

Food Trade:
new challenges and new
standards—
European, American and
international perspective

United States Food Law: Consumers, controversies, current issues

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ABSTRACT

United States food law is in a state of change. This article offers an overview of issues and developments in United States food law in recent years. The author identifies trends that fit into broader historical currents in United States food law. These include the proliferation of qualified health claims on food, use of food law in dealing with the obesity epidemic, the past decade of American experimentation with food safety deregulation, and the growing American sense of the failure of their government to ensure food safety. The federal agencies have been found lacking in their ability to handle basic matters such as the honesty of food labels and the safety of fresh produce. This fundamental deficiency is more disturbing in light of the more complicated matters facing the agencies, such as nanotechnology and biotechnology. Systemic problems are behind many of these concerns. In particular, FDA's chronic funding shortages have forced the agency into a reactive mod. The federal agencies face gaps in scientific knowledge, and an eroded science base leads to poor decisions or lack of ability to devise appropriate solutions.

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I. INTRODUCTION

“The universe is change”
MARCUS AURELIUS (121–180)²

Our relationship with food, including food law, is woven into the fabric of our culture, history, and values. Food holds a special place in our lives and could brag to be the most important subject in the world.³ Pure food assumes an iconic quality. Food is our *pia mater*, our nourishing mother. Thus, food is often forefront of our cultural changes, and food is a mirror that reflects our culture and societal values. United States food law is in a state of change. One factor is rapid change in food science and technology. Another is an ascendant global marketplace. Add shifts in demographics and culture. Mix in escalating concerns over food safety, changing tastes, and growing interest in diet and health. All propel rapid change in the food regulation landscape.

This article offers an overview of issues and developments in United States food law in recent years. Not every issue or change is included. Rather the author identifies trends that fit into broader historical currents in United States food law.

Diet and health have been the subject of considerable attention in recent years. The American population is aging, and interest grows in consumers and marketers

² JOHN BARTLETT, FAMILIAR QUOTATIONS, attribution Meditations. iv. 3 (10th ed. 1919).

³ See, e.g., REAY TANNAHILL, FOOD IN HISTORY 371 (rev. ed. 1998).

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for foods with health claims. The United States Food and Drug Administration (FDA) abandoned its strict guard over false and misleading claims after a humiliating rebuke in *Pearson v. Shalala*.⁴ Subsequent proliferation of qualified health claims has resulted in consumer confusion.

At the same time, Americans are getting fatter. Food law is looked to as one dimension of the solution to this public health dilemma. Numerous regulatory approaches have been proposed. In the vacuum of federal inaction, state and local governments have begun to regulate with measures such as mandatory calorie labeling for fast food restaurant menus.

The past decade has been an American experiment with food safety deregulation. The Dietary Supplement and Health Education Act of 1994 (DSHEA) was a major statutory deregulation. In addition, gross underfunding of the FDA—starving the agency—created an overall deregulatory effect.

In the end, Americans have a growing sense of the failure of their government to ensure food safety. A series of foodborne disease outbreaks—melamine in pet food and then in human food, *E. coli* in spinach, lettuce, *Salmonella* recalls on tomatoes and peppers, and more—have left the public feeling vulnerable and intensified calls for reform of the food safety system.

As confidence drops in the ability of the government to ensure food safety or to even to control the accuracy of food labels, the confidence in the government's ability to safeguard the food supply regarding genetically engineered foods has come into question. Confidence was shaken by two recent events. Despite a massive investigation, the government was unable to trace a source of rice contamination by a genetically engineered (GE) variety. Next, the United States Department of Agriculture's (USDA) approval of commercial use of a variety of GE alfalfa was found in lacking in proper oversight and scrutiny. For the first time in the history of GE foods, a court permanently banned a GE variety's commercialization.

II. HISTORICAL BACKGROUND

Colonial era food regulation in the United States was nearly all a state and local activity. Federal activity was limited to imported foods. The first

⁴ *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

federal laws began to appear in the late 1800s and early 1900's. Like today, it was an era of rapid change. Advancements in chemistry and food science brought new food additives and colorings, and new means of adulteration. Food production began shifting from local to interstate, shifting from purchases of basic ingredients locally to purchases from food handlers and manufacturers at a distance.

This shift made it harder for consumers and local government to determine the safety and quality of the food. So a shift in regulation from state and local government to the national government began. However, this change in oversight and responsibility for ensuring the safety of foods did not happen in an orderly, planned manner. More often than not, major change in the food laws only occurred after a tragedy or major event precipitated the already growing public attention to a concern.

A. The 1906 Acts

In 1883, Dr. Harvey Wiley became the chief chemist of the U.S. Bureau of Chemistry (the predecessor of the U.S. Food and Drug Administration). Dr. Wiley expanded the testing of food and documented the widespread adulteration.⁵ He spurred public indignation by his publications and by dramatically focusing attention on chemical preservatives as adulterants with his "Poison Squad." The Poison Squad consisted of live volunteers who consumed questionable food additives, such as boric acid and formaldehyde. Observation and documentation of the ill effects on the volunteers, although a crude gauge of food additive safety, galvanized public attention.⁶

At the same time, muckraking journalists exposed in shocking detail the dangers of the food industry, such as the use of poisonous preservatives and dyes in food. A final catalyst was the 1905 publication of Upton Sinclair's *The Jungle*. Sinclair's portrayal of nauseating practices and unsanitary conditions in the meat-packing industry precipitated the concerns. On June 30, 1906, President Theodore Roosevelt signed both the Pure Food and Drug Act⁷ and the Meat Inspection Act⁸ into law.⁹

⁵ FDA, FDA BACKGROUNDER: MILESTONES IN U.S. FOOD AND DRUG LAW HISTORY, available at <http://www.fda.gov/opacom/backgrounders/miles.html> (last accessed Aug. 5, 2002).

⁶ The data is collected in the USDA, Bureau of Chemistry, bulletin no. 84 (1902-1908).

⁷ 21 U.S.C. § 1 *et seq.*

⁸ 21 U.S.C. § 601 *et seq.*

⁹ FDA, Milestones in U.S. Food and Drug Law History, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm081229.htm>.

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B. Evolution of the Food Statutes

These acts responded to the concerns of the day, but limitations were recognized soon after their passage. The Food and Drug Administration (FDA) wanted broader power and authority. Food industry leaders called for product quality standards to create a level playing field. Congress called for better safety standards and fair dealing.

However, it took a tragedy to spur legislative action. A drug manufacturer added diethylene glycol to sweeten the bitter taste of a new drug. The mixture, called elixir of sulfanilamide, shipped in the fall of 1937. Within weeks, deaths were reported to FDA. The manufacturer had performed no safety tests. The 1906 Act required none. Many of the more than 107 dead were children who died an agonizing death after receiving the elixir for strep throat.¹⁰ The tragedy precipitated legislative action, and in 1938 the Federal Food, Drug, and Cosmetic Act (FD&C Act) was enacted.

This pattern for major revision of the national food law repeats itself. A tragedy alone is not enough. Concerns of a few interested parties are not enough. Typically, the agency, the food industry, and the public must all be interested in addressing the issue of the day. This still may not be enough. Change often stalls until a precipitous event occurs while significant segment of the interested parties are paying attention.

III. NUTRITION AND HEALTH

Interest in diet and health was growing among the public health community and consumers through the 1970s and 1980s. This created a growing interest in marketing nutritional and health benefits for food. FDA lagged behind consumer and industry interest in this area. FDA considered all health claims on food to be illegal drug claims. As a practical matter, the full strictness of the law was applied just to disease claims. Structure-function claims, like “Calcium builds strong bones,” were tolerated as were claims that a food was healthful.

As diet and health awareness grew, consumers showed a keen interest in nutrition and health. Industry pressure mounted to use nutrient and health

¹⁰ Philip J. Hiltz, *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation 89-92* (2003).

claims as marketing tools. The food industry forced FDA's attention to health claims in 1984 by beginning to make disease prevention claims in labeling. Kellogg was first when it promoted its All-Bran Cereal to reduce the risk of cancer based on authoritative reports issued by the highly respected National Academy of Sciences and the National Cancer Institute.¹¹ The Federal Trade Commission endorsed this approach for advertising. In 1985 FDA followed by dropping blanket opposition to health claims. However, before FDA could implement its new policy, Congress enacted the Nutritional Labeling and Education Act (NLEA) of 1990,¹² which directed FDA to write regulations allowing health claims for foods under limited conditions.¹³

C. Health Claims

FDA defined "health claim" to be any claim made on the label or labeling that expressly or by implication characterizes the relationship of any substance to a disease or health-related condition.¹⁴ This definition is strikingly broad, but FDA removes four different types of health-related claims from scrutiny as health claims.¹⁵ Statements of dietary guidance and general well-being from consumption of food,¹⁶ classical nutrient-deficiency disease and nutrition statements,¹⁷ structure-function claims,¹⁸ and

¹¹ Peter Barton Hutt, Richard A. Merrill, & Lewis A. Grossman, *Food and Drug Law* 272 (3d ed. 2007).

¹² Nutritional Labeling and Education Act of 1990, Pub. L. No. 101-535, § 301, 104 Stat. 2,353 (1990) (codified in part at FD&C Act §§ 403(Q), (R) [21 U.S.C. §§ 343(Q), (R)]).

¹³ See General Requirements for Health Claims for Food, 58 Fed. Reg. 2,478 (Jan. 6, 1993) (codified at 21 C.F.R. pts. 20 and 101).

¹⁴ 21 C.F.R. § 101.14(a)(1).

¹⁵ FDA has used the term "statements of nutritional support" to categorize these three types of exceptions, but the agency discontinued the term because some claims may be for substances without nutritional value. See 62 Fed. Reg. 49,859-49,868 (Sept. 23, 1997) available at: <http://www.cfsan.fda.gov/~lrd/fr97923b.html>.

¹⁶ See General Requirements for Health Claims for Food, 58 Fed. Reg. 2,478, at 2,487 (Jan. 6, 1993) (distinguishing health claims and dietary guidance statements) and FDA, Claims That Can Be Made for Conventional Foods and Dietary Supplements (Sept. 2003) available at: <http://www.cfsan.fda.gov/~dms/hclaims.html> ("statements that address a role of dietary patterns or of general categories of foods (e.g., fruits and vegetables) in health are considered to be dietary guidance rather than health claims, provided that the context of the statement does not suggest that a specific substance is the subject.")

¹⁷ 21 C.F.R. § 101.93(a)(2); see also, FDA, Structure/Function Claims <http://www.cfsan.fda.gov/~dms/labstruc.html> (last visited Sept. 29, 2008). FDA has grouped statements about nutrition and classical nutrient deficiency disease (like vitamin C and scurvy) as a type of structure-function claim, but these claims do not meet FDA's definition for structure function claims because they include a disease claim.

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nutrient level descriptors¹⁹ are not considered health claims for regulatory purposes.

For a number of years FDA restricted health claims to those that met the stringent requirements of its “significant scientific agreement” standard.²⁰ Congress attempted to fast track the acceptance of health claims with the FDA Modernization Act of 1997 (FDAMA).²¹ FDAMA permits health claims based on an “authoritative statement” from certain federal scientific bodies and the National Academy of Sciences. This provision was intended to expedite acceptance of health claims by replacing the formal petition process with a notification of FDA, but the flow of accepted claims never increased as hoped. FDA interpreted “authoritative statements” so that they must reflect a consensus within the identified scientific body and be based on a deliberative review by the scientific body of the scientific evidence. In theory, the authoritative-statement standard is slightly less stringent than FDA’s prior requirement for “significant scientific agreement.” However, in application, the standards show little difference.

¹⁸ *Id* § 101.93(f) (defining “structure/function claim” as a statement describing the role of a nutrient intended to affect the structure or function of humans, so long as it is not a disease claim); *see also* FDA, Discussion of a Conceptual Framework for Structure and Function Claims for Conventional Foods, <http://www.cfsan.fda.gov/~dms/labstru2.html> (last visited Sept. 29, 2008), and the January 6, 2000 65 Fed. Reg. 1,000 Jan. 6, 2000) (describing types of claims that can and cannot be made for dietary supplements) available at: <http://www.cfsan.fda.gov/~lrd/fr000106.html> (last visited Sept. 29, 2008).

¹⁹ 21 C.F.R. § 101.13. FDA uses the terminology “nutrient content claim” and “nutrient descriptor” interchangeably. However, FD&C Act § 403(r)(1)(A) uses the language, “characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food.” Neither “nutrient content claims” nor “nutrient descriptors” precisely convey the language in the Act. Nutrient content claims that merely indicate the factual quantity of a nutrient without characterizing the level (high, low, and so forth) are outside the scope of § 403(r)(1)(A). Nutrient descriptors that merely indicate the function of a nutrient without characterizing the level are also outside the scope of § 403(r)(1)(A). Therefore, I use the terminology “nutrient level descriptor.”

²⁰ FDA, Guidance for Industry, Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements (Dec. 22, 1999), available at: <http://www.cfsan.fda.gov/~dms/ssaguide.html>.

²¹ FDAMA §§ 303 & 304 amended FDC & Act §§ 403(r)(3) and 403(r)(2) [21 U.S.C. 343(r)(3) and (2)].

D. Qualified Claims.

As FDA continued to reject outright all petitions for health claims that lacked significant scientific agreement, the pressure grew. Finally, manufacturers pushed back in *Pearson v. Shalala*. The U.S. Court of Appeals found that FDA had infringed the First Amendment by banning misleading health claims without first considering the use of curative disclaimers, and FDA violated the arbitrary and capricious standard of the Administrative Procedure Act by failing to clarify their of “significant scientific agreement” standard.²²

Health claims are a form of “commercial speech” and, under First Amendment protections, the FDA cannot unnecessarily restrain such speech. FDA argued that health claims lacking “significant scientific agreement” are inherently misleading to consumers and, therefore, are incapable of being cured by disclaimers. However, the Court of Appeals ruled that the FDA had no basis to reject the health claims without first assessing whether the use of a disclaimer could communicate meaningful, non-misleading information to the consumer. Where commercial speech is potentially misleading but can be “presented in a way that is not deceptive,” the government cannot ban it.²³

As a consequence, in 2002 FDA announced the availability of qualifying statements for claims when the quality and strength of the scientific evidence falls below that required for FDA’s significant scientific agreement standard.²⁴ An example of a qualified health claim follows:

“Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts, as part of a low saturated fat and low cholesterol diet and not resulting in increased caloric intake, may reduce the risk of coronary heart disease. See nutrition information for fat [and calorie] content.”²⁵

²² See generally, *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

²³ *Id.* at 655.

²⁴ FDA, Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements, 67 Fed. Reg. 78,002 (Dec. 20, 2002).

²⁵ Office of Nutritional Products, Labeling and Dietary Supplements, FDA, Qualified Health Claims: Letter of Enforcement Discretion - Walnuts and Coronary Heart Disease (Docket No 02P-0292) (Mar. 9, 2004) available at: <http://www.cfsan.fda.gov/~dms/qhcnuts3.html>.

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E. Did FDA Go Too Far After Pearson?

At a time when there is an aging, health-conscious population, the ability to make a health claim on a food product is a substantial marketing tool. Recent studies of consumer understanding of food health claims show mixed results.²⁶ Nutrient content claims help consumers avoid negative nutrients, increase consumption of positive nutrients, but the permitted health claims appear less helpful.²⁷

Text sentences with adjectives appear to incorrectly convey the strength of the science.²⁸ On the other hand, FDA's A, B, C, D rankings (the "report card grades") appeared easier for consumers to understand, and they conveyed the relative strength of the scientific support for claims, but consumers misunderstand qualified claims to have *greater* product confidence than claims with no qualification (those with greater scientific significance).²⁹ In addition, health claims give consumers a general perception that a product is healthier, but only provide a weak increase in disease risk perception.³⁰

The strength of the disclaimers or qualifications did not significantly diminish consumer perceptions of the health benefits. Conversely, statements conveying *more* scientific certainty about a claim can create a negative perception by consumers and lower confidence in the health benefits.³¹ The perturbing result may be explained by the phenomenon of psychological reactance, where people react negatively to a perceived

²⁶ See, Bryan Endres, United States Food Law Update: Labeling Controversies, Biotechnology Litigation, and the Safety of Imported Food, 3 J. FOOD L. & POL'Y 253, 254 (2007).

²⁷ J. Craig Rowlands & James E. Hoadley, FDA *Perspectives on Health Claims for Food Labels*, 221 TOXICOLOGY 35, 35 (2006) (noting that consumers may not be able to distinguish between a nutrient content claim and a health claim).

²⁸ Brenda M. Derby & Alan S. Levy, FDA, *Working Paper: Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claim* 3, 34 (Sept. 2005) available at: <http://www.fda.gov/OHRMS/dockets/dockets/03N0496/03N-0496-rpt0001.pdf> (last visited Sept. 30, 2008) (this paper does not represent FDA official position and was only disclosed after a Freedom of Information request).

²⁹ Center for Food Safety & Applied Nutrition (CFSAN), FDA, Questions and Answers, Qualified Health Claims in Food Labeling Report on Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims (Sept. 28, 2005) <http://www.cfsan.fda.gov/~dms/qhc-qa.html> (last visited Sept. 23, 2008); see also Derby & Levy *supra* note 28.

³⁰ Andreas C. Drichoutis et al., *Consumer' Use of Nutritional Labels: A Review of Research Studies and Issues*, 9 ACAD. OF MKTG. SO. REV. 1, 1 (2006) <http://www.amsreview.org/articles/drichoutis09-2006.pdf> (last visited Sept. 23, 2008).

³¹ Derby & Levy *supra* note 28 ("In some cases conveying more scientific certainty for a claim actually led to more negative perceptions of product health benefits.")

inappropriate attempt to influence them.³² A fundamental problem with qualifications on claims is not just a problem with comprehension, but also that consumers appear to be exercising skepticism on disclaimers the same as they do advertising puffery.³³

This situation creates controversy among nutrition policy experts.³⁴ In addition to perturbing results of disclaims, some experts are concerned that the prolific spinning of weak qualified claims may crowd out the claims with scientifically significant support.³⁵ Thus, even when understood, qualifying statements may have unexpected results on consumer behavior and understanding of health benefits. Some believe that allowing marginal health claims creates misleading labels and less information for consumers, adding noise instead of clarity and undermining credibility of regulatory statements.³⁶

Ironically, this is nearly exactly the position that FDA took in the *Pearson v. Shalala* case nearly ten years ago, in particular that “consumers would be considerably confused by a multitude of claims with differing degrees of reliability.”³⁷ The *Pearson* court objected to the fact that FDA had not even considered disclaimers in the context of evaluating health claims. Further, FDA merely offered its own conclusory opinion without empirical evidence of consumer confusion.³⁸ This recent research provides the exactly the type of empirical evidence that FDA needed to back up its opinion in the *Pearson* case.

³² *Id.* at 37 (“The crucial perspective applicable here is the idea that the claim/disclaimer on the product label is perceived by consumers as an explicit influence attempt. This suggests that rather than assuming that consumers view health claims/disclaimers on product labels as authoritative and authorless information, it may be that consumers think of health claims as marketing, intended to influence them to buy the product.”)

³³ *Id.*

³⁴ See, Endres, *supra* note 26 at 260-261 (citing Winning the Claim Game: Confused by Label Claims for Health Benefits for Everything from Walnuts to Corn Oil? Here’s How to Read the Fine Print, 25 TUFTS UNIV. HEALTH & NUTRITION LETTER S1 (Aug 1, 2007) (noting consumers blurring the fine distinction between disclaimers and the “confusing maze of health labeling rules.”)

³⁵ *Id.*

³⁶ See Press Release, Center Science Public Interest, FDA Study Proves FDA Confuses Consumers by Allowing Dubious Health Claims on Foods (Sept. 29, 2005) *available at*: <http://www.cspinet.org/new/200509291.html>; and Parke Wilde, New study on FDA website casts doubt on qualified health claims (Sept. 30, 2005) <http://usfoodpolicy.blogspot.com/2005/09/new-study-on-fda-website-casts-doubt.html>.

³⁷ *Pearson v. Shalala*, 164 F.3d 650, 659 (D.C. Cir. 1999) At (“The government disputes that consumers would be able to comprehend appellants’ proposed health claims in conjunction with the disclaimers we have suggested--this mix of information would, in the government’s view, create confusion among consumers. But all the government offers in support is the FDA’s pronouncement that ‘consumers would be considerably confused by a multitude of claims with differing degrees of reliability.’ 59 Fed.Reg. at 405.”)

³⁸ *Id.* (“Although the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the product affects health, it must still meet its burden of justifying a restriction on speech—here the FDA’s conclusory assertion falls far short.”)

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FDA took the *Pearson* decision as a demoralizing rebuke. Afterward the agency retreated from its earlier position on health claims. Now FDA appears unwilling to do more than reject those claims that totally lack scientific support. Nonetheless, the recent research points in the direction that FDA's hunches ten years ago about health claim confusion were correct.

Having been stung by the *Pearson* decision, FDA is unlikely to change its current stance on modified claims without outside pressure. However, *Pearson* did not require FDA accept qualified health claims. The *Pearson* decision only directed FDA to *consider* whether qualifications could cure a misleading claim, the agency was not prevented from prohibiting misleading claims or prohibiting misleading claims that could not be cured by disclaimer language.³⁹

Pressure is building on FDA and Congress for some type of change regarding confusing labels.⁴⁰ The perception is growing that FDA is not fairly and rationally enforcing its requirements on health claims, and may lack the resources to do so.⁴¹

³⁹ *Id.* at 659-660 ("Nor do we rule out the possibility that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright. . . . Finally, while we are skeptical that the government could demonstrate with empirical evidence that disclaimers similar to the ones we suggested above would bewilder consumers and fail to correct for deceptiveness, we do not rule out that possibility.")

⁴⁰ *E.g.*, Government Accountability Office (GAO), *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods*, GAO-08-597 (Sept. 2008) (GAO found that FDA's oversight and enforcement efforts have not kept pace with the growing number of food firms, and FDA has little assurance that companies comply with food labeling laws and regulations); and George A. Burdock, *The Importance of GRAS to the Functional Food and Nutraceutical Industries*, 221 *Toxicology* 17, 27 (2006) ("The pressure on FDA and Congress for change is again building with increased dissatisfaction among consumers as the result of confusing labels.")

⁴¹ *E.g.*, GAO, *Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical* (Jan. 29, 2008) (citing numerous challenges that FDA faces, including a lack of a coherent structure and vision, insufficient capacity in risk assessment, and inadequate human capital recruitment and retention.) available at: <http://www.gao.gov/new.items/d08435t.pdf>, and *The F.D.A. in Crisis: It needs More Money and Talent*, N.Y. Times, (Feb. 3, 2008) ("In a hearing before a House Energy and Commerce subcommittee, members of the agency's own scientific advisory board outlined the F.D.A.'s many weaknesses. It lacks scientists who understand rapidly emerging technologies — including genomics and nanotechnology — relevant to product safety. The agency is further hobbled by a high turnover rate of scientists, a decrepit information technology system, a weak organizational structure, and a shrinking inspection force," and quoting FDA former chief counsel, Peter Barton Hutt that FDA was "barely hanging on by its fingertips.")

F. The Battle of the Bulge⁴²

Pressure is also growing to do something about obesity. Today Americans are more overweight than ever before.⁴³ Food regulation is often looked to as a part of the remedy for this alarming epidemic.⁴⁴ Although The Nutritional Labeling and Education Act (NLEA) of 1990 was never intended to directly change consumer behavior, but was intended to provide accurate information to people actively seeking to improve their nutrition.⁴⁵ Someone buying a product labeled “low fat” should be able to expect the product to truly be low fat. However, FDA’s oversight over the accuracy of food labeling has diminished, and the agency is failing to enforce regulations on food labels that consumers rely on for nutrition information to improve their health.⁴⁶

With its limited resources, FDA believes it has prioritized “food labeling in the appropriate context given the agency’s overall public health mission” and “competing priorities.”⁴⁷ One cannot help but wonder how the public can trust the agency to protect the safety of our food when it cannot ensure the honesty of basic food labeling.⁴⁸ Ensuring that consumers will find honest labeling that assists them in choosing healthier food is an important public health mission. The perception is that FDA no longer has control over false and misleading health claims, which impairs consumers’ ability to select healthier foods.⁴⁹

⁴² The title of Margaret Sova McCabe’s article in the JOURNAL OF FOOD LAW & POLICY (Fall 2007).

⁴³ Nat’l Ctr. for Health Statistics, Centers for Disease Control & Prevention (CDC), National Health & Nutrition Examination Study, Prevalence of Overweight and Obesity Among Adults: United States, 2003-2004, available at: http://www.cdc.gov/nchs/products/pubs/pubd/hestats/overweight/overwght_adult_03.htm (last accessed Sept. 26, 2008) (66% of adults either overweight or obese).

⁴⁴ See generally, Margaret Sova McCabe, *The Battle of the Bulge*, JOURNAL OF FOOD LAW & POLICY (Fall 2007).

⁴⁵ That is, NLEA was intended to provide honest information to those seeking nutrient information, not to change the behavior of those not seeking this information.

⁴⁶ GAO, Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods, GAO-08-597 (Sept. 2008) available at: <http://www.gao.gov/new.items/d08597.pdf> (“FDA’s oversight and enforcement efforts have not kept pace with the growing number of food firms. As a result, FDA has little assurance that companies comply with food labeling laws and regulations for, among other things, preventing false or misleading labeling.”)

⁴⁷ *Id.* at 50.

⁴⁸ Paraphrasing a statement by then FDA Commissioner David Kessler, which the author recalls from a talk in 1991. Dr. Kessler was Commissioner of FDA from November 8, 1990, to February 28, 1997 <http://www.fda.gov/oc/commissioners/kessler.html>.

⁴⁹ *Supra* note 46.

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Controlling obesity and proper nutrition are more than individual health problems but are matters of great public health concern. The total costs attributed to people being overweight and obese amounted to \$117 billion in the year 2000 – \$400 for every man, woman and child in the United States.⁵⁰ Health care for overweight and obese individuals costs on average 37 percent more than for those of normal weight.⁵¹

The cost of treatment for illnesses related to obesity rivals the financial toll of smoking-related disease at about nine percent of all health care expenditures.⁵² The public debate on obesity often raises the question of whether it is a personal or societal matter. However, the economic burden falls heavily on the federal health care programs, particularly Medicaid and Medicare, the government health programs for the poor, disabled and elderly. Therefore, it is not surprising that the federal government has claimed a stake on this issue irrespective of the political philosophy of the administration.⁵³ Rising federal deficits shine a spotlight on where tax dollars going, and an obese, senior Medicare recipient spends roughly \$1,500 more on medical care than a non-obese senior.⁵⁴

Numerous alternate approaches have been proposed, such as advertising campaigns for healthier eating, a tax on fatty foods or sugary foods, zoning to restrict the number of fast food restaurants, and subsidies for fruit and vegetable purchases. The Institute of Medicine (IOM) proposed bans on soft drinks, sugary snacks, and other junk foods sold in schools to combat obesity in children.⁵⁵

⁵⁰ The President's Council on Physical Fitness and Sports, *Steps to Preventing Overweight and Obesity*, available at: http://www.fitness.gov/news/obesity_america.html (July 7, 2003).

⁵¹ Ceci Connolly, *Obesity Adds \$93 Billion to U.S. Health Costs*, WASHINGTON POST, May 21, 2003.

⁵² *Id.*

⁵³ *E.g.*, The President's Council on Physical Fitness and Sports, *Steps to Preventing Overweight and Obesity*, available at: http://www.fitness.gov/news/obesity_america.html (July 7, 2003).

⁵⁴ *Supra* note 51 (quoting Finkelstein).

⁵⁵ INSTITUTE OF MEDICINE (IOM), NUTRITION STANDARDS FOR FOODS IN SCHOOLS: LEADING THE WAY TOWARD HEALTHIER YOUTH (Apr. 25, 2007) <http://www.iom.edu/CMS/3788/30181/42502.aspx>.

G. Obesity Litigation

Litigation serves as a form of regulation, but it has played only an indirect role in efforts against obesity. Consumers cannot make healthy food choices if they lack accurate information or are deceived in some way by marketing. Litigation plays a role in preventing false or misleading representations of the nutrient content of food.⁵⁶

Obesity lawsuits—"you made me fat" lawsuits—have captured the public's imagination and grown to the stature of urban mythology. However, no "you made me fat" legal cause of action exists, so these lawsuits only involve obesity indirectly. These actions attempt to sue for misrepresentation of unhealthy food as nutritious, arguing that the plaintiff's reliance on the false misrepresentation is alleged to have resulted in obesity.⁵⁷ But even the most prominent and successful of these lawsuits ultimately failed, highlighting the nearly insurmountable hurdles for this type of litigation.⁵⁸

For all the attention these lawsuits have gathered, it surprises most to find out there have been only two such lawsuits filed in America over the past years.⁵⁹ Perhaps the attention derives from obesity lawsuits becoming symbolic of frivolous lawsuits.⁶⁰ Perhaps people associate obesity lawsuits with the successful lawsuits against the tobacco companies in recent years. Just as likely, politicians and others stoked the growing mythology as opportunistic fire for their ideological opposition to consumer lawsuits and animosity against trial lawyers.⁶¹

⁵⁶ See, e.g., *McDonald's Settles Fat Lawsuit for \$8.5 Million*, INSURANCE JOURNAL (Feb. 15, 2005) available at: <http://www.insurancejournal.com/news/national/2005/02/15/51451.htm> (The fast food company publicized a promise to reduce the use of trans fats but failed to inform the public that it did not change its oil as planned).

⁵⁷ See, *Pelman et al. v. McDonald's Corp.* S.D.N.Y. (Sept. 3, 2003) WL 22052778 (not Reported in F.Supp.2d).

⁵⁸ *Id.*

⁵⁹ David Burnett, *Fast-Food Lawsuits and the Cheeseburger Bill: Critiquing Congress's Response to the Obesity Epidemic*, 14 VA. J. SOC. POL'Y & L. 357, 393 (Spring 2007) ("Only a handful of lawsuits have been filed against the food industry, of which only two have alleged that the industry made consumers fat, and all of the lawsuits have failed in court or settled.")

⁶⁰ Burnett, *supra* note 59, at 391-393 (describing the congressional Cheeseburger Bill introduced to protect restaurants against frivolous obesity-related lawsuits).

⁶¹ See, Burnett, *supra* note 59, at n.176 and n.173 (n.173 Professor John Banzhaf agrees: "There seems to be a hysteria that a couple of law professors are going to pick on poor little defenseless companies like McDonald's, Kraft and KFC. . . It just doesn't make sense.")

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H. Trans Fat

Although there has never been a successful obesity lawsuit, there have been a few successful lawsuits against businesses for misrepresentation of the nutrient content of their food. Trans fat content has been a recent target where firms promised to remove trans fat but then did not.⁶²

The intake of trans fatty acids is associated with increased incidence of coronary heart disease.⁶³ Citing the Institute of Medicine conclusion that the only safe level of trans fat in the diet is zero, the Center for Science in the Public Interest (CSPI) in 2004 petitioned FDA requesting the agency revoke GRAS status for hydrogenated oil that contains trans fatty acids.⁶⁴ Most trans fatty acids are created in the hydrogenation of vegetable oil. Hydrogenation is the forcing of hydrogen atoms into the double bonds of unsaturated oil. This saturation of the oil is accomplished with high pressure, heat, and catalysts.

Rather than ban trans fat, FDA took a more moderate approach. FDA promulgated a rule to require the labeling trans fat in packaged foods.⁶⁵ However, states and local governments have stepped in to take stricter action. In 2008, California became the first state to ban trans fat from use in restaurants.⁶⁶ In the past two years, a number of cities and localities have banned trans fat as well, including New York City, Philadelphia, Boston, and Montgomery County, Maryland.

⁶² *Supra* note 56.

⁶³ Amanda Spake, *The Truth on Foods and Fats*, 124, 126, U.S. NEWS & WORLD REPORTS (2004) (quoting Walter Willett, professor of epidemiology at Harvard School of Public Health, who in 1997 estimated that the use of hydrogenated oils was resulting in 30,000 heart-disease deaths per year, representing “the biggest food processing disaster in U.S. history.”)

⁶⁴ *CSPI petitions FDA to ban hydrogenated vegetable oil*, FOOD CHEMICAL NEWS DAILY, Vol. 6, No. 96 (May 19, 2004) (“Unlike fats that occur in nature, partially hydrogenated vegetable oil is totally artificial and absolutely unnecessary in the food supply,” said CSPI’s Michael Jacobson.) CSPI’s entire petition to FDA is available on their website, www.cspi.org.

⁶⁵ See *Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims*, 68 Fed. Reg. 41433-41506 (July 11, 2003), available at: <http://www.cfsan.fda.gov/~lrd/fr03711a.html> (last accessed Mar. 10, 2008).

⁶⁶ Jennifer Steinhauer, *California Bars Restaurant Use of Trans Fats*, NY TIMES (July 26, 2008) (quoting California Governor Arnold Schwarzenegger, a physical-fitness advocate and crusader against obesity, “California is a leader in promoting health and nutrition, and I am pleased to continue that tradition by being the first state in the nation to phase out trans fats.”) A copy of the law is available at: http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_0051-0100/ab_97_bill_20080715_enrolled.pdf.

IV. FOOD LABELING

A. Menu Labeling

Of course, trans fat free does not mean healthy. Under federal law, restaurants are also exempt from nutritional labeling requirements. Even without trans fat, food still may contain an unhealthy amount of saturated fat, cholesterol, sodium, and calories, of which the consumer may be unaware. However, the restaurant industry has stiffly opposed any menu nutritional labeling requirements.

In the vacuum of federal action, local governments have stepped in. Federal law preempts the states from requiring full menu nutritional labeling, but some states and local governments have passed calorie posting requirements for restaurants. New York City was in the lead, and its calorie-posting requirement for certain restaurants was upheld against challenges based on federal preemption and free speech.⁶⁷

On September 30, 2008, California became the first state to pass a menu labeling law.⁶⁸ The California menu labeling law will put calorie counts on chain restaurant menus and menu boards. The law applies only to fast-food and other chain restaurants having twenty or more outlets in California and only to standardized menu items, not daily specials or customized orders.⁶⁹

B. Allergen Labeling

The Food Allergen Labeling and Consumer Protection Act ("FALCPA") was effective January 1, 2006.⁷⁰ Designed to make it easier for allergic consumers and caregivers of allergic children to identify allergens in foods,⁷¹ major food allergens must be identified in clear, simple language.⁷² The major allergens requiring labeling are: milk, eggs, fish, Crustacea (shellfish), tree nuts, wheat, peanuts, and soybeans.⁷³ These eight allergens

⁶⁷ N.Y. State Restaurant Assn. v. N.Y. City Board of Health, et al., No. 08-cv-01000-RJH (Apr. 16, 2008) 2008 WL 1752455 (S.D.N.Y.) available at: <http://www2a.cdc.gov/php/docs/Calorie%20decision.pdf>.

⁶⁸ California enrolled SB 1420 available at: http://www.leginfo.ca.gov/pub/07-08/bill/sen/sb_1401-1450/sb_1420_bill_20080903_enrolled.html (last visited Oct. 6, 2008).

⁶⁹ Id.

⁷⁰ Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, 118 Stat. 891 (2004) (codified at 21 U.S.C. § 343) (hereinafter "FALCPA").

⁷¹ See, e.g., Michael T. Roberts & Margie Alsbrook, *United States Food Law Update*, 1 *Journal of Food Law & Policy* 187, 192-193 (2005); and Press Release, Food Allergy Initiative, *Food Allergy Initiative Celebrates the Food Allergen Labeling & Consumer Protection Act Becoming Law: Millions of Americans Will Be Able to Easily Identify Safe and Unsafe Foods* (Aug. 5, 2005).

⁷² FALCPA § 203(a) & (d).

⁷³ FALCPA § 203(c) (to be codified as FD&C Act § 201(qq)).

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are estimated to account for 90 percent of food allergies in the United States.⁷⁴

Before FALCPA, the collective listings of colors, flavorings, and spices could hide major food allergens. For example, an ingredient labeled as “natural flavoring” might include milk or soy protein. The collective ingredient listing “flavoring” created some surprising combinations, chicken patties containing flavoring from beef extracts.⁷⁵ This exemption from ingredient labeling has been involved in a number of reported food allergen reactions in recent years.⁷⁶

One unresolved issue with allergen labeling is the lack of scientific thresholds. The zero-detectable standard for food allergens has resulted in widespread use of precautionary statements, such as “may contain” labeling. This results in far fewer foods available for allergic consumers.

Decreased choices for allergic consumers might not be a dilemma if these products truly were a risk, but trivial amounts of allergens probably pose no risk for most allergy sufferers.⁷⁷ Being overly cautious can also create other risks.⁷⁸ Over labeling can result in consumer confusion.⁷⁹ For instance, allergic consumers may wonder why a food they have eaten for years suddenly is labeled with an ingredient to which they know they are allergic.⁸⁰ Some consumers may incorrectly believe they have recovered from their allergies, while others may get in the habit of ignoring the excessive and unhelpful warnings.⁸¹ Both situations result in health risk to

⁷⁴ FALCPA § 202(2)(A); and Ricardo Carvajal, *New Food Labeling Requirements on the Horizon: The Food Allergen Labeling and Consumer Protection Act of 2004*, UPDATE: FOOD AND DRUG LAW, REGULATION, AND EDUCATION 20 (January/February 2005).

⁷⁵ Eric Schlosser, *Why McDonald's Fries Taste So Good*, THE ATLANTIC MONTHLY 50-56 (Jan. 2001) available at: <http://www.theatlantic.com/issues/2001/01/schlosser.htm>.

⁷⁶ Raymond Formack, Jr., *When Food Becomes the Enemy*, FDA CONSUMER (August 31, 2001) available at: http://www.fda.gov/fdac/features/2001/401_food.html (last visited Apr. 12, 2005).

⁷⁷ *Id.*

⁷⁸ *Id.* (“But unless provisions are made, the act could become a nightmare for food-allergy sufferers,” paraphrasing Steve Taylor, professor and chair of Food Science and Technology at the University of Nebraska).

⁷⁹ See, e.g., Tom Trautman, *Labeling Food Allergens*, 59 FOOD TECH. 92 (Feb. 2005); and Presentation of Stephen L. Taylor, “Food Allergens: From Chaos, Confusion and Concern to Commitment and Control,” Ohio State University (Oct. 28, 2004).

⁸⁰ Martha Filipic, *Food Law Confusing the Allergic*, CINCINNATI POST C1 (Nov. 10, 2004) available at: 2004 WLNR 7345175 (quoting Steve Taylor, professor and chair of Food Science and Technology at the University of Nebraska “Consumers will say, ‘I’ve been eating this for 20 years and never had a problem, and now it has this allergen on the label.’”)

⁸¹ See UNITED KINGDOM FOOD STANDARDS AGENCY, NUT ALLERGY LABELLING: REPORT OF RESEARCH INTO THE CONSUMER RESPONSE (2002) available at: <http://www.foodstandards.gov.uk/multimedia/pdfs/nutallergyresearch.pdf> (indicating that too many allergen warnings run the risk of devaluing the label); and Institute of Food Science and Technology, Information Statement, Food Allergy 12 (Oct. 2005) available at: <http://www.ifst.org/allergy.pdf>.

consumers from missing information that is truly helpful.⁸² In the face of overly cautious warnings, other consumers may simply engage in risk taking behavior.⁸³ In addition, too much information crowded onto food labels conflicts with the need to make this information clear and simple to read.⁸⁴

C. *Naturally Confusing*

Misleading uses of the term “natural” has drawn federal agency attention a number of times in the past.⁸⁵ Most recently, the USDA initiated a rulemaking to resolve growing controversy.⁸⁶ Since 1982, USDA policy has defined “natural” as a product that contains no artificial flavoring or coloring, chemical preservative, or any other artificial or synthetic ingredient. In addition, a natural product and its ingredients may not be more than minimally processed. USDA also requires a brief statement that explains what is meant by “natural.”⁸⁷

At the heart of the dilemma are the two different contexts for use of the term, naturally occurring and naturally processed. Fructose is a naturally occurring sugar, but most would not considered fructose synthesized from corn starch and enzymes to be natural. Natural ingredients, however, may be used in nontraditional ways. Salt and water are natural, but many do not consider a chicken breast injected with saline solution to be natural.

Trickier yet are ingredients with dual functions, such as sodium lactate, which is a flavor and a preservative. Sodium lactate produced by fermentation of corn would be considered a natural ingredient. But a food that is normally without preservative would not be considered natural if it contains added preservative.

Adding more complexity to this issue are the various misunderstandings

⁸² Institute of Food Science and Technology, Information Statement, Food Allergy 12 (Oct. 2005) available at: <http://www.ifst.org/allergy.pdf>.

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ In the 1970s the Federal Trade Commission (FTC) proposed regulating natural claims, 39 Fed. Reg. 39,842 (Nov. 11, 1974); 40 Fed. Reg. 23,086 (May 28, 1975); 41 Fed. Reg. 8,980 (Mar. 2, 1976). In 1985, the Bureau of Alcohol, Tobacco, and Firearms withdrew its proposal on “natural,” Use of “Natural” in the Labeling and Advertising of Alcoholic Beverages, 50 Fed. Reg. 906, 960-61 (Jan. 8, 1985). In 1991, FDA considered defining the term but declined to do so in 1993, Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (Nov. 27, 1991); Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2,302, 2,407 (Jan. 6, 1993).

⁸⁶ Product Labeling: Definition of the Term “Natural,” 71 Fed. Reg. 70,503, 70,504 (Dec. 5, 2006).

⁸⁷ Food Safety & Inspection Service (FSIS) , USDA, FOOD STANDARDS AND LABELING POLICY BOOK 116-117 (Aug. 2005), available at: http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf (last visited Oct. 15, 2008).

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that arise in consumers' minds. "Natural" may be confused as a synonym for "organic." In 2005, USDA revised its policy because some people were confusing organic and natural as synonyms. Other may confuse "natural" beef as an animal production claim, such as "naturally raised," "grass fed," or "free range."

After seeing this briar patch of controversies, it is no surprise FDA has repeatedly declined to formalize a definition a number of times over the past 20 years.⁸⁸ Instead, FDA relies on the law's general prohibition of any false or misleading labeling. As seen in other situation of subdued regulatory activity, private actions increase. The Center for Science in the Public Interest (CSPI) recently sued over products containing high-fructose corn syrup being labeled "all natural."⁸⁹

V. BIOTECHNOLOGY

A. Rice Contamination with GE Genes

In 2006, Riceland cooperative discovered trace amounts of genetically engineered (GE) DNA in the 2005 long-grain rice crop.⁹⁰ The rice "tested positive for Bayer's herbicide-resistance trait."⁹¹ After announcement of the contamination, Japan banned imports of long grain rice from the United States, and the European Union implemented testing of all rice from the United States.⁹² Lawsuits were filed against Riceland and Bayer by farmers who lost export sales.

⁸⁸ The Sugar Association petitioned FDA to be consistent with USDA, see Sugar Association Petition, Re: Definition of the Term "Natural" For Making Claims on Food and Beverages Regulated by the Food and Drug Administration (Feb. 28, 2006), available at: <http://www.fda.gov/ohrms/dockets/dockets/06p0094/06p0094.htm>. See also, Sara Lee Corp., Citizen Petition Requesting the FDA to Develop Requirements for the Use of the Term "Natural" Consistent with the USDA's Food Safety and Inspection Service (Apr. 9, 2007), available at: <http://www.fda.gov/ohrms/dockets/dockets/07p0147/07p0147.htm>.

⁸⁹ The Center for Science in the Public Interest (CSPI) sued Kraft for its "natural" claim on Capri Sun drinks sweetened with high-fructose corn syrup. Kraft agreed to drop the claim. See Complaint, *Linda Rex v. Kraft Foods, Inc.* (Fla. Palm Beach County Ct, Jan. 8, 2007), available at: <http://cspinet.org/new/pdf/complaint.pdf>. Cadbury Schweppes also agreed to drop a similar "all natural" claim after the CSPI threatened suit. See Press Release, CPSI, CPSI to Sue Cadbury Schweppes of "All Natural" 7 UP available at: <http://www.cspinet.org/new/200605111.html>.

⁹⁰ See Bill Reed, Vice President for Public Affairs, Riceland Foods, Statement Regarding Genetically Engineered Material in Rice (August 18, 2006), available at: http://www.riceland.com/about/ge_docs/Statement%20Regarding%20Material%20in%20Rice%20Updated.pdf.

⁹¹ Id.

⁹² Andrew Pollack, *Unapproved Rice Strain Found in Wide Area*, N.Y. TIMES, Aug. 22, 2006, at C2.

There was no known commercial production of the GE rice in the United States so it is puzzling where the contamination arose. The contamination was traced to a GE-gene similar to LLRice601, but the crop was never approved for commercialization.⁹³ USDA announced that it was unable to identify how the GE rice line entered the commercial rice supply.⁹⁴

After the event, the Animal and Plant Health Inspection Service (APHIS) of USDA announced that the agency “remains dedicated to fulfilling its role as part of the Federal framework for the regulation of biotechnology. . . . Rare occurrences involving the LLP [low-level presence] of GE material in commercial seed or grain must be considered in light of USDA’s long record of success in biotechnology regulation. USDA remains confident that its regulation of biotechnology is effective.”⁹⁵ USDA reassurances have not comforted critics or the lessened the controversy.⁹⁶

I. Court Bans Planting of GE Alfalfa

In 2004, Monsanto Company and Forage Genetics International petitioned the USDA APHIS for deregulation of a GE variety of glyphosate tolerant alfalfa.⁹⁷ During the comment period, many comments to APHIS raised concerns over genetic contamination of both organic and conventional alfalfa, which would cause loss of farm export business.⁹⁸ The GE alfalfa allows farmers to use Monsanto’s Roundup herbicide without damaging the alfalfa. Concerns were also raised that this GE alfalfa could create super weeds resistant to the herbicide.⁹⁹ Nonetheless, APHIS issued a determination of nonregulated status for the GE alfalfa without conducting

⁹³ USDA, REPORT OF LIBERTYLINK RICE INCIDENTS 1, available at: <http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf>.

⁹⁴ *Id.*

⁹⁵ *Id.* at 7.

⁹⁶ See, Roger McEowen, Two federal courts rule that USDA improperly advanced genetically modified crops, AgDM Whole Farm Legal and Taxes, Significant Opinions from Other Courts (updated May 2007) available at: <http://www.extension.iastate.edu/agdm/articles/mceowen/McEowOthCourtsFeb07b.html> (“Some of the problem is the result of the USDA pushing the introduction of biotech crops too quickly without adequate field testing and regulation.”)

⁹⁷ APHIS, USDA, Environmental Assessment: Monsanto Co. & Forage Genetics Intl Petition 04-110-Olp for Determination of Non-regulated Status for Roundup Ready Alfalfa Events J101 and J163 (Oct. 2004), available at http://www.aphis.usda.gov/brs/aphisdocs/04_110Olp_pea.pdf; see also Monsanto Co. & Forage Genetics International; Availability of Petition & Environmental Assessment for Determination of Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to Herbicide Glyphosate, 69 Fed. Reg. 68,300 (Nov. 24, 2004).

⁹⁸ *Geertson Seed Farms v. Johann*, No. C 06-01075 CRB, 2007 W L 518624, *2 (N.D. Cal. Feb. 13, 2007).

⁹⁹ *Id.* *Geertson Seed Farms v. Johann*, No. C 06-01075 CRB, 2007 W L 518624, *2 (N.D. Cal. Feb. 13, 2007).

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an environment impact statement.¹⁰⁰

Subsequently, some farmers, the Sierra Club, and various farmer and consumer organizations took APHIS to court with a challenge to the agency's decision. During the case, APHIS acknowledged the potential coexistence concerns with organic and conventional alfalfa, but the agency considered this a stewardship issue for those farmers that wished to keep their alfalfa from comingling with the GE variety.¹⁰¹

The court concluded that APHIS was erroneous and inadequate in its analysis.¹⁰² The court noted that APHIS failed “to analyze the likely extent of gene flow and whether any measures could be effectively implemented to prevent such contamination did not demonstrate the ‘hard look’ required by NEPA”¹⁰³ (the National Environmental Protection Act). The court also found that APHIS had violated the law by failing to assess the possible environmental impacts before approving the GE alfalfa.¹⁰⁴

On March 12, 2007, the court issued a preliminary injunction that temporarily halted the planting of the GE alfalfa in the United States. On May 3, 2007, the court upheld the ban on planting the GE alfalfa and made it permanent until USDA complies with the court's order for a thorough analysis of the environmental impact.¹⁰⁵ This is the first United States judicial ban of a GE crop in the fourteen years of GE crop production.

¹⁰⁰ Monsanto Co. & Forage Genetics Int'l; Availability Determination of Nonregulated Status, 70 Fed. Reg. 36,917 (June 27, 2005).

¹⁰¹ APHIS, USDA, Response to Comments to the Finding of No Significant Impact for the Determination of Non-regulated Status for Roundup Ready Alfalfa Events 3101 and J163, at 2, available at: http://www.aphis.usda.gov/brs/aphisdocs2/04_11001p_com.pdf [hereinafter “Comments to Alfalfa FONSI”].

¹⁰² Geertson Farms Inc. v. Johanns, Not Reported in F.Supp.2d, 2007 WL 130298 at *1,*5 (N.D.Cal.)

¹⁰³ *Id.* at *1.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.* at *9.

VI. GROWING SENSE OF FAILURE OF GOVERNMENT TO FOOD SAFETY

The American food safety system has been called a “train wreck.”¹⁰⁶ The years 2007 and early part 2008 experienced a dramatic increase in the number of beef recalls for *E. coli* O157:H7, going from 181,900 pounds in 2006 up to 40 million pounds in the recent year and a half.¹⁰⁷

A. Melamine in pet food

In March 2007, wide recalls began for many brands of pet foods that were noted for sickening and killing cats and dogs.¹⁰⁸ The pet food was found to be tainted with melamine from adulterated wheat gluten imported from China. Later other vegetable proteins imported from China were also found to be contaminated.

The melamine contamination incident shook the confidence of many in the global food supply. Certainly, the inability of FDA to police the safety of food imports was criticized.¹⁰⁹ Americans consume a continually increasing amount of imported food. Imports in 2006 accounted for about 16 percent of the total vegetable supply and about 44 percent of the total United States fruit supply. The quantity of imported food is escalating while FDA’s resources to inspect them are not keeping up.¹¹⁰

B. Increasing Foodborne Disease Outbreaks from Produce

Confidence in the United States food safety system had already been rocked by a series of foodborne illness outbreaks have been associated with fresh produce. In 1996, more than 1,465 cases of *Cyclospora* foodborne illness were reported associated with raspberries.¹¹¹ In 1997, more than 200

¹⁰⁶ William Marler, *American Food Safety System a “Train Wreck”* (Aug. 6, 2008) <http://www.marlerblog.com/2008/08/articles/lawyer-oped/american-food-safety-system-a-train-wreck/> (last visited Oct. 20, 2008).

¹⁰⁷ Id.

¹⁰⁸ FDA, *Pet Food Recall (Melamine)/Tainted Animal Feed* (update: Feb. 6, 2008) <http://www.fda.gov/oc/opacom/hottopics/petfood.html>.

¹⁰⁹ See, e.g., GAO, *FOOD SAFETY: WEAK AND INCONSISTENTLY APPLIED CONTROLS ALLOW UNSAFE IMPORTED FOOD TO ENTER U.S. COMMERCE*, Statement of Lawrence J. Dyckman, Director, Food and Agriculture Issues, Resources, Community, and Economic Development Division, Testimony Before the Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate, GAO/T-RCED-98-271 (Sept. 10, 1998); and *The Dangers of Imported food*, 7 THE WEEK 315 at 15 (2007).

¹¹⁰ FDA, *FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology* (2007) available at: http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20science%20and%20Technology.pdf (last visited Jan. 31, 2008).

¹¹¹ Linda Calvin et al., *Response to a Food Safety Problem in Produce: A Case Study of a Cyclosporiasis Outbreak*, in *GLOBAL FOOD TRADE AND CONSUMER DEMAND FOR QUALITY* (Barry Krissoff, Mary Bohman, & Julie Caswell, eds., 2002).

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schoolchildren and teachers contracted hepatitis A from strawberries.¹¹² In 2000, forty-seven people became ill with *Salmonella poona* from cantaloupe, and in 2002, fifty-eight became ill.¹¹³ In 2003, 555 people fell ill and three people died from Hepatitis A associated with green onions.¹¹⁴

In the fall of 2006, an *E. coli* O157:H7 outbreak from contaminated Baby Spinach and resulted in 205 confirmed illnesses and three deaths.¹¹⁵ The combined investigational efforts by the California Food Emergency Response Team (CalFERT), a team of experts from FDA's district office in San Francisco and California's Department of Health Services (CDHS), with assistance by experts from the Centers for Disease Control and Prevention (CDC) and Animal and Plant Health Inspection Service (APHIS) of USDA were able to identify the "environmental risk factors and the areas that were most likely involved in the outbreak, but they were unable to definitely determine how the contamination originated."¹¹⁶

In the spring of 2008, FDA warned consumers not to eat certain types of raw tomatoes due to what appeared to be a link to salmonellosis from *Salmonella* serotype Saintpaul, an uncommon type of *Salmonella*.¹¹⁷ By August 25, 2008, a total of 1,442 people in 44 states had been reported infected with the outbreak strain, at least 286 were hospitalized, and two died.¹¹⁸ Near the end of its investigation, FDA switched its attention from tomatoes to jalapeño and Serrano peppers, but the mystery was never solved after a two month investigation.¹¹⁹

¹¹² Yvan Hutin et al., *A Multistate, Foodborne Outbreak of Hepatitis A*, 340 NEW ENGLAND J. OF MED. 595-602 (1999) (cases were reported in other states as well).

¹¹³ J. Anderson et al., *Multistate Outbreaks of Salmonella Serotype Poona Infections Associated with Eating Cantaloupe from Mexico—United States and Canada, 2000-2002*, 51(46) MORBIDITY AND MORTALITY WEEKLY REP. 1044-1047 (Nov. 22, 2002).

¹¹⁴ Centers for Disease Control (CDC), *Hepatitis A Outbreak Associated With Green Onions at a Restaurant — Monaca, Pennsylvania*, MORBIDITY MORTALITY WEEKLY REP., at 1155-57 (Nov. 28, 2003).

¹¹⁵ Press Release, FDA, *FDA Finalizes Report on 2006 Spinach Outbreak* (Mar. 23, 2007), available at: <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01593.html>.

¹¹⁶ Id.

¹¹⁷ Press Release, FDA, *FDA Warns Consumers in New Mexico and Texas Not to Eat Certain Types of Raw Red Tomatoes* (June 3, 2008) <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01843.html>.

¹¹⁸ CDC, 57 (34) MORBIDITY AND MORTALITY WEEKLY REPORT 929, 930 (Aug. 29, 2008) available at: <http://www.cdc.gov/mmwr/PDF/wk/mm5734.pdf>.

¹¹⁹ FDA, *Salmonella Saintpaul Outbreak* (updated: Aug. 28, 2008) <http://www.fda.gov/oc/opacom/hottopics/tomatoes.html>.

The handling of the outbreak raised ire from many sides.¹²⁰ It has been known for years that raw produce is a growing foodborne illness concern and produce-associated outbreaks have caused an increase proportion of all outbreaks since the 1970s.¹²¹

Part of FDA response was to hold public hearings to gather information regarding production and processing of fresh produce. The agency also issued a revised, *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*.¹²² As guidance, however, the document contains non-binding recommendations.¹²³ The agency has been criticized for failing to write enforceable regulations even though it has done so for other food risks and food handling (FDA's good manufacturing practice regulations exempt raw produce), and some in the industry have asked the agency to do so.¹²⁴

A recent Government Accountability Office (GAO) report criticized FDA's handling of fresh produce safety over the past decade.¹²⁵ The significant concerns mentioned by GAO are that: (1) FDA faced resource constraints that caused the agency to delay key fresh produce initiatives, for instance, issuing guidance for fresh-cut produce operations was delayed six years. Lack of resources also put FDA in a reactive mode and forced it to cannibalize programs to funds others. (2) FDA faced gaps in scientific knowledge and the agency's science base eroded to the point where it cannot conduct or fund the research needed to devise appropriate

¹²⁰ E.g., Jane Zhang, Julie Jargon & A.J. Miranda, *Tomato Industry Stews Amid Salmonella Outbreak: Lack of Identified Source Stirs Anger*, San Diego Union-Tribune (July 2, 2008); Press Release, CSPI, FDA Inaction to Blame for Salmonella Outbreak (June 10, 2008) ("Since 1990, more than 3,000 Americans have gotten sick from tomatoes contaminated in 24 known outbreaks . . . The Food and Drug Administration deserves any rotten tomatoes thrown its way in the wake of this latest outbreak.") <http://www.cspinet.org/new/200806101.html>.

¹²¹ S. Sivapalasingam, CR Friedman, L. Cohen, & RV Tauxe, *Fresh Produce: a Growing Cause of Outbreaks of Foodborne Illness in the United States, 1973 through 1997*, 67(10) J. Food Prot. 2342-53 (Oct. 2004).

¹²² Draft Final Guidance for Industry: Guide to Minimize Food Safety Hazards for Fresh-Cut Fruits and Vegetables; Availability; Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request, 72 Fed. Reg. 11,364 (Mar. 13, 2007) *also available at*: <http://www.cfsan.fda.gov/~dms/prodgui4.html>.

¹²³ *Id.* (From the Guidance Introduction, "FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.")

¹²⁴ GAO, *FOOD SAFETY: IMPROVEMENTS NEEDED IN FDA OVERSIGHT OF FRESH PRODUCE 24*, GAO-08-1047 (Sept. 2008) *available at*: <http://www.gao.gov/new.items/d081047.pdf>.

¹²⁵ GAO, *FOOD SAFETY: IMPROVEMENTS NEEDED IN FDA OVERSIGHT OF FRESH PRODUCE*, GAO-08-1047 (Sept. 2008), *available at*: <http://www.gao.gov/new.items/d081047.pdf>.

See EUROPEAN JOURNAL OF CONSUMER LAW 1/2009, *Food Trade: New Challenges and New Standards—European, American, and International Perspectives* 15-42 (2009)

solutions. (3) FDA has not issued regulations requiring firms to take necessary actions to prevent contamination (even with some industry support for such regulations). (4) FDA relied on voluntary compliance and corrective action when problems were observed. (5) FDA need for additional statutory authorities, such as explicit statutory authority to adopt preventative controls for high-risk fresh produce and to enhance access to firm records during food-related emergencies.

C. *Creekstone Farms v. USDA*

Creekstone Farms wanted to test its beef for bovine spongiform encephalopathy (BSE), but USDA denied the company the test kits. USDA was concerned that Creekstone's use of the test kits would be inappropriate because the kits were not designed to test cattle at a young age. However, Creekstone wanted to test its cattle so the company could export the meat to Japan and Korea. Creekstone was attempting to demonstrate to buyers for foreign countries that Creekstone beef was as tested as beef produced in those foreign countries.

In a split decision, the U.S. Court of Appeals in *Creekstone Farms Premium Beef v. USDA*,¹²⁶ upheld the agency authority to deny bovine spongiform encephalopathy (BSE) test kits to Creekstone Farms. The majority found that the Virus-Serum-Toxin Act (VSTA or the Act) authorizes USDA to prohibit use of a test kit for bovine spongiform encephalopathy (BSE).

The Act authorizes USDA to enact regulations “as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, or otherwise to carry out this chapter.”¹²⁷ The court accepted USDA's interpretation of “analogous products” to include test kits that are used in the diagnosis of disease. Diagnosis of disease is integral to the treatment of disease, so this is not too far of a stretch to include diagnosis as part of treatment. But Creekstone Farms never intended to use the test for the treatment of disease. Creekstone would have tested only already dead animals. Further, BSE is invariably fatal and untreatable. USDA's argument that Creekstone's testing would be a form of treatment stretches plausibility. Nonetheless, a diagnostic test that helps control of the spread

¹²⁶ *Creekstone Farms Premium Beef, L.L.C., v. USDA*, 539 F.3d 492 (D.C.Cir. Aug. 29, 2008) available at: <http://pacer.cadc.uscourts.gov/common/opinions/200808/07-5173-1135720.pdf>.

¹²⁷ 21 U.S.C. § 154.

of a disease might be squeezed into “treatment.”

But the stretching must continue because VSTA applies to products that are used in treatment of domestic animals *and* are a “worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product.” The agency appears to lack authority to restrict useful, non-contaminated, non-dangerous, non-harmful products. USDA finds this BSE test kit worthwhile enough to use in its own testing, so it is not clear how this BSE test kit is worthless, contaminated, dangerous, or harmful.

USDA argues, not that the test kits are worthless, but only Creekstone’s proposed *use* is worthless. Given the young age of most cattle at slaughter and the long incubation period for BSE, USDA argues the test would produce meaningless results. This authority to regulate the use of otherwise acceptable test needs to be pulled from VSTA general empowerment of USDA to enact regulations to, “otherwise carry out” the Act. What if Creekstone wanted to use home pregnancy test kits on its cattle? Would USDA have the authority to ban this use?

In his dissent, Judge Sentelle remained unpersuaded that VSTA grants this “use” authority. Sentelle found USDA “exceeded the bounds of reasonableness” in aggregating power to itself. Sentelle explained, “congressional provision of an expressed authority mandate to accomplish statutory goals does not create for the agency ‘a roving commission’ to achieve those or ‘any other laudable goal,’ by means beyond the authority granted in the statute.”¹²⁸ [Citations omitted.]

This matter has not ended. One count remains to be decided by the district court. Creekstone argues that USDA’s refusal to allow Creekstone to purchase BSE test kits to test its own cattle is arbitrary and capricious.¹²⁹ USDA offered two reasons for the denial. The agency asserts that this use would not be scientifically sound, and USDA has a mandate to “maintain domestic international confidence in U.S. cattle and beef products.”¹³⁰

However, Creekstone did not want to test to ensure the safety of its beef but, rather, to allow the company export its meat to Japan and Korea. From Judge Sentelle’s dissent, “It seems that the Department’s fear is that Creekstone’s use of the test kits would enable it to provide buyers with a false assurance that the cattle from which its beef is obtained are free of Bovine Spongiform Encephalopathy. However, as I read the record, all Creekstone hopes to do is assure foreign buyers that the beef is as well-tested as would be the case with beef produced in the home countries of

¹²⁸ *Supra* note 1.

¹²⁹ *Creekstone Farms Premium Beef, L.L.C. v. USDA, et al.*, 517 F.Supp.2d 8 (Mar. 29, 2007) n.5.

¹³⁰ *Id.* at 12-13.

See EUROPEAN JOURNAL OF CONSUMER LAW 1/2009, *Food Trade: New Challenges and New Standards—European, American, and International Perspectives* 15-42 (2009)

those buyers.”¹³¹ The purpose of VSTA is not to prevent false claims, and USDA has other authorities to prevent false claims, as does the Federal Trade Commission.

Granted, USDA has a mandate to maintain domestic international confidence in U.S. cattle and beef products. How USDA finds these reasons within its authority under VSTA is unclear. It is also unclear how a ban on testing will reassure consumers. Particularly to those how lack the subtle details of BSE pathogenesis and the test kit capabilities, the ban on the test kits may look like stonewalling to prevent embarrassing exposure of food safety concerns. It will be interesting to see whether USDA reasons can survive the arbitrary and capricious test on the district court’s review.

VII. CONCLUSION

The growing sense of failure of the United States food regulatory system, more changes are likely. Diet and health likely will remain an area of keen interest for the public and food manufacturers. At the same time, obesity presents a growing public health dilemma. After a series of high profile foodborne disease outbreaks, the American public is feeling vulnerable with both domestic and imported food. The federal agencies have been found lacking in their ability to handle basic matters such as the honesty of food labels and the safety of fresh produce.

This fundamental deficiency is more disturbing in light of the more complicated matters facing the agencies, such as nanotechnology and biotechnology. In particular, confidence in the ability of the government to safeguard the food supply regarding genetically engineered foods has been shaken by recent agency actions, such as the approval of commercialization of a variety of GE alfalfa without the oversight and scrutiny required by law.

Systemic problems are behind many of these concerns. With FDA, chronic funding constraints have forced the agency into a reactive mode and forced it to cannibalize programs to funds others. More than ever, the agencies must close their gaps in scientific knowledge. An eroded science base leads to poor decisions or lack of ability to devise appropriate solutions. Resource limits may also explain part of FDA’s failure to issue regulations (even with industry support for some regulations), and the agency’s reliance on voluntary compliance. Additional statutory authorities may be needed as well. However, without the needed human and scientific resources, it is not clear how the agencies would be able to write effective regulations or

¹³¹ *Supra* note 1.

appropriately use new authorities.

Thirty bills have been introduced into Congress to revise the food regulatory system. Discussion of major changes is being taken seriously by all parties. More change in the coming year is likely.

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