commerce.

3. NEGLIGENCE

Negligence, as opposed to strict liability, is used less often because it requires a higher burden of proof—duty of care and foreseeability. In fact, factors that may be considered favorable to proving that reasonable care *was* exercised include current industry standards, current state of the technology and knowledge, and *compliance with government regula-*

253. *Id.* at 754. This seems to be a workable standard in light of the inherent differences between each human body. *See* discussion *supra* p. 236.

254. *Id.* at 740 (internal citations omitted).

255. *Id.* at 754–55.

256. *Id.* at 732–33.

257. *Id.* at 733.

258. *Id.* at 739 (internal quotations omitted).

tions.²⁵⁹ In other words, we have created a regulatory catch-22: The regulations by which producers must abide are rife with ambiguities and loopholes, yet as long as they can prove they did not run afoul of those regulations, courts won't find them negligent. If "everyone else is doing it," so, too, can producers. We have a regulatory scheme in place that admittedly allows violations to fall through the cracks, yet the judiciary does not provide a remedy to consumers in the form of a more secure safety net for damages.

Despite this loophole, under the standard framework of negligence food producers *should* routinely be found liable. We, as consumers, have no choice but to purchase our food through a food retailer, which in turn has no choice but to do business with food producers; gone is the era of family farms and self-sufficiency. In an ironic sense, food producers have a veritable monopoly on the food we eat—as "the only game in town," producers have an inherent duty of care to consumers. Historically, this duty has been well recognized by courts in the context of food safety but is notably absent from modern jurisprudence. As early as the beginning of the twentieth century, the Supreme Court of Washington recognized that in the context of food the duty-of-care standard is much higher than in the context of other products because even slight negligence can result in "fearful consequences."²⁶⁰ In the context of canned food, courts have held that producers must "exercise the highest degree of care to see that such food is wholesome."²⁶¹ Ohio courts have framed such a high duty of care as a demand of public policy.²⁶² Courts in Massachusetts have recognized the serious and extreme consequences to human life that are likely to result from food producers' negligence.²⁶³ The Supreme Court of Tennessee has gone so far as to hold all producers of food products to "the *highest* degree of care," citing public interest as the driving force behind such a policy.²⁶⁴

Foreseeability likewise should not be a barrier to consumer vindication, though it has been more difficult to prove in the context of food.

259. FORTIN, *supra* note 3, at 609.

260. Flessner v. Carstens Packing Co., 160 P. 14, 16 (Wash. 1916) (finding liability in an action for damages as a result of eating diseased dried beef).

261. Davis v. Van Camp Packing Co., 176 N.W. 382, 387 (Iowa 1920) (finding proof of injury as prima facie case of negligence where plaintiff had no knowledge of the degree of care used).

262. Ward Baking Co. v. Trizzino 161 N.E. 557, 560 (Ohio Ct. App. 1928) ("Considerations of public policy demand that the utmost care and caution be exacted from the manufacturer of articles of food . . .").

263. Flynn v. First Nat'l Stores, Inc., 6 N.E.2d 814, 815 (Mass. 1937) (action for negligence as a result of selling a pound of "hamburg steak" containing small pieces of wire).

264. Jones v. Mercer Pie Co., 214 S.W.2d 46, 49 (Tenn. 1948) (emphasis added) (finding liability against a bakery for sale of pie contaminated due to unsanitary conditions where pies were purchased from a retailer, not from the bakery).

"[S]cienter is *presumed* as a matter of law, especially where . . . the vendor for immediate consumption is not only the dealer, but also the manufacturer."²⁶⁵ In a case where a frankfurter containing a particle of wire was in the exclusive control of the manufacturer before being purchased by the consumer, the manufacturer was held liable under a theory of negligence without the necessity of showing any "particular dereliction of the manufacturer."²⁶⁶ In an analogous way, although modern food passes through a complex chain of commerce, much of it is sealed by the manufacturer and any bacterial contamination or other deleterious condition can be attributed to the producer. Pennsylvania courts have recognized that manufacturers are liable "due to that uncertain human quality—carelessness somewhere along the line," even where the most up-to-date methods are used to eliminate injurious substances in our food.²⁶⁷ Similarly, a Massachusetts court found an inference of negligence where a "hamburg steak" sold to the plaintiff contained small pieces of wire, and evidence suggested that the wire did not get into the steak after leaving the store.²⁶⁸ One Tennessee court held:

There must be more than a mere probability that the defendant was negligent. But the plaintiff is not bound to exclude the possibility that the accident might have happened from some other cause than that alleged. . . . The facts must tend to exclude any other cause, but the inference of exclusion of any other cause than that alleged need not be urged beyond mere doubt²⁶⁹

Historically, courts have relied on a "foreign-natural" test to determine negligence, drawing a distinction between the "foreign" and "natural" characteristics of a food product.²⁷⁰ "[I]f an object or substance in a food product is natural to any of the ingredients of the product, there is no liability for injuries caused"²⁷¹ Not unlike the *Green* case, recent cases have rejected this test because the distinction cannot be determinative of what is harmful for human consumption.²⁷² By utilizing a reasonable expectation test, the Minnesota Supreme Court in *Schafer v. JLC Food Systems, Inc.* addressed the issue of foreseeability: "The defendant has the duty of ordinary care to eliminate or remove in the preparation of the food served such harmful substance as the consumer of the food, as

265. *Flessner*, 160 P. at 17.

266. *Newcomb v. Armour*, 39 F. Supp. 716, 720 (M.D. Pa. 1941).

267. *Id.*

268. *Flynn*, 6 N.E.2d at 814.

269. *Jones*, 214 S.W.2d at 49 (quotation marks omitted) (finding evidence sufficient for jury to conclude that evidence of unsanitary conditions at bakery proved negligence where two consumers were made ill by contaminated pies).

270. *Schafer v. JLC Food Sys., Inc.*, 695 N.W.2d 570, 574 (Minn. 2005).

271. *Id.*

272. *Id.*

served, would not ordinarily anticipate and guard against.”²⁷³ The *Schafer* court found that a prima facie case of negligence had been made where a restaurant customer sued after injuring her throat by eating a defective pumpkin muffin.²⁷⁴ Significantly, the court found that circumstantial evidence of the harmful substance was sufficient to preclude summary judgment; it was impossible to identify with complete certainty the exact nature of the harmful substance in the muffin, yet the question presented was one for a jury to decide.²⁷⁵

Negligence per se, rarely invoked in food safety litigation, allows plaintiffs to assert liability merely for violation of a statute, arguing that such violation constitutes the requisite breach of care.²⁷⁶ Some states do not apply negligence per se, and the states that do often do not apply it uniformly: “The guiding principle in determining the applicability of the doctrine of negligence per se is whether its application is necessary to effectuate the legislative purpose.”²⁷⁷ Fortin explains:

In some states, violation of a statute is merely a rebuttable presumption of negligence, and violation of a regulation is merely evidence of negligence. When violation of a statute designed for the protection of human life or property does not constitute negligence per se but is only prima facie evidence of negligence, the presumption may be rebutted by proof that the defendant acted reasonably under the circumstances, despite the violation.²⁷⁸

Though the application of negligence per se seems obvious in the context of a consumer suit against a producer, the “rebuttable presumption” has also been used in suits between producers.

Jurisdictions not willing to find a prima facie case upon mere proof of injury find important policy implications in doing so, since it would inherently make the seller of food an insurer of its product.²⁷⁹ The mere phrase “insurer of its product” seems to suffice for these courts, without further explanation of why such insurance is undesirable for society. A flood of litigation or the risk of a highly publicized media war seems unlikely:

It is important to understand that the U.S. legal system is designed to toss frivolous lawsuits long before they reach trial. In addition the system allows judges to reduce excessive verdicts. In the [McDonald’s] hot coffee case, for example, the judge reduced the \$2.9 mil-

273. *Id.* at 575 (“The majority of jurisdictions that have dealt with the defective food products issue have adopted some formulation of the reasonable expectation test.”).

274. *Id.* at 572.

275. *Id.* at 577–78.

276. FORTIN, *supra* note 3, at 621.

277. *Id.*

278. *Id.* at 625.

279. *See, e.g., Goodwin v. Misticos*, 42 So. 2d 397, 399 (Miss. 1949) (en banc).

lion verdict by two-thirds to \$640,000, and the parties reportedly settled out of court for less than \$600,000.²⁸⁰

In essence, at least in those jurisdictions, the FD&C Act provides the floor below which no producer can go—you *shouldn't*, in theory, open a box of cereal and find a whole cockroach inside—and the courts provide the ceiling above which no producer need go. The message to the American consumer is clear: We statutorily accept that there will be violations that won't be prosecuted and that some contamination is inevitable, and we do not judicially require that producers insure their product for safety. From a policy standpoint, the right answer seems to be entirely to the contrary: Requiring such insurance would force food producers to be more internally vigilant about the quality of the food under their control (excluding some breach by grocery store negligence, for example) because the cost of potential litigation would be just too high. The producers' cost-benefit analysis would be inverted because in the event of a claim against them, the options would be limited to settlement or an uphill evidentiary battle. One possible way in which producers could perform better quality control as a result would be simply to have more employees performing inspections, creating jobs that require relatively no skilled training—an attractive incentive in today's hostile recession job market. In the long run, less litigation means that fewer potential plaintiffs are getting sick, proportionately decreasing soaring healthcare costs.

V. CONCLUSION

There can be no question that "food safety is an important regulatory responsibility"²⁸¹ that demands reform. Some believe that meaningful change cannot come without significant changes in government regulation.²⁸² In response to calls for reform, the FDA has continued to implement new regulatory structures, adding more confusion to the chaos of the existing scheme. The new Hazards Analysis and Critical Control Points ("HACCP") require producers to identify potential risks at all stages of food processing.²⁸³ Once the producer has self-identified a critical control point ("CCP"), it must establish a minimum value at

280. FORTIN, *supra* note 3, at 606. Of course, it is unclear why such a media war would be a bad consequence of litigation, particularly if the resulting pressure forces producers to put out a better quality product.

281. Cary Coglianese & David Lazer, *Management-Based Regulation: Prescribing Private Management to Achieve Public Goals*, 37 LAW & SOC'Y REV. 691, 696 (2003).

282. Rothenberg, *supra* note 45 (discussing the context of fighting the obesity epidemic).

283. *Hazards Analysis and Critical Control Point Principles and Application Guidelines*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/HACCPPrinciplesApplicationGuidelines/default.htm> (last updated June 18, 2009).

which the hazard can be controlled or eliminated.²⁸⁴ In keeping with the tradition of flawed self-regulation, producers need not get government pre-approval for their HACCP plans, and the FDA guidelines provide broad discretion to producers in managing their own food safety risks.²⁸⁵ Government inspectors rely on the records given them by the producers, who “have little reason *not* to falsify records, particularly in the absence of whistleblower protections or other incentives for someone knowledgeable to verify what went on in the production line.”²⁸⁶ Since remedying hazardous problems is often costly, if the inspectors are unlikely to find the problem themselves producers are reluctant to bring it to their attention.²⁸⁷ In fact, it is becoming clear that many food producers are still not in compliance with the HACCP rule.²⁸⁸ Government inspections to ensure compliance have only occurred in 1% of plants subject to inspection, and of that 1%, 94% had significant violations of the requirements and 89% had incomplete hazard analyses.²⁸⁹ One possible solution to the failure of the HACCP guidelines is third-party auditing. This has several potential advantages:

First, [it] may create incentives for the inspections themselves to be as efficient as possible. Second, if there are economies of scale in understanding the relevant management systems, third-party certifiers specializing in different types of facilities or processes may better capture those scale effects. Finally, third-party auditing can help offset or augment the limited resources of government regulators.²⁹⁰

One pair of authors has suggested that even voluntary auditing is a step in the right direction: Producers’ choice about whether to be audited sends a message about the risky nature of their product, allowing the agency to allocate inspection resources to the higher risk producers who choose not to be audited.²⁹¹

Consider now the various pieces of the puzzle: a flawed, chaotic regulatory scheme, whose constant patchwork amendments have not ensured compliance or safety; judicial remedies that are not often sought, and when they are, may fail due to statutory compliance; and a theory that third-party auditing of inspections—even if voluntary—may effect change. Third-party auditing would be just that—*audits* of the

284. *Id.*

285. Coglianese & Lazer, *supra* note 279, at 698. “The rules direct firms to choose for themselves what limits to set on the CCP and what internal procedures and technologies they deploy.” *Id.*

286. *Id.* at 721–22 (emphasis added) (internal citations omitted).

287. *Id.* at 722.

288. *Id.* at 722–23.

289. *Id.* at 723.

290. *Id.* at 718.

291. *Id.*

inspections the appropriate regulatory agency should be undertaking. Inherent in such a scheme would either be a lack of uniformity—because not every plant subject to inspection would necessarily be audited all the time—or merely another layer in the already complex failure of regulation. Moreover, it is unclear what remedies would be available against a producer who fails an audit. For that matter, would a producer have to fail multiple audits in order to trigger a remedy—and if so, how many? This additional layer of regulation, which would overlap with that already in place, would not ensure compliance but create more, albeit possibly smaller, cracks through which producers' transgressions might fall. Significantly, such third-party auditing may merely be an inspection for statutory compliance—and certainly any sort of self-risk analysis (such as that required by the HACCP) is destined to allow for degrees of failure.

An essential issue is once again highlighted: Food producers are proverbially getting away with murder.²⁹² There simply is no threat of punishment or bottom-line pain that exists for deterrence purposes. As one duo of authors posited in the case of obesity, under the status quo the courts provide the only solution.²⁹³ Food producers may be in the business of producing food, but quarterly profits drive their business models.²⁹⁴ In the face of regulatory failure, the only way for producers to “feel it” in their bottom line is to be haled into court to answer financially for their decisions and consequent actions. The framework has already been put in place: Courts have already recognized that food producers owe an even higher duty of care to consumers than other merchants—a duty of care that, arguably, could be assigned to the government when analyzing its flawed regulatory scheme. In any given case based on a failure of food safety, a producer can be found independently liable on three theories: implied warranty of merchantability, strict liability, and negligence. The essential nature of the product—food—demands the kind of harsh punishment strict liability imposes. Food that causes life-threatening obesity or illness is unreasonably dangerous in a way beyond that contemplated by traditional products liability; unlike a lighter, an automobile, or a microwave, food is a product that we cannot

292. To add insult to injury, in some states food producers have the right to sue anyone they allege has made disparaging statements or promulgated false information about the safety of their product. Michael E. Rosman, *Challenges to State Anti-Preference Laws and the Role of Federal Courts*, 18 WM. & MARY BILL RTS. J. 709, 762 (“Those who wish to comment about the safety of food products in those states are taking their chances that they could be sued in state court . . .”). However, the outcome of at least one high-profile case suggests that such a suit may not always be successful. See *Tex. Beef Group v. Winfrey*, 11 F. Supp. 2d 858 (N.D. Tex. 1998).

293. See discussion *supra* pp. 212–13.

294. See discussion *supra* p. 210.

live without.²⁹⁵ It can hardly be seriously argued that producers do not know, or should not know, of the potential dangers of their products—particularly in the context of obesity-inducing food and in the face of a statutory scheme that not only highlights dangers, but actually permits them. There is no difference between a frozen or fried meal that leads to diabetes or a lot of ground beef rife with *E.coli* and a hamburger with a piece of wire in it.²⁹⁶ The courtroom door, as the gateway to justice, cannot close; the foundation is laid and waits only for consumers to take action.

Real change, however, demands a significant rethinking about the way we approach food. A large number of food safety-related recalls and “whistle blows” about the relative safety of food products seem to come from the state of Minnesota.²⁹⁷ It is perhaps sheer coincidence that Minnesota is also home to the esteemed Mayo Clinic, the veritable gold standard for medical care facilities. Another possible impetus for these “whistle blows” is the implementation of a program called “Safe or Sorry,” a curriculum taught by the Minnesota Department of State in key locations throughout the state covering a range of topics, including food-borne illnesses, cross-contamination, and food irradiation.²⁹⁸ Furthermore, the state department has individualized divisions dedicated solely to a particular health topic and, most notably for the purposes of this comment, a specific office of food safety.²⁹⁹ Finally, the State of Minnesota has enacted a Food Code, establishing policies and procedures for food safety that are often more stringent than the federal guidelines.³⁰⁰ It would be unrealistic to ignore the obvious fact that state governments often have vastly more resources than the federal government to support these kinds of programs, but that doesn’t mean we can’t learn something from Minnesota. By highlighting the importance of food safety and, sig-

295. Two professors at Stanford Law School recently argued that the costs associated with products liability litigation outweigh its benefits, particularly since market forces are likely to produce similar or identical benefits. A. Mitchell Polinsky & Steven Shavell, *The Uneasy Case for Products Liability*, 123 HARV. L. REV. 1437 (2010). However, it is significant to note that their analysis did not extend to products of such magnitude of importance to human life as food and instead constrained their argument to traditional products—such as drugs and automobiles. See also discussion *infra* p. 246 (analyzing the inherently different nature of food from other types of products).

296. See *supra* notes 261, 266 and accompanying text.

297. See, e.g., Stephen J. Hedges, *Food Safety Lacks Teeth, Critics Say Recalls Underscore Gaps in Oversight*, CHI. TRIB., July 16, 2007, http://archives.chicagotribune.com/2007/jul/16/food/chi-recall_hedges_16jul16.

298. *What is Safe or Sorry (SOS)?*, MINN. DEP’T OF HEALTH, <http://www.health.state.mn.us/foodsafety/sos/basics.html> (last visited Jan. 2, 2011).

299. *Food Safety*, MINN. DEP’T OF HEALTH, <http://www.health.state.mn.us/foodsafety/index.html> (last visited Jan. 2, 2011).

300. MINN. R. 4626.0010–.1870 (2010).

nificantly, affording proportional funding to its health department to promote safe food practices, Minnesota sends a clear message to its citizens—public health is a fundamental part of a government's duty of care to its citizens, and as such the government is entrusted with the responsibility of regulating the safety of the food we eat.

While it may seem obvious at the conclusion of this comment that food producers can be found liable to consumers for less-than-pure products, such liability cannot be deemed obvious given the multitude of legal loopholes that are conveniently built in to the American food regulatory scheme. As the sole realistic providers from which Americans can get their food, producers must be deemed to owe a higher duty of care to us; if a particular cosmetic or appliance is harmful to consumers, they have the option of merely purchasing that product from a different manufacturer—a built-in remedy in the event a products liability suit fails. Food presents a wholly different scenario: Competition is virtually nonexistent.³⁰¹ The meat and produce available in the average supermarket is pre-selected for the consumer, and options outside of that selection are unobtainable for the vast majority of Americans. More importantly, the strict liability analysis this comment puts forth for food producers applies equally to the government. Once again, food safety is a one-man show: Consumers are powerless to “vote with their feet,” and as such are powerless to meaningfully voice their opinions about food safety issues. If that isn't enough to create a heightened duty of care to consumers, the American food safety statutory scheme is. The FD&C Act vests shared responsibility in the FDA and food producers themselves to keep consumers safe from the minefield of dangers present in the food supply. Americans are essentially on notice, in the same way patients in hospitals or citizens relying on the city police department are, that some entity other than they are responsible for food safety. Yet as is made clear in this comment, the regulatory scheme fails and allows food that makes us sick—but makes food producers' profits skyrocket—not only to enter the food supply, but to dominate it. The FDA's attitude toward genetically modified food does not differ in any material way from its attitude toward conventional food, despite the fundamental fact that genetic engineering essentially makes a science fair project out of our food—and virtually no data exists regarding the health consequences. However, sufficient evidence exists that the FDA has full knowledge of the potential dangers of the food products it regulates, but approves them anyway until such time as enough people get sick that consumers demand change. The demand must come now—we, as consumers, deserve food

301. See discussion *supra* pp. 206–07.

that doesn't kill us and a government that takes the kind of responsibility the State of Minnesota does for our health and safety.

