When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004

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"What is food to one man may be fierce poison to others."
Lucretius (c. 99 B.C.E.–c. 55 B.C.E.), Roman poet and philosopher

I. INTRODUCTION

For the more than thirteen million Americans with a food sensitivity, eating can be a terrifying experience. Phrases like "walking through a mine field," "playing Russian roulette," and "being imprisoned" frequently are employed when food allergy sufferers discuss the daily task of eating.[1] For approximately one out of every twenty-three Americans,[2] eating common food staples like wheat, milk, or fish is like eating poison.[3]

Millions of people risk adverse reactions that range from irritating to debilitating with every bite they take. Harmful reactions to food may induce such symptoms as nausea, vomiting, gastrointestinal distress, hives, eczema, dizziness, migraines, ear and sinus infections, pneumonia, drops in blood pressure, chest pain, mental uneasiness, lethargy, depression, arthritis, osteoporosis, malabsorption of nutrients, increased risk of various cancers, and acute life-threatening systemic anaphylaxis, asthma, and swelling of the tongue and throat.[4]

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[1] These quotes are from responses to an informal survey posted by the author on the Food Allergy Survivors Together (FAST) website (http://www.angelfire.com/mi/FAST/news.html) between January 9 and April 20, 2005, to gauge the reaction of people with food sensitivities to the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) [hereinafter Allergen Labeling Survey]. The FAST website provides information and support for people with food allergies and their caregivers. The site is not geared toward a particular food allergy and, thus, is visited by people who are concerned about a variety of food allergies. In addition to being announced on the FAST website, existence of the Allergen Labeling Survey also was spread by e-mail and word of mouth. The purpose of the survey was to obtain anecdotal responses about the perceived effect of the FALCPA on the lives of those individuals who responded to the survey, not to obtain a random sample and produce quantifiable or statistically-significant results. Nineteen individuals with food sensitivities or their caregivers responded to the survey. To protect anonymity, only the initials of survey respondents are cited. All survey responses are on file with the author.

[2] About one in 27 Americans has a food allergy and another one in 133 has celiac disease. *See* S.H. Sicherer et al., *Prevalence of Seafood Allergy in the United States Determined by a Random Telephone Survey*, 114(1) J. ALLERGY CLIN. IMMUNOL. 159-65 (2004) (discussing the prevalence of food allergies in America); AMERICAN CELIAC TASK FORCE, UNIVERSITY OF MARYLAND CENTER FOR CELIAC RESEARCH, CELIAC DISEASE: FACTS AND FIGURES 2 (2003); http://www.celiaccenter.org/taskforcefactsheet.pdf (discussing the prevalence of celiac disease in America). Thus, based on the population of the United States in 2005, roughly one in twenty-three Americans has a food sensitivity of the type that will be discussed in this article.

[3] One parent whose son is allergic to soy, for instance, likened a food label stating "contains soy" to a label stating "contains arsenic." E-mail from CM to Author, Response to Allergen Labeling Survey (Jan. 11, 2005).

[4] Adverse reactions vary depending on numerous factors, including the specific sensitivity, the amount of unsafe food ingested, and the individual's particular body chemistry. *See, e.g.*, Hugh A. Sampson & Dean D. Metcalfe, *Food Allergies*, 268 JAMA 2840, 2841 (1992); Susan L. Hefle et al.,

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For people with food sensitivities, access to accurate, comprehensive information about the contents of the foods they consume means the difference between a good and a poor quality of life. For many, it literally means the difference between life and death. An estimated 150 to 200 Americans, mostly children, die each year from food-induced anaphylactic shock, and thousands more rush to emergency rooms to receive life-saving treatments.[5] Experts have concluded that fatalities due to the ingestion of allergenic foods in susceptible individuals are "a major health problem."[6]

Despite the estimated hundreds of people who have died from—and the millions who have struggled with—food sensitivities in the United States since the passage of the first bill to regulate food and drugs nearly a century ago, the Food Allergen Labeling and Consumer Protection Act of 2004[7] (FALCPA), signed into law in August 2004, is the first amendment to the Federal Food, Drug, and Cosmetic Act[8] (FDCA) to directly address food allergy concerns.[9] By requiring manufacturers to disclose on the food label the presence of any of the eight most prevalent food allergens in plain English, the FALCPA implements the most sweeping changes to the food label in America since the Nutrition Labeling and Education Act of 1990 (NLEA).[10]

The FALCPA received broad and bipartisan congressional support. Its passage was hailed as a victory by food allergy sufferers and advocacy groups and was endorsed by the food industry. The passage of this legislation is indeed momentous. It represents a national, public recognition of the health, safety, and attendant legal needs of people with food allergies, and it provides a strong foundation to begin to address those needs. Passage of the FALCPA marks the culmination of years of grassroots consumer activism, efforts by the Food and Drug Administration (FDA) to deal with food allergies, and initiatives by the food industry to respond to consumer safety concerns. The FALCPA

Allergenic Foods, 36(S) CRIT. REV. FOOD SCI. & NUTRITION S69, S70, S81 (1996); Hugh A. Sampson, *Food Allergies*, 278 JAMA 1888-94 (1997) (discussing a variety of symptoms/adverse reactions associated with different types of food sensitivities); Jean Bousquet et al., *Food Allergy*, *in* REPORT OF THE FOOD AND AGRICULTURE ORGANIZATION (FAO) TECHNICAL CONSULTATION ON FOOD ALLERGIES, Annex 3, at 5-6 (Nov. 13-14, 1995) (on file with author); *see also infra* note 78. This list includes some symptoms associated only with food allergies (e.g., anaphylaxis), some symptoms associated only with celiac disease (e.g., malabsorption and increased risk of cancer and osteoporosis), and many symptoms associated with both types of food sensitivity.

[5] *See* S. Allan Bock et al., *Fatalities Due to Anaphylactic Reactions to Foods*, 107 J. ALLERGY CLIN. IMMUNOL. 191, 193 (2001); FDA, Advice to Consumers: Food Allergen Labeling and Consumer Protection Act of 2004, Questions and Answers (Dec. 12, 2005), http://www.cfsan.fda.gov/~dms/alrgqa.html [hereinafter FDA, Advice to Consumers] ("Approximately 30,000 consumers require emergency room treatment and 150 Americans die each year because of allergic reactions to food."). Peanut allergies alone account for 50 to 100 deaths per year. *See Teen With Peanut Allergy Dies After Kiss*, ASSOCIATED PRESS, Nov. 28, 2005, *available at* http://www.msnbc.msn.com/id/10243950/.

[6] Bock et al., *supra* note 5, at 191.

[7] The FALCPA constitutes Title II of Pub. L. No. 108-282, 118 Stat. 891, and is so named by section 201 of the FALCPA. Title I of Pub. L. No. 108-282, the Minor Use and Minor Species Animal Health Act (MUMSA), is an unrelated law that seeks to improve the availability of pharmaceuticals for certain "minor" animal species and to promote the use of drugs to treat less prevalent animal diseases. The FALCPA was combined with MUMSA to help ease the FALCPA's passage. When citing the FALCPA, this article employs the FALCPA's internal labeling system and, where helpful, parallel citations to the *United States Code Annotated*.

[8] Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. §§ 301-399). When this article refers to the FDCA it cites the *United States Code Annotated*.

[9] *See, e.g.*, H.R. REP. NO. 108-608, at 3 (2004) ("There are no labeling standards currently in place for food allergies.").

[10] Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified at 21 U.S.C.A. § 343(q)(1)).

reflects an increasing awareness of the serious—and growing—problem of food allergies today and is a remarkable achievement for the over thirteen million Americans with food sensitivities.

Nevertheless, the FALCPA's enactment follows decades of congressional, regulatory, and private sector indifference and *ad hoc*, chaotic approaches to food allergen management. And as with any legislation, the FALCPA is not without drawbacks. The benefits of the FALCPA are limited significantly in several key respects.

This article examines the progress that has been made in the United States to help food-sensitive consumers. It explores how far the law has come to improve the lives and safety of people with food sensitivities, as well as how far legal reform efforts can—and, arguably, should—continue to go. Part II of this article provides an introduction to food allergies and presents the case for improved food labeling. Part III reviews the history of food allergen labeling issues in the United States within the context of four different interested groups—FDA, consumers, the food industry, and Congress. Part IV summarizes and analyzes the provisions of the FALCPA. Lastly, Part V evaluates certain limitations of the FALCPA and offers suggestions for future food sensitivity-related legal reforms.

II. LIVING WITH A FOOD SENSITIVITY: THE PERILS ENDURED AND PROBLEMS ENCOUNTERED

"People with a food allergy typically walk around with a little bit of fear all the time."
Robert A. Wood, M.D., Director of the Pediatric Allergy Clinic, Johns Hopkins Medical Institutions, Baltimore, MD[11]

"When my kids are at school, when I hear the phone ring I sometimes 'freak' a little, wondering if this is a call from school about my [peanut-allergic] son. I guess I'm paranoid that someday a reaction will happen at school and I will get that dreaded call. ... Sometimes I'll take a deep breath before I pick up the phone and look at the caller id."
Parent of a peanut-allergic son (Mar. 23, 2005)[12]

To appreciate the significance and drawbacks of the FALCPA, it is instructive to first have a basic understanding of the nature of food sensitivities and to examine the problems faced by food-sensitive individuals that motivated the FALCPA's drafting and passage.

A. *An Introduction to Food Sensitivities*

1. *Biology Basics*

The blanket term "food sensitivity" encompasses three basic types of ailments associated with adverse responses to foods that are safe for the vast majority of people to

[11] Ray Formanek Jr., *Food Allergies: When Food Becomes the Enemy*, FDA CONSUMER MAG. July/Aug. 2001 (rev. Apr. 2004), http://www.fda.gov/fdac/features/2001/401_food.html.

[12] Posting of Renny to http://www.peanutallergy.com/bbpage.htm, Thread: Living With Peanut Allergy, Topic: Hate to Hear the Phone Ring (Mar. 22, 2005).

ingest—food intolerances (e.g., lactose intolerance),[13] immediate hypersensitivity reactions (typically known as "food allergies"), and delayed hypersensitivity reactions (the most notable of which, for purposes of this article, is celiac disease). The three types of food sensitivities are differentiated by the specific biological mechanisms that lead to adverse reactions when a sensitive individual comes into contact with an offending food. Because the FALCPA addresses food allergies and celiac disease, this article focuses on these two ailments. The term "food sensitivity" when it is used in the remainder of this article refers only to food allergies and celiac disease.[14]

Food allergies and celiac disease both involve abnormal immunological responses to proteins in food. When someone is allergic to a food, that person's immune system mistakenly reacts to certain proteins in the food as if the protein were an invading pathogen; the immune system responds in an exaggerated fashion to counter this perceived invasion. The most common types of food allergies (those mediated by allergen-specific immunoglobulin E, or IgE, antibodies) are known as "immediate hypersensitivity" reactions because symptoms occur within minutes to a few hours after exposure to the allergen.[15] In some

[13] Food intolerances are characterized by abnormal physiological responses to food or food additives that are nonimmunological in nature. *See* Sampson & Metcalfe, *supra* note 4, at 2840. Food intolerances are more common than food allergies. *See* Bousquet et al., *supra* note 4, Annex 3, at 1; National Digestive Diseases Information (NDDI) Clearinghouse, National Institutes of Health (NIH), Lactose Intolerance, http://digestive.niddk.nih.gov/ddiseases/pubs/lactoseintolerance (last visited Feb. 15, 2006) (indicating, for instance, that lactose intolerance is experienced by as many as thirty to fifty million Americans). The symptoms of food intolerance resemble many of those associated with food allergies, but adverse reactions are not life-threatening and often can be mitigated or prevented by reducing (rather than completely eliminating) consumption of the offending food. *See, e.g.*, Steve L. Taylor, *Emerging Problems—Food Allergens*, *in* FAO, CONFERENCE ON INTERNATIONAL FOOD TRADE BEYOND 2000: SCIENCE-BASED DECISIONS, HARMONIZATION, EQUIVALENCE AND MUTUAL RECOGNITION (ALICOM 99-15) (1999), *available at* http://www.fao.org/docrep/meeting/x2670e.htm [hereinafter Taylor, *Emerging Problems*]:

> From a practical viewpoint, true food allergies should be distinguished from other types of food sensitivities because they can elicit serious adverse reactions in some individuals and because individuals with food allergies can tolerate little of the offending food in their diets. For example, it is important to distinguish between milk allergy and lactose intolerance. Milk allergy can involve systemic and sometimes serious reactions, and individuals with milk allergy can tolerate little milk in their diets. In contrast, lactose intolerance, which results from an enzyme deficiency in the small intestine, involves only gastrointestinal symptoms, and affected individuals can often tolerate appreciable quantities of milk in their diets.

In the case of the common intolerance to lactose, the intolerance can be further managed through the use of over-the-counter products that allow an intolerant individual to nonetheless consume dairy products. *See, e.g.*, NDDI Clearinghouse, *supra*.

[14] This article focuses on food allergies and celiac disease because these two disorders pose particularly serious health and safety risks, such as anaphylaxis and intestinal damage, respectively, that are not associated with food intolerance. No medicine exists that can allow people with food allergies or celiac disease to ingest the offending food; the only treatment for people with food allergies and celiac disease is to strictly avoid exposure to offending proteins.

These also are the two disorders the FALCPA is designed to address. Although people who experience an intolerance to a food that is one of the eight major allergens also may benefit from some of the FALCPA's labeling requirements, the FALCPA's scheme will in some instances be overly inclusive. For instance, not every product that must be labeled under the FALCPA as containing milk necessarily contains lactose. The new labeling scheme imposed by the FALCPA, therefore, will not necessarily provide a lactose-intolerant individual with the information needed to make an informed decision about whether to consume a product.

[15] *See, e.g.*, Steve L. Taylor, *Topic 1: Overview of the Current Approach to Determine the Allergenicity of Genetically Modified Foods (Decision Tree Approach)*, *in* JOINT FAO/WHO (FOOD AND AGRICULTURE/WORLD HEALTH ORGANIZATION) EXPERT CONSULTATION ON FOODS DERIVED FROM BIOTECHNOLOGY 2 (Jan. 2001), *available at* http://www.fao.org/ag/agn/food/pdf/bi03al.pdf; Sampson & Metcalfe, *supra* note 4, at 2840.

cases, exposure to an allergen can induce anaphylaxis that can cause death within minutes.[16]

In contrast with food allergies, celiac disease[17] involves a cell-mediated immune response against gluten (proteins found in wheat,[18] barley, and rye). The onset of symptoms in cell-mediated food reactions, also known as delayed hypersensitivity reactions, begins within six to twenty-four hours after ingestion of the offending food, and it can take up to ninety-six hours for a reaction to subside.[19] Ingestion of gluten is responsible for a wide variety of health dangers, including damage to intestinal lining, malnutrition, stomach pain, nausea, mental distress, migraine headaches, osteoporosis, neurological conditions, additional autoimmune disorders, and cancer.[20] Thus, although people with celiac disease are not at risk of anaphylactic shock, the consequences of not following a strict gluten-free diet can be "just as grave and deadly."[21]

2. *Prevalence of Food Sensitivities and Severe Adverse Reactions*

Until the 1990s, little was known about the prevalence of food allergies,[22] the incidence of severe allergic reactions, which foods were responsible for most allergic reactions, and whether people with food allergies could safely consume an allergenic food below a threshold amount. Understanding of food allergies has increased substantially in the past decade as greater scientific and public attention has focused on the issue of food allergies. Much of the progress has been the result of private and nongovernmental public initiatives.[23]

Despite advances, many facts about food allergies in America remain uncertain, unstudied, uncollected, or unnoticed. Indicative of the inattention to food sensitivities within the medical community is the fact that food allergies do not appear among the

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[16] *See, e.g.*, Hugh A. Sampson, *Fatal Food Induced Anaphylaxis*, 53 ALLERGY 125, 127 (1998); Taylor, *Emerging Problems*, *supra* note 13:

> The most frightening symptom associated with food allergies is anaphylactic shock. Anaphylactic shock involves the gastrointestinal tract, the skin, the respiratory tract, and the cardiovascular system, with symptoms often occurring in combination and developing rapidly. Severe hypotension can occur, and death can ensue within minutes of ingestion of the offending food without proper treatment. Only a few people with food allergies are at risk of such serious consequences, but numerous deaths resulting from inadvertent exposure to the offending food have been documented among individuals with food allergies.

[17] Celiac disease also is known as "celiac sprue" or "gluten-sensitive enteropathy."

[18] Wheat includes subtypes such as triticale, spelt, and kamut.

[19] Susan L. Hefle & Steve L. Taylor, *Food Allergies and Other Food Sensitivities*, 55(9) FOOD TECH. 69, 75 (Sept. 2001).

[20] AMERICAN CELIAC TASK FORCE REPORT, *supra* note 2, at 1-2; *see also* S. REP. NO. 107-322, at 2 (2002) (accompanying S. 2499, as reported in Senate).

[21] 150 CONG. REC. H6100 (July 20, 2004) (statement of Rep. Lowey).

[22] *See, e.g.*, 44 Fed. Reg. 75,990, 75,999 (Dec. 21, 1979) ("[FDA and the U.S. Department of Agriculture (USDA)] recognize and sympathize with those individuals who may be allergic to the protein fractions in some fats and oils. Although the agencies know this medical problem occurs, they do not know the extent of the problem.").

[23] *See* S. REP. NO. 107-322, at 4. Researchers have partnered with food allergy consumer groups on several occasions to conduct studies that otherwise might have lacked sufficient funding or interest to be pursued. *See* The Food Allergy & Anaphylaxis Network (FAAN), Food Allergy Research, Published Research Highlights, http://www.foodallergy.org/Research/publishedresearch.html (last visited Feb. 15, 2006) (providing a nonexhaustive list of summaries of peer-reviewed, published food allergy research articles, many of which were funded in full or in part by FAAN). FAAN is a consumer group that seeks to "raise public awareness, to provide advocacy and education, and to advance research on behalf of all those affected by food allergies and anaphylaxis." *See* FAAN, About FAAN, http://www.foodallergy.org/about.html (last visited Feb. 15, 2006).

over 330 "diseases and conditions" topics presented on the website of the Centers for Disease Control and Prevention (CDC),[24] nor does the site offer morbidity and mortality statistics related to food sensitivities as it does for nearly one hundred other health conditions.[25] As a Senate Committee Report accompanying an earlier version of the FALCPA notes:

> Although several studies have provided estimates, the prevalence of food allergies is uncertain. Currently, the CDC does not sufficiently track data on the prevalence of food allergies, incidence of clinically significant and serious adverse events related to food allergies, and the use of different modes of treatment for and prevention of allergic responses to foods. The CDC should improve the collection of this information to better determine the national significance of food allergies.[26]

FDA also has opined that "a national assessment of the extent of food allergenicity would be helpful to clarify ... to what extent consumers experience allergic reactions to food."[27] In recognition of ongoing informational deficiencies in the area of food sensitivities, the FALCPA directs CDC to collect and publish data related to food allergies[28] and calls for the National Institutes of Health (NIH) to convene a panel of allergy experts to make recommendations for enhancing and coordinating future food allergy-related research.[29]

Although the number of Americans with food allergies is unknown and projections vary, estimates have been improving in recent years. While food allergies were thought to affect two to four percent of children and as few as one percent of adults[30] as recently as ten years ago, the estimated prevalence of food allergies among both children and adults has more than doubled in the past five years.[31] Results of a 2004 telephone

[24] *See* CDC, Diseases and Conditions A–Z, Health and Safety Topics, http://www.cdc.gov/az.do/id/0900f3ec8000e035#A (last visited Feb. 15, 2006).

[25] *See* CDC, National Center for Health Statistics, FastStats A to Z, Data and Statistics, http://www.cdc.gov/nchs/fastats/Default.htm (last visited Feb. 12, 2006).

[26] S. REP. NO. 107-322, at 4.

[27] Kenneth J. Falci et al., *Food Allergen Awareness: An FDA Priority: New Initiatives Focus on Allergens in 2001*, at 3, http://www.cfsan.fda.gov/~acrobat/alrgawar.pdf (last visited Feb. 15, 2006).

[28] *See* FALCPA § 207, 42 U.S.C.A. § 242r(note).

[29] *See* FALCPA § 208, 42 U.S.C.A. § 242r(note); *see also, e.g.*, S. REP. NO. 107-322, at 8:

> The committee is concerned that the prevalence of food allergies is uncertain and the incidence of clinically significant and serious adverse events is not being systematically monitored. In response to these concerns, the legislation requires the Centers for Disease Control and Prevention to better capture information on the prevalence of food allergies, the incidence of clinically significant or serious adverse events related to food allergies, and the use of different modes of treatment for and prevention of allergic responses to foods. In addition, the legislation requires the National Institutes of Health to convene a panel of nationally recognized experts to review current clinical research efforts and develop a plan for expanding research activities concerning food allergies.

[30] *See, e.g.*, Bousquet et al., *supra* note 4, Annex 3, at 14; Sampson & Metcalfe, *supra* note 4, at 2840 ("In clinical surveys, 8% of children younger than 6 years had evidence of food intolerance; 2% to 4% of these children experienced reproducible allergic reactions to foods. Similar studies are not available in adults, although some surveys suggest that 1% to 2% of the general adult population are sensitive to foods or food additives.").

[31] The bills introduced by Representative Nita M. Lowey (D-NY) to improve food allergen labeling reflect the rapidly increasing numbers and evolving estimate of the number of food allergic individuals in the United States. *Compare* H. RES. 309, 106th Cong. (1999) (stating that an estimated 5.2 million Americans have a food allergy) *with* H.R. 4704, 107th Cong. § 2(1) (2002) (stating that approximately seven million Americans, or over two percent of Americans, suffer from food allergies). The findings section of the FALCPA states that food allergies afflict approximately two percent

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survey indicate that closer to 3.7% of Americans are afflicted with food allergies—that is roughly eleven million people, or approximately one in every twenty-seven people.[32] Over six million people are allergic to fish and shellfish alone. Roughly three million people are allergic to peanuts or tree nuts.[33] Food allergies are estimated to be as much as four times more common in children than adults.[34]

Estimates about the prevalence of celiac disease similarly has sky rocketed. According to a 2004 study by the University of Maryland Center for Celiac Research, the most comprehensive study of celiac disease in the United States to date:

> Celiac disease affects 1 in 133 healthy, average Americans. That means 2.2 million people are living with celiac disease—97% of them are undiagnosed. ... The number of people with celiac disease in the U.S. is roughly equal to the number of people living in the state of Nevada.[35]

Celiac disease may be "one of the most common genetic diseases."[36]

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of adults and about five percent of children in the United States. *See* FALCPA § 202(1)(A), 21 U.S.C.A. § 343(note) [the parallel citation for FALCPA § 202, the findings section, hereinafter will be omitted]. By the time the FALCPA reached the floor of the House of Representatives for a vote, a 2004 study had been released reporting that the number of individuals with food allergies in America is roughly eleven million. *See, e.g.*, 150 CONG. REC. H6100 (July 20, 2004) (statement of Rep. Lowey) ("[T]he 11 million Americans with food allergies face a daily struggle."); Sicherer, *Prevalence of Seafood Allergy*, *supra* note 2; Hefle & Taylor, *supra* note 19, at 71 (stating that the prevalence of food allergy among children appears to be five percent to eight percent).

[32] The new figure reflects a rise in seafood (fish and seafood) allergies discovered by a 2004 nationwide, cross-sectional, random telephone survey that found that approximately 2.3% of the general population, or 6.6 million Americans, have a seafood allergy. *See generally* Sicherer et al., *Prevalence of Seafood Allergy*, *supra* note 2; *see also* National Institute of Allergy and Infectious Diseases (NIAAD), NIH, Allergy Statistics (Aug. 2005), http://www.niaid.nih.gov/factsheets/allergystat.htm.

[33] *See generally* Sicherer et al., *Prevalence of Peanut and Tree Nut Allergy in the United States Determined by Means of a Random Digit Dial Telephone Survey*, 112(6) J. ALLERGY CLIN. IMMUNOL. 1203-07 (2003); *see also* European Public Health Alliance, EU and US Laws on Food Labelling for Common Allergens, http://www.epha.org/a/1384 (last visited Feb. 15, 2006) ("Recent studies estimate that over 11 million Americans have a food allergy. Over six million are allergic to fish and shellfish alone. Over three million are allergic to peanuts and tree nuts and the number of children with peanut allergy has doubled in the past five years.").

[34] Food Allergy Initiative, Food Allergy Resources, Food Allergy Information, http://www.foodallergyinitiative.org/ (last visited Feb. 12, 2006) ("More than 11,000,000 Americans have food allergies of varying degrees of severity—at least 8% of children less than 3 years of age and 2% of the adult population in the United States.").

[35] AMERICAN CELIAC TASK FORCE REPORT, *supra* note 2, at 2; *see also, e.g.*, NIH Consensus Development Program, NIH Consensus Development Conference on Celiac Disease, Consensus Development Conference Statement on Celiac Disease (June 28-30, 2004), *available at* http://consensus.nih.gov/2004/2004CeliacDisease118html.htm [hereinafter NIH Consensus Development Conference Statement] ("Celiac disease has been considered until recently to be a rare disease in the United States. Studies, primarily in Europe but also in the United States, now suggest that its prevalence is much greater than previous estimates, possibly affecting as many as 3 million Americans (roughly 1 percent of the U.S. population), indicating that the disease is widely under recognized."); FALCPA § 202(6)(C) (stating that it is estimated that the prevalence of celiac disease in the United States is 0.5% to 1% of the general population).

[36] David Brown, *An Ailment's Common Grain: Survey Finds Surprising Incidence of Gluten Reaction*, WASH. POST, Feb. 11, 2003, at A1.

> The rapid expansion of a disease's prevalence is not a new phenomenon, but the rise in celiac disease is virtually without precedent. A generation ago, physicians were taught the disease was so rare that a practitioner might go a lifetime without seeing a case. In 1993, researchers at Children's Hospital in Buffalo published a study estimating celiac disease's

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Experts suspect that fatal and near-fatal anaphylactic reactions to food allergens likewise have increased.[37] Researchers expect this trend of increasing prevalence of food allergies to continue.[38]

Thus, current best estimates indicate that as many as thirteen to fourteen million Americans may be afflicted with food sensitivities. This number is approximately the same as the number of adults in the United States afflicted with diabetes.[39] For further comparison, approximately 2.7 million Americans have epilepsy,[40] four million suffer from Alzheimer's Disease, twenty million have been diagnosed with cancer at some point during their life, and twenty-three million have been diagnosed with heart disease.[41]

A large percentage of documented food allergens have been reported to be responsible for severe allergic reactions.[42] Although only a subset of people with food allergies are at risk for a life-threatening reaction to food, it is estimated that 150 to 200 people die of food-induced anaphylaxis each year and food allergies are responsible for 29,000 emergency room visits annually.[43] Tens of thousands more anaphylactic reactions are experienced each year that do not receive hospital care.[44] Food allergy is believed to be the leading cause of anaphylaxis.[45]

To help put these serious adverse reaction statistics in perspective, another critical food safety hazard, *E. coli* contamination, is responsible for approximately sixty-one

> prevalence to be 1.3 cases per 10,000 children. Mayo Clinic researchers the next year measured a rate of 1.1 cases per 5,000 people in the Minnesota population the clinic serves. [The work of Dr. Alessio Fasano, the gastroenterologist who heads the Center for Celiac Research at the University of Maryland School of Medicine in Baltimore] suggests, however, that celiac disease is 50 times more common than that. ... The new estimate "is basically in the same ballpark as Europe," said Stephen P. James, head of digestive diseases research at the National Institutes of Health.

Id.

[37] *See* Hugh A. Sampson et al., *Fatal and Near-Fatal Anaphylactic Reactions to Food in Children and Adolescents*, 327 NEW ENG. J. MED. 380, 384 (1992).

[38] Formanek, *supra* note 11 ("'The prevalence of food allergy is growing and probably will continue to grow along with all allergic diseases,' says Robert A. Wood, M.D., director of the pediatric allergy clinic at Johns Hopkins Medical Institutions in Baltimore. Wood says that research over the last three decades indicates that the number of people with allergies is skyrocketing in developed and developing countries, but not in underdeveloped areas.").

Several factors may account for the recent and substantial increases in prevalence estimates. Research efforts have been intensifying to identify and quantify the existence of food allergies, so estimates are likely becoming more accurate. A growing awareness of food allergies among physicians and patients may be leading to diagnoses of food sensitivities that previously would have gone undiagnosed.

Moreover, evidence suggests that the prevalence is in fact growing. For years scientists have suspected that the prevalence of food sensitivity is expanding. *See, e.g.*, Hefle & Taylor, *supra* note 19, at 71; Sicherer et al., *Prevalence of Peanut and Tree Nut Allergy*, *supra* note 33.

[39] CDC estimates that as of 2003, fourteen million American adults were diagnosed with diabetes. CDC, Data and Statistics, *supra* note 25.

[40] Epilepsy Foundation, Epilepsy: An Introduction, http://www.epilepsyfoundation.org/answerplace/About-Epilepsy.cfm (last visited Feb. 25, 2005).

[41] *See* CDC, Data and Statistics, *supra* note 25.

[42] *See* Hefle & Taylor, *supra* note 19, at 71.

[43] *See* Bock et al., *supra* note 5, at 193.

[44] *See* FDA, Transcript: Public Meeting On: The Challenge of Labeling Food Allergens 32 (Aug. 13, 2001) (statement of Anne Muñoz-Furlong, President and Founder, FAAN), *available at* http://www.fda.gov/ohrms/dockets/dockets/00p_1322/00p1322tr.htm.

[45] *See* Hugh A. Sampson, *Food Allergy: From Biology Toward Therapy*, HOSP. PRAC., May 15, 2000, http://www.hosppract.com/issues/2000/05/sampson.htm [hereinafter Sampson, *From Biology Toward Therapy*] ("Four studies, including one at the Mayo Clinic in Minnesota, another by a Florida group, and two in England, have now tallied the causes of anaphylactic episodes addressed in emergency rooms. The leading cause, accounting for a third of all cases, is food, with twice the incidence, and three times the mortality, of anaphylactic reactions to bee sting."); *see also* NIAAD, Allergy Statistics, *supra* note 32; Bock et al., *supra* note 5, at 193.

deaths each year in the United States.[46] Given today's more effective management of food borne pathogens, food allergens now have been called "arguably the most important chemical hazard posing a threat to processed meat and poultry products."[47]

The growing recognition of food sensitivities as a major health concern is a relatively recent phenomenon[48] made possible by increasing information and understanding about food sensitivities. For many years, some physicians had believed that true food sensitivities were exceptionally rare or did not exist at all,[49] and others too often dismissed all forms of allergy as "nuisance conditions."[50] Celiac disease did not receive formal recognition by NIH until June 2004 when NIH held a Consensus Development Conference regarding the disease.[51]

3. *The Culprits*

Any protein in a food has the potential to trigger an allergic response. Studies have documented the allergenicity of naturally-occurring proteins in over 170 foods, ranging from such American food favorites as potatoes, corn, chicken, chocolate, coffee, and strawberries, to spices (e.g., pepper, garlic, and cinnamon) and even nutrients (e.g., vitamin A).[52] Eight foods, however, have been found to account for about ninety percent of severe allergic reactions worldwide. These foods—milk, eggs, soybeans, wheat, fish,[53] crustacean shellfish,[54] peanuts, and tree nuts[55]—are commonly known as the "Big Eight."[56]

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[46] *See* Chris Bodendorfer, Jennifer Johnson & Sue Hefle, *Got (Hidden) Food Allergens?*, NAT'L PROVISIONER, Oct. 2004, http://www.nationalprovisioner.com/content.php?s=NP/2004/10&p=8 (citing CDC *E. coli* estimates).

[47] *Id.*

[48] *See* Hefle & Taylor, *supra* note 19, at 80.

[49] *See, e.g.*, S.A. Bock & F.M. Atkins, *Patterns of Food Hypersensitivity During Sixteen Years of Double-Blind, Placebo-Controlled Food Challenges*, 117(4) J. PEDIATRICS 561, 564 (1990) ("For those skeptics who do not believe that food hypersensitivity exists, these objective observations and those of other authors demonstrate the ability of food proteins to produce immunologically mediated reactions."); Sampson, *From Biology Toward Therapy*, *supra* note 45 ("[F]ood allergy is more common than some physicians may think.").

[50] NIAAD, NIH, *Current Trends in Allergic Reactions: A Multidisciplinary Approach to Patient Management*, 21(3) CLINICIAN 18 (2003) [hereinafter NIAAD, *Current Trends*].

> Allergic diseases affect millions of Americans annually, and their prevalence continues to increase. Although they have a tremendous impact on daily functioning and quality of life and predispose patients to much more serious and costly conditions, they are too often dismissed as nuisance conditions. Even when healthcare providers are committed to treatment, the time constraints of today's clinical practice limit the amount of attention that can be devoted to meticulous analysis of symptoms, repeated adjustments of therapy, and thorough patient education.

[51] Dr. Alessio Fasano, Director, Center for Celiac Research, University of Maryland, Remarks at a Meeting of the Washington Area Celiac Sprue Support Group (Mar. 5, 2005) (notes on file with author); *see also* NIH Consensus Development Conference Statement, *supra* note 35.

[52] *See* Hefle et al., *supra* note 4, at S70, tbl. 2 (summarizing a comprehensive review of scientific literature regarding allergic reactions to food).

[53] Fish allergy includes all species of finfish, both fresh water and salt water. *See* Taylor, *Emerging Problems*, *supra* note 13.

[54] For food allergy purposes, "crustacean shellfish" includes shrimp, prawns, crab, lobster, and crayfish. *See id.*

[55] The category "tree nuts" comprises almonds, walnuts, pecans, cashews, Brazil nuts, pistachios, hazelnuts, pine nuts, macadamia nuts, chestnuts, and hickory nuts. *See id.*

[56] *See, e.g.*, Hefle & Taylor, *supra* note 19, at 71; FDA, Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens (issued Apr. 19, 2001, updated Nov. 29, 2005), http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg555-250.htm (new Compliance Policy Guide (CPG) and update to the *Compliance Policy Guides Manual*) [hereinafter FDA, CPG on Cross-contact] ("FDA believes there is scientific consensus that the following [Big Eight] foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies"); Bock & Atkins, *supra* note 49, at 565 ("Foods purported to produce adverse

continued

Food sensitivity can develop at any age.[57] Children with allergies to milk, soy, eggs, or wheat may outgrow their allergy by age three,[58] whereas adults less frequently lose their allergies.[59] Peanut, tree nut, shellfish, and fish allergies—those allergies most frequently responsible for producing life-threatening reactions[60]—are rarely, if ever, outgrown by children or adults.[61] Celiac disease also is a life-long disorder that currently has no cure.[62]

4. *Quality-of-Life Impact*

Food sensitivity experts recognize that food sensitivities can "profoundly alter a person's life."[63] As a parent of a teenager with a soy allergy explained in his response to the informal survey of food-sensitive individuals conducted by this author (Allergen Labeling Survey),[64] "It is really in today's culture a horrible burden to have a life-threatening soy allergy."[65] He further described the maintenance of an allergen-free lifestyle in this way:

> I am aware that my tone is one of frustration, but we have been in the game for a long time; and we have little illusion of a workable solution to the constant threat, other than eating at home all the time. As my son gets closer to young adulthood it is unfathomable for any of us to figure out how he will cope when he goes to college, travels, etc. On the one hand we welcome all opportunities to be away from home, travel alone; and then on the other hand there is no safe way; also the people (chaperones, teachers, schools, restaurants, hotels, airlines) are

reactions [in the children studied] compose a long list, but those which regularly elicit symptoms form a much shorter list. Ninety-five percent of the food reactions objectively confirmed in this study were to egg, peanut, milk, tree nuts, soy, fish, and wheat. Seventy-three percent of the symptomatic reactions were triggered by egg, peanut, and milk."); *see also* FALCPA § 202(2)(A). For a more detailed analysis of this statistic that became the basis of the principal provisions of the FALCPA, see *infra* Part V.B.1.c. of this article.

Among American children, the most frequent food allergies are to milk, soy, eggs, peanuts, tree nuts, and wheat. *See* Sampson, *From Biology Toward Therapy*, *supra* note 45 (estimating that these foods are responsible for ninety percent of allergic reactions in American children); Hugh A. Sampson, *Food Allergies*, 278(22) JAMA 1888 (1997); Formanek, *supra* note 11. Many children are allergic to more than one food. A seminal study of 480 children with food allergies found that nearly thirty percent of the children were sensitive to more than one food. *See* Bock & Atkins, *supra* note 49, at 564. Another study found that over fifty percent of children allergic to milk appeared to be hypersensitive to one or more other foods. *See* J.M. Bishop et al., *Natural History of Cow's Milk Allergy: Clinical Outcome*, 116 J. PEDIATRICS 862 (1990).

Among American adults, the most frequent food allergies are to crustacean shellfish, fish, peanuts, and tree nuts. *See, e.g.*, Sampson, *From Biology Toward Therapy*, *supra* note 45 (estimating that these foods are responsible for eighty-five percent of allergic reactions in American adults).

[57] *See* Hefle & Taylor, *supra* note 19, at 73.

[58] *See, e.g., id.*; Sampson, *Food Allergies*, *supra* note 56.

[59] *See, e.g.*, Sampson, *Food Allergies*, *supra* note 56; Sampson & Metcalfe, *supra* note 4, at 2843.

[60] *See, e.g.*, Sampson & Metcalfe, *supra* note 4, at 2841; Bock et al., *supra* note 5, at 191.

[61] *See, e.g.*, Sampson & Metcalfe, *supra* note 4, at 2843.

[62] *See, e.g., id.* at 2842 ("Once the diagnosis of celiac disease is established, life-long elimination of gluten-containing foods is necessary to control symptoms and to avoid the increased risk of malignancy.").

[63] Sampson, *From Biology Toward Therapy*, *supra* note 45 ("For patients with a food allergy, places such as supermarkets, restaurants, and even a home dining room can be a minefield. Unable to be certain that what they eat is free of allergen, many patients do not dine at restaurants at all and become uneasy whenever human sociability includes food consumption.").

[64] For more information about the Allergen Labeling Survey, see *supra* note 1.

[65] E-mail from CM to Author, Response to Allergen Labeling Survey (Jan. 12, 2005).

> not at all interested in accommodating and supporting the special diet. So, every potential outing/trip/travel is a puzzle as to how to make it somewhat safe and find out what and where to eat, especially at this age when he is escorted on a planned trip and not free to drive and come and go on his own yet. You are with a group and no one else is coping with this minefield of finding out whether there are any safe food choices without soy hidden either in preparation or processing.[66]

The challenging lifestyle of people with celiac disease was discussed on the floor of the House by Representative Bill Shuster (R-PA) during congressional consideration of the FALCPA:

> I have had the unfortunate experience to learn more about the trials and tribulations of food allergen sufferers when one of the members of my staff, Christy Farmer, was diagnosed with Celiac Disease earlier this year. ... Having a food allergy, especially something that is found in so many different foods, can add a level of complication to a person's life that can be difficult to imagine. Christy was required to undergo a total lifestyle change due to her gluten sensitivity. Spontaneously stopping at a restaurant for dinner is no longer possible, traveling not knowing in advance what foods will be available is no longer an option, and giving up your favorite foods is not as easy as it sounds.[67]

At a July 2005 conference for patients with celiac disease, Dr. Ramasamy Manikam presented information about how celiac disease, as a chronic illness, can have a strong psychological impact on people with the disease. Dr. Manikam's presentation handouts to attendees stated that research suggests that emotional symptoms are common among children with celiac disease, adolescents with celiac disease have a higher lifetime prevalence of major depressive disorder and disruptive behavior disorder than adolescents without the disease, and adult celiac patients with psychiatric symptoms have histories that suggest undetected celiac disease in childhood.[68]

Shopping and preparing food for an allergen-free diet can be a time-consuming and expensive endeavor, particularly because the most commonly allergenic foods, such as milk, wheat, egg, and soy, are ubiquitous in the American diet. Food-sensitive individuals often must prepare food from scratch or purchase expensive specialty products. Eating outside the home poses even greater challenges. In the words of one individual with celiac disease, "I think the most underappreciated aspect of being diagnosed with a chronic disease is the psychological impact. You have to be very diligent about it. If we order something [in a restaurant and] a barbecue sauce had beer in it[,] and they say it didn't, we get sick."[69]

Diligently monitoring food consumption, living with constant anxiety about mistakes, managing the frustrations of refusing tempting foods of uncertain safety, and feeling "abnormal" or different from peers can take its toll on food-sensitive individuals. One need look no further than the numerous support groups available in most cities or

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[66] *Id.*

[67] 150 CONG. REC. HR 6100 (July 20, 2004) (statement of Rep. Shuster).

[68] Ramasamy Manikam, Ph.D., Director of the Center for Feeding Disorders, St. Mary's Hospital for Children, Bayside, NY, Psychosocial Aspects of Living with Celiac Disease, Presentation to Center for Celiac Research, University of Maryland, Conference on Making Tracks for Celiacs: A Patient Education Day (July 9, 2005) (copy of presentation slides on file with author).

[69] Seth Sutel, *More Restaurants Offer Gluten-Free Menus*, ASSOCIATED PRESS, Aug. 30, 2005, *available at* http://abcnews.go.com/Health/wireSTORY?id=1081780.

the multitude of organizations,[70] discussion boards, and chat groups on the Internet to observe the widespread desire of people dealing with food sensitivities for information sharing and community.

Children with food sensitivities are particularly affected. Parents have witnessed their young food-allergic children excluded from social events due to the extra care and supervision they require. Research on children with food allergies has confirmed that the food and social restrictions associated with food allergies can diminish their quality of life. A study conducted in 2003 in the United Kingdom found that children with a peanut allergy reported higher anxiety and an overall poorer quality of life than children with insulin-dependent diabetes.[71] These children reported more fear of an adverse event, felt more threatened by potential hazards within their environment, felt more restricted in their physical activities, and expressed more worry about being away from home.

"Families with food-allergic children must live with constant vigilance and fear," noted researchers who conducted a 2001 survey of parents of children with food allergies analyzing various quality of life measures.[72] Families of children with food allergies report significantly more negative perceptions of general health, greater distress and worry experienced by parents, and heightened limitations and interruptions to family activities than that experienced by other families. "Accidental exposures are common and occur both in the home and in locations such as schools, restaurants, and virtually every location where food is served. Families must diligently read food ingredient labels, a process with numerous pitfalls, and be prepared for treatment of reactions."[73]

Despite the challenges of living with a food sensitivity, a person's health and sense of well-being is enhanced following diagnosis and an elimination diet. The primary complaint of food-sensitive individuals has not been about the effort and inconvenience involved in avoiding the consumption of allergens but rather, that despite their best efforts, avoidance of allergens has been impossible to achieve.[74]

B. *When What You Do Not Know Can Hurt You: Problems Related to Allergen Avoidance and the Importance of Food Labels*

"When I learned to read five years ago in kindergarten,
I started with Dr. Seuss, Mother Goose, and ingredients labels."
Sarah Gitlin, age 10 (allergic to peanuts, tree nuts, and fish)[75]

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[70] The following are but a handful: Celiac.com (www.celiac.com), FAAN (www.foodallergy.org), Food Allergy Initiative (www.foodallergyinitiative.org), Food Allergy News for Kids and Food Allergy News for Teens (http://www.fankids.org/), Food Allergy Survivors Together (http://www.angelfire.com/mi/FAST/), PeanutAllergy.com (www.peanutallergy.com), and Parents of Food Allergic Kids (http://kidswithfoodallergies.org/eve).

[71] *See generally* N.J. Avery et al., *Assessment of Quality of Life in Children With Peanut Allergy*, 14(5) PEDIATRIC ALLERGY IMMUNOL. 378-82 (2003).

[72] *See* S.H. Sicherer et al., *The Impact of Childhood Food Allergy on Quality of Life*, 87(6) ANN. ALLERGY ASTHMA IMMUNOL. 461, 461 (2001).

[73] *See id.* at 461-63.

[74] FDA has acknowledged the impossibility of obtaining dependable allergen avoidance information given the current state of food labeling and food preparation and has advised people with severe food allergies to be sure to wear medical alert bracelets and carry epinephrine at all times. *See* Formanek, *supra* note 11; *see also* FDA, CPG on Cross-contact, *supra* note 56 ("Frequently [allergic reactions] occur because the presence of the allergenic substances in the foods is not declared on the food label."). Additionally, the absence of plain English labeling was one of the three primary issues addressed at a 2001 Public Meeting sponsored by FDA regarding food allergen labeling. *See* 66 Fed. Reg. 38,591, 38,591 (July 25, 2001).

[75] FDA, 2001 Public Meeting Transcript, *supra* note 44, at 223 (statement of Sarah Gitlin).

No cure exists for food sensitivities. As little as one-fifth to one-five-thousandth of a teaspoon of an offending food has been demonstrated to cause death.[76] The recent tragic death of a peanut-allergic fifteen-year-old, who—despite the prompt administration of adrenaline to treat anaphylaxis—died after kissing her boyfriend who had eaten a peanut butter snack, demonstrates the danger that even minute traces of allergens pose to certain individuals.[77] Whether and in what amount a food allergen may be consumed safely by a sensitive individual, as yet, is unknown and likely varies by individual.[78] Thus, the only prophylactic treatment available for people with food sensitivities is strict avoidance of the allergenic food.[79]

Unlike most medical treatments, treatment of a food sensitivity depends on the adequate disclosure of information possessed by third parties. The food label is the primary method by which information about product contents is conveyed to

[76] *See* FDA, *Food Allergies: Rare But Risky*, FDA CONSUMER MAG., May 1994, updated Dec. 2004, http://www.cfsan.fda.gov/~dms/wh-alrg1.html [hereinafter FDA, *Rare But Risky*].

[77] *See Teen With Peanut Allergy Dies After Kiss*, *supra* note 5.

[78] Evidence indicates significant variability in thresholds and concomitant symptoms among allergic consumers. *See, e.g.*, Hefle et al., *supra* note 4, at S70 ("The variability in symptoms is quite large both between individual patients and between different studies (groups of patients). Even individual patients display variable responses depending on such factors as the exposure dose to the offending food."); Hefle & Taylor, *supra* note 19, at 74 ("The precise threshold doses for allergenic foods have not been carefully investigated and are likely to be variable from one allergic individual to another. ... While this experiment clearly demonstrates that the threshold level is not zero, the threshold dose is quite low. Whether other allergenic foods have thresholds as low as those for peanuts remains to be determined."); Taylor, *Emerging Problems*, *supra* note 13 ("Celiac sufferers are thought to react to ingestion of trace amounts of the offending food, although the threshold dose has not been carefully established."); *see also* CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN), FDA, THE THRESHOLD WORKING GROUP, DRAFT REPORT, APPROACHES TO ESTABLISH THRESHOLDS FOR MAJOR FOOD ALLERGENS AND FOR GLUTEN IN FOOD (June 15, 2005), *available at* http://www.cfsan.fda.gov/~dms/alrgn.html [hereinafter CFSAN, FDA, THRESHOLD WORKING GROUP, DRAFT REPORT]:

> The specific symptoms and severity of an allergic reaction are affected by the concentration of allergen, route of exposure, and the organ systems involved. ... The severity of an allergic reaction is affected by several factors that include genetic predisposition (atopy), age, type of food allergen, nature of any food processing, environment, and physiological conditions (Taylor and Hefle, 2001; Sampson, 2003; Maleki, 2004). For example, exercise, medications (e.g., non-steroidal anti-inflammatories), alcohol consumption, and asthma may enhance the severity of an allergic reaction (Sampson, 2005). ... Numerous studies have described alterations in allergens as a result of processing or cooking. Various types of processing (heating, milling, fermentation, etc.) may alter the antigenic properties of allergens because these processes can affect the 3-dimensional structure of proteins and thus the IgE binding epitopes. ... The nature of the testing material is very important, as this can enhance or diminish the overall immunogenicity of the native allergen (Beyer et al., 2001; Maleki et al., 2003). The matrix used (e.g., fatty substances) can delay absorption, thus affecting the time interval to a reaction, or may affect the intrinsic allergenic properties of the food.

One Allergen Labeling Survey respondent describes the variability she personally has observed with regard to thresholds and the severity of adverse reactions in this way:

> I have found my threshold for different foods is also affected by my overall health and stress level on that particular day, and the percentage of the food that is allergen in relation to the total meal. For example one cheese stuffed jalapeno is usually fine if I eat it with a full meal, but if eaten alone would cause a severe reaction. Half a hamburger bun with a meal causes less reaction than a communion wafer at church.

E-mail from MP to Author, Response to Allergen Labeling Survey (Jan. 10, 2005).

[79] *See, e.g.*, Sampson & Metcalfe, *supra* note 4, at 2843; *see also* FALCPA § 202(2)(B)-(C). Some symptoms of immediate hypersensitivity allergic reactions can be mitigated after-the-fact through use of antihistamines and epinephrine.

consumers.[80] The FALCPA was passed in response to the fact that the information contained on the label has been inadequate to meet the needs of food-sensitive individuals.

Few people without thorough research would suspect that corn protein is found in iodized salt and orange juice, that products labeled "non-dairy"[81] and bread may include milk protein, that soy protein may be present in canned tuna, and that turkey[82] and cheese[83] may contain wheat protein. In today's world of great scientific and technological advances in food production—where most food is processed (rendering ingredients unknown unless communicated to consumers)[84] and even nonprocessed foods can be

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[80] In 1995, food allergy experts from around the world discussed the critical importance of the food label and what standards food labels in the global marketplace should follow during a conference sponsored by FAO (the Consultation):

> The food label is the vehicle used by the consumer, and the retailer, for that matter, to obtain information about a product at the point of purchase. If the label is deficient or not transparent as to contents, the health of the consumer may be at risk. The label is the vehicle for risk communication with consumers, probably the most effective vehicle available. It is doubtful that experts involved with the treatment of individuals suffering from a food allergy, hypersensitivity or intolerance can do other than advise their patients to avoid certain specific foods or ingredients. They may have limited information on specialized products or refer patients for diet counseling and design to eliminate problem foods or substances. Consumers, for their part, must educate themselves about their particular needs. They must be prepared to exercise extreme caution when approaching a new food product and deny themselves any questionable choice. Ultimately, however, governments have the responsibility, as they approve an ever increasing number of technological innovations, ingredient modifications and the manipulation of familiar foodstuffs, to meet the information needs of consumers and ensure even more transparency about the food products they allow into national markets.

Bousquet et al., *supra* note 4, Annex 4, at 9. *See also* 44 Fed. Reg. 75,990, 75,991-92 (Dec. 21, 1979) ("The purpose of food labeling is to enable consumers to select and use products that meet their individual needs and preferences. To achieve that purpose, labeling must provide sufficient information to enable the public to identify foods and their characteristics, including their ingredients and nutritional value.").

[81] *See, e.g.*, Formanek, *supra* note 11 ("Current labeling guidelines allow the use of 'nondairy' when the foods contain milk byproducts.").

[82] Meat and poultry products increasingly are a source of concern to food-sensitive individuals. The use of ingredients derived from soy, milk, wheat, and egg in meat and poultry products has been increasing as "manufacturers search for ways to lower product fat levels and provide customers with an array of differently priced proteins." *See* Bodendorfer et al., *supra* note 46.

[83] Wheat flour may be used as an anticlumping agent for shredded cheese or a thickener for melted cheese, and Roquefort cheese may be contaminated by bread due to the unique way in which it is made.

[84] In 1979, FDA publicly recognized the changing nature of food products and the difficulty consumers have in determining the contents of products by simply looking at the product or relying on food "standards of identity" that had been established by the agency:

> Since [the FDCA was] enacted, significant changes have occurred in the food industry, in Americans' attitudes toward the food supply, and in their dietary habits. Widespread and rapid advances in food processing and distribution have made a greater variety of foods available to more people. This new technology has so increased the number of processed foods on the market that such products now account for more than half of the American diet. ... The central point that emerges from the comments is this: as the number of processed foods and the number of unfamiliar ingredients in these foods has grown, the task of interpreting names of ingredients and their functions has become extremely difficult for many consumers.

44 Fed. Reg. 75,990, 75,991, 76,000 (Dec. 21, 1979).

contaminated with allergens[85]—virtually any food item may have the potential to poison a food-sensitive individual.

For food-sensitive consumers, navigating the approximately 300,000 food labels[86] in the U.S. marketplace and hundreds of restaurant menus becomes a critical investigation of medical necessity.[87] Consumers have consulted with physicians and nutritionists, contacted manufacturers, and scoured Internet resources to continually refine their knowledge about ingredient and product safety. They have found that the search required to obtain the information upon which their safety and well-being depends can be time consuming,[88] research intensive, and as likely as not, unsuccessful. The problem of inadequate labeling has affected millions of Americans—not only people with food sensitivities themselves, but also their families, friends, and caregivers.[89]

This subsection discusses some key obstacles that have impeded allergen-free eating: confusing "usual or common" names of ingredients, hidden ingredients, cross-contamination during processing or preparation, the inability or unwillingness of manufacturers to reveal information about product composition or preparation,[90] mislabeling,

[85] Contamination of nonprocessed foods can occur during the preparation and/or packaging of the items. It is possible also to introduce allergens to otherwise allergen-free foods through genetic engineering. *See generally* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,987, 22,991 (May 29, 1992); FDA, *Rare But Risky*, *supra* note 76; FDA, Biotechnology, Food Labeling; http://www.cfsan.fda.gov/~lrd/biotechm.html#label (last visited Feb. 21, 2006) (lists FDA guidance documents related to bioengineered foods).

Allergens may further contaminate produce through waxes, pesticides, and fertilizers. FDA encourages that the presence of colors, preservatives, and waxes be declared at the point of sale of fresh fruits and vegetables, but it is unclear to what extent this position has been actively supported or enforced. FDA has not sought statutory authority to impose allergen declaration requirements for pesticides and fertilizers. *See* 44 Fed. Reg. 75,990, 76,000 (Dec. 21, 1979).

In 1998, the Environmental Protection Agency (EPA) gave blanket permission for food to be used in pesticides when it issued an exemption to its normal tolerance requirements for residues on crops. In recognition of the allergenicity problems this new position posed for consumers, EPA continued to require compounds containing the eight major food allergens to undergo the typical approval procedure. *See* 63 Fed. Reg. 66,999 (Dec. 4, 1998) ("This document establishes an exemption from the requirement of a tolerance for residues of *any edible food commodity (except for peanuts, tree nuts, milk, soybeans, eggs, fish, crustacea, and wheat)* used as a pesticide, when applied in accordance with good agricultural practices, in or on all food commodities.") (emphasis added); 70 Fed. Reg. 1357 (Jan. 7, 2005) (stating the final rule establishing an "exemption from the requirement of a tolerance for residues of peanuts, tree nuts, milk, soybeans, eggs, fish, crustacea, and/or wheat when used as inert or active ingredients in pesticide products, for certain use patterns.").

[86] H.R. REP. NO. 108-608, at 9.

[87] This point was stressed by Representative Lowey, the primary sponsor of the FALCPA in the House, when she spoke on the floor to urge the FALCPA's passage. 150 CONG. REC. H6100 (July 20, 2004) (statement of Rep. Lowey) ("Navigating insufficient labels is much more than an irritation for the millions with food allergies. It is a matter of life and death.").

[88] A mother of twin twenty-month-old boys with multiple allergies expressed frustrations typical of food-sensitive individuals in response to the Allergen Labeling Survey: "I can tell you first hand that it is a part time job reading and investigating food labels." E-mail from DT to Author, Response to Allergen Labeling Survey (Jan. 10, 2005).

[89] As the parent of a peanut-allergic child notes: "With the purchase of food for an allergenic individual, there is a ripple effect. For the millions of allergic people, there are tens of millions who are affected. Think of the number of people who are involved in feeding a single child." FDA, 2001 Public Meeting Transcript, *supra* note 44, at 168 (statement of Victoria Geduld).

[90] The author does not suggest that food manufacturers have intended to deceive consumers or subvert existing law. The state of asymmetrical information between food manufacturers and consumers that historically has existed can be attributed to numerous factors, including: ingredient disclosure can be technically accurate but nonetheless unintelligible; the law has not required full disclosure of ingredients; good manufacturing practices (GMPs) have not been updated to account for allergen concerns; there has been a lack of awareness in industry of food allergies as a priority food safety concern; the cost of improving practices and disclosure to accommodate people with food sensitivities can be sizeable; and manufacturers may be reluctant to reveal information that they view as proprietary.

and insufficient measures taken by restaurants to prepare and help consumers identify allergen-free foods. These impediments to following an allergen-avoidance diet were the primary concerns that informed the drafting of and debate surrounding the FALCPA and supported its ultimate passage.

1. *Food Labels Have Been Incomprehensible: The Problem of "Usual or Common" Ingredient Names*

The FDCA requires that all ingredients appearing on the food label be listed according to their "common or usual name."[91] For many ingredients, the "common or usual" name of a food hardly is common or usual. Consumers have long desired more easily comprehensible ingredient terminology.[92]

Given the following list of food ingredients—bulgur, couscous, durum, farina, modified food starch, hydrolyzed vegetable protein, kamut, spelt, artificial flavors, semolina, and buckwheat—few people would expect that the only ingredient in this list that is certain *not* to contain allergenic wheat protein is the one ingredient actually containing the word "wheat": buckwheat. Terms like albumin, lecithin, livetin, lysozyme, emulsifier, globulin, ovalbumin, and vitellin indicate the presence of egg protein. And the words caramel color, casein, caseinate, high protein flavor, lactalbumin, natural flavoring, solids, and whey can signal the presence of milk protein in a food product.[93]

Even diligent label readers can find these terms mystifying. Consumer confusion was demonstrated in a study published in the American Academy of Allergy, Asthma and Immunology in 2002 that reported most parents of food-sensitive children are unable to identify common allergenic food ingredients.[94] Fully ninety-three percent of parents of children with a milk allergy and seventy-eight percent of parents of children with a soy allergy could not correctly identify commercial products containing the offending ingredient based on ingredient statements. Nearly half of the parents of children with peanut allergies failed to identify labels containing peanuts. Researchers noted that the study, in fact, may have overestimated parents' abilities to discern allergens in food labels because it was performed in a food allergy clinic where half of the participants had undergone a prior consultation and the controlled surroundings of the clinic were more conducive to label reading than "the realities of shopping for and selecting appropriate products in the food market setting." The study concluded "these results strongly support the need for improved labeling with plain-English terminology and allergen warnings as well as the need for diligent education of patients about reading labels."[95] According to Anne Muñoz-Furlong, founder and CEO of the Food Allergy

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[91] 21 U.S.C.A. § 343(i).

[92] *See, e.g.*, 44 Fed. Reg. 75,990, 75,995 (Dec. 21, 1979) (discussing results of a survey conducted by FDA in 1978 of consumers regarding the food label and stating that "the most frequently cited problem was the use of technical and chemical names in the ingredient list, noted by a third of those expressing problems with labels."); *id.* at 75,993 ("The majority [of commenters on FDA's proposed rule regarding ingredient labeling] urged that ingredient labeling be precise and easily understood by the average consumer."). The FALCPA cites concerns about confusing ingredient terminology as a primary impetus for labeling reform. *See* FALCPA § 202(5)(B), 21 U.S.C.A. § 343(note) ("[I]n some cases, the common or usual name of an ingredient may be unfamiliar to consumers, and many consumers may not realize the ingredient is derived from, or contains, a major food allergen.").

[93] For more information regarding other common and usual names for the Big Eight allergens, see generally H.A. Steinman, *Hidden Allergens in Foods*, 98(2) J. ALLERGY CLIN. IMMUNOL. 241-50 (1996), *available at* http://www.allergyadvisor.com/hidden.htm.

[94] *See* Preeti Joshi et al., *Interpretation of Commercial Food Ingredient Labels by Parents of Food-Allergic Children*, 109(6) J. ALLERGY CLIN. IMMUNOL. 1019, 1020 (2002).

[95] *Id.*

and Anaphylaxis Network (FAAN), this study "confirms what we've known for quite some time—that ingredient statements are written for scientists and regulators, not for the average consumer."[96]

Scouring ingredient labels for dozens of terms that might appear in lengthy ingredients lists can be time consuming (especially when the individual has multiple food allergies), and the number and complexity of terms invites mistakes. These prolific and technical names have contributed to the challenge of eating out by making it difficult to effectively explain to food service staff willing to check ingredient labels exactly what ingredients they should look for on the labels.

Difficulties have been greater for nonEnglish speakers and the population with the highest incidence of food allergies—children. Children often are incapable of deciphering a label themselves.[97] And educating all those who help care for children—daycare providers, teachers, babysitters, relatives, and the parents of friends—can be infeasible as well as insufficient, because only one overlooked or forgotten ingredient term has the potential to produce serious health effects.[98]

As a parent of an allergic child explained at a 2001 Public Meeting concerning the labeling of food allergens held by FDA:

> Plain English in the labeling of food ingredients is critical to empowering individuals to take control of their condition, restoring a certain amount of independence and equally as important is the power and freedom it gives to friends and relatives [and] non-food allergic individuals to make responsible selection of food items to share with or entertain their food allergic friends and relatives.[99]

Indicative of the dangers of unintelligible labeling, a 2001 study of thirty-two people who died of food-induced anaphylactic shock found that seventy-seven percent of fatal allergic reactions occurred outside the home,[100] including nine incidents at school, nine incidents in food service establishments, one incident at camp, one at a dance class, and

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[96] FAAN, Consumers Find Food Allergen Labeling Confusing, Inconsistent (June 28, 2002), http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/06-28-2002/0001756038&EDATE=.

[97] This argument was one that Representative Lowey emphasized while advocating for passage of the FALCPA. *See, e.g.*, 150 CONG. REC. H6100 (July 20, 2004) (statement of Rep. Lowey) ("[I]f adults cannot easily determine terms like whey, casein, lactose, how can you expect food-allergic children to remember so many complicated terms? The answer is, we cannot and we should not.").

[98] One parent of a milk-allergic son who responded to the Allergen Labeling Survey illustrates this problem with a personal example:

> The other problem was when my husband or someone else says, "No, I read the label, there is no milk in [this product]." I then read the label and say, "No, he cannot have it, there is whey protein in it, which is milk." I made the mistake of letting [my son once] have some salad dressing ... which contained whey in it, and I noticed he was clearing his throat continually. I looked at him and noticed his lips were swelling and hives were breaking out all over his body. At this point I was aware he had a milk allergy but was never told of all the other names it could be called. I am now very educated—which I had to do. The problem is that mistakes like this could cost my son his life. I truly feel that labels need to be in plain print with the ingredients printed clearly right after it.

E-mail from DT to Author, Response to Allergen Labeling Survey (Jan. 10, 2005). Thousands, if not millions, of Americans have similar stories and share DT's anxiety and frustration.

[99] FDA, 2001 Public Meeting Transcript, *supra* note 44, at 222 (statement of Kimberly Johnson Scott).

[100] *See* Bock et al., *supra* note 5, at 192. More than ninety percent of the fatalities were caused by an adverse reaction to peanuts and tree nuts. *Id.* at 191. Four individuals appeared to have received epinephrine in a timely fashion and yet did not survive. *Id.* at 193.

one at daycare.[101] The researchers concluded that confusing food labels contributed to these deaths: "It is our opinion that only more stringent food-labeling requirements and improved education can bring an end to these tragic fatalities. ... In addition to education of the allergic individual, it is imperative that we improve the knowledge of families, friends, caregivers, schools, restaurants, and the general public."[102]

Members of FAAN—those individuals most likely to know how to effectively read the food label, according to the 2002 label study—have confirmed that labels have been dangerously inadequate.[103] A survey of 550 attendees at a conference held by FAAN in 2000 revealed that eighty-eight percent of respondents believed food labels then on the market were not easy to understand, and ninety-nine percent of respondents disagreed with the statement that labels could be understood by a seven-year-old. Additionally, ninety-eight percent believed then-current food labels could not be easily understood by a babysitter, teacher, or other individual giving information or food to a child.

2. *Food Labels Have Been Incomplete: The Problems of Hidden Ingredients, Cross-contamination, Advisory Labeling, and Manufacturer Ignorance and Resistance*

Even more problematic than the fact that what is on the food label has been hard to decipher is the fact that some information crucial to allergen avoidance has not appeared on the label at all. Food-sensitive individuals, in the words of a petition drafted by nine state Attorneys General, have "often fallen prey to ambiguous or insufficient ingredient labeling."[104] Of the 550 individuals who participated in the 2000 FAAN food labels survey, ninety-eight percent said the information on food labels was not enough to allow them to make effective safety decisions.[105] Four out of five respondents reported calling manufacturers to obtain more product information.[106] According to FAAN's Muñoz-Furlong, "our members are one of the best educated, highly motivated people in the food allergy community and this country. If they are struggling with these labels, I can only imagine what the general public is going through."[107] One food-allergic consumer asserts that inadequate information is her "biggest frustration" with her allergies. "There is nothing like having to pass up a food because you just don't know if it is safe or not."[108] A parent of a soy-allergic teenager describes the dilemma of insufficient information disclosure on the food label in this way:

> We find many processed items not labeled for soy in fact cause a reaction. So we stay away from 'types' of processed foods. You develop an instinct, but it

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[101] *See id.* at 192. For instance, a three-year-old child reacted fatally to milk at day care. A six-year-old died after ingesting fish protein during lunch at school.

[102] *Id.* at 193.

[103] *See* FDA, 2001 Public Meeting Transcript, *supra* note 44, at 34 (statement of Anne Muñoz-Furlong, FAAN).

[104] Eliot Spitzer et al., Citizens Petition for Rules Regarding the Labeling and Manufacture of Foods Containing Allergenic Substances, FDA Docket No. 00P-1322 (May 26, 2000), *available at* http://www.idfa.org/membonly/reg/labeling/allergen.pdf [hereinafter Nine State Attorneys General Citizens Petition].

[105] *See* FDA, 2001 Public Meeting Transcript, *supra* note 44, at 34 (statement of Anne Muñoz-Furlong, FAAN).

[106] *See id.* at 141.

[107] *Id.*

[108] E-mail from MP to Author, Response to Allergen Labeling Survey (Jan. 10, 2005).

> is very wrenching to live that way. I compare it to playing a jack in the box. The music goes along and then 'pop' goes the unexpected exposure.[109]

What food labels omit are so-called "hidden ingredients" and information regarding inadvertent allergen contamination of otherwise-safe food. Two methods viewed as supposedly solving this lack of critical information on the label—contacting food manufacturers directly and "advisory" labeling—all too often provide more aggravation than relief.

a. *Hidden Ingredients*

Not all ingredients are specifically identified on the food label. Allergens have been commonly disguised within more general, seemingly innocuous terms.[110] Words like "natural flavors," "artificial flavors," and "spices" can conceal the presence of allergens. As a parent of food-allergic children emphasized in the Labeling Survey, "I already know the words I am looking for (to avoid) on labels. It's just those questionable listings! What exactly ARE the ingredients for 'flavorings'? We just usually don't eat these products (and there are A LOT of them), it's not worth the risk."[111]

Federal law has sanctioned two exceptions to general labeling requirements that have deprived allergic consumers of the information they need to make informed decisions. The statement of findings in the FALCPA cites these "loopholes" as a primary reason for the legislation.[112]

First, the FDCA has provided since its inception that "spices, flavorings, and colors" may be designated by those generic terms on the food label rather than naming each food source component.[113] Second, FDA regulations have exempted incidental additives, such as processing aids, from ingredient declaration when they are present in a food at "insignificant" levels and do not have a technical or functional effect in the finished product.[114] FDA, thus, has recognized that "in some cases food labels may not provide consumers with food allergies with information about all the ingredients that are in the foods that they eat."[115]

In addition to the spices, flavorings, and colorings and incidental additives exemptions, manufacturers were not required to disclose information about the source of certain listed ingredients, nor the way in which the ingredient was processed. For example, "starch" and "modified food starch" can be derived from corn or wheat. "Hydrolyzed vegetable protein" may contain a variety of grains, vegetables, or animal products, many of which contain the proteins of known allergens. Manufacturers simply could list "caramel color" on the label without identifying whether the ingredient was produced using sugar or wheat. "Lecithin" and "gelatin," which also may contain a variety of allergenic proteins, did not require elaboration.[116] Whether offending proteins

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[109] E-mail from CM to Author, Response to Allergen Labeling Survey (Jan. 12, 2005). In the words of another Allergen Labeling Survey respondent, "I find it very frustrating finding food that my boys can have, and some I choose not to feed them because they are just too vague."). E-mail from DT to Author, Response to Allergen Labeling Survey (Jan. 10, 2005).

[110] *See, e.g.*, Taylor, *Emerging Problems*, *supra* note 13 ("As with IgE-mediated food allergies, the cereal grains involved in celiac disease can be 'hidden' in foods as a result of the lack of source labelling [sic] of certain ingredients.").

[111] E-mail from CM to Author, Response to Allergen Labeling Survey (Jan. 23, 2005).

[112] *See* FALCPA § 202(5)(C), 21 U.S.C.A. § 343(note).

[113] 21 U.S.C.A. § 343(g), (i).

[114] 21 C.F.R. § 101.100(a)(3); *see also* 44 Fed. Reg. 75,990, 76,000 (Dec. 21, 1979).

[115] 66 Fed. Reg. 38,591, 38,591-92 (July 25, 2001).

[116] *See* Hefle & Taylor, *supra* note 19, at 73.

are removed from an allergenic food during the refining, distillation, and other processes involved in producing ingredients varies based on the type of process employed in each case.[117] Even where a food's allergenicity is reduced during processing, remaining protein residues can be enough to trigger adverse reactions in highly-sensitive individuals. And some ingredient terms are more expressly deceptive, such as the term "egg substitute," which may be used to describe ingredients that, nevertheless, can contain egg protein.[118]

Incomplete labeling of sources produces numerous headaches and perils for consumers. Research-savvy consumers with celiac disease, for instance, discover through research that dextrin may contain gluten, whereas maltodextrin is thought to be safe for consumption. Modified food starch in products manufactured in the United States tends to be derived from corn, whereas a product containing modified food starch that was produced overseas is more likely to contain wheat.

Without knowing the source of these ubiquitous ingredients, people with food allergies must either unnecessarily avoid a host of products or attempt to determine product safety through risky trial and error.

b. *Cross-contamination*

Even if a product's ingredients do not contain a particular allergenic protein, the food label can mislead because the label does not reflect whether a product has become contaminated by allergens during the manufacturing process.[119] "Contamination of food with undeclared allergens is what makes life so fearful for people with severe allergies," Dr. Michael Jacobson of the consumer watchdog group Center for Science in the Public Interest (CSPI) stated at the 2001 Public Meeting held by FDA addressing food allergen labeling. "They live in terror that a food contains an allergen not listed on the label."[120] As a petition submitted by nine state Attorneys General observes, FDA regulations establish good manufacturing practices (GMPs) "aimed at preventing the adulteration of food with contaminants such as microorganisms or hazardous chemicals. ... [H]owever, foods that contain even trace amounts of allergenic substances can be as deadly to food-allergic consumers as adulterated food is to ordinary consumers."[121] At least one state legislature even has proposed a resolution urging FDA to create guidelines to minimize cross-contact.[122] The serious concerns posed by the inadvertent introduction of allergenic ingredients into foods also prompted FDA to name cross-contamination as one of the principal issues to be discussed at the 2001 Public Meeting on the topic of food allergens.[123]

[117] For instance, the degree of hydrolysis for hydrolyzed vegetable protein affects the ingredient's ultimate allergenicity. *See, e.g.*, Bodendorfer et al., *supra* note 46.

[118] *See* Joshi et al., *supra* note 94, at 1019.

[119] *See generally* Office of Scientific Analysis and Support, CFSAN, FDA, Food Allergen Partnership (Jan. 2001), www.cfsan.fda.gov/~dms/alrgpart.html [hereinafter FDA, Food Allergen Partnership] ("Food allergens may become a part of a food through unintended routes. Examples of these are inadequate scheduling to protect against cross-contamination; improper cleaning between different products without analytical verification methods; use of allergen containing rework in non-allergen containing products. A firm should address these critical control points of manufacturing in an allergen control plan.").

[120] FDA, 2001 Public Meeting Transcript, *supra* note 44, at 96 (statement of Michael Jacobson, Co-Founder and Executive Director, Center for Science in the Public Interest (CSPI)).

[121] Nine State Attorneys General Citizens Petition, *supra* note 104, at 9.

[122] *See* House Joint Resolution 2 (Delegate Stern), United States Food and Drug Administration—Labeling Laws and Policies Relating to Allergenic Ingredients in Food, Maryland General Assembly (2001 Session), Department of Legislative Services, *available at* http://mlis.state.md.us/PDF-Documents/2001rs/fnotes/bil_0002/hj0002.PDF (asking FDA to, *inter alia*, "create guidelines to prevent the migration of allergenic ingredients from one food product to another during processing and preparation.").

[123] *See* 66 Fed. Reg. 38,591, 38,591 (July 25, 2001).

Cross-contamination can occur in numerous ways.[124] A product without allergens may be processed on the same line as allergen-containing products,[125] produced utilizing utensils and equipment that has not been cleaned sufficiently after touching allergens,[126] or exposed to dust from allergenic foods processed nearby.[127] Manufacturers may "rework" some unfinished food products or components into other, different food products without identifying the reworked source foods on labels.[128] Allergen-containing substances like wheat flour may be used to prevent foods such as candies from sticking to machinery during processing.[129] And although a particular flavor itself may not contain a major allergen, it may be delivered onto food using a "spray dry flavor system" that uses a major allergen to "carry the flavor" to the product.[130]

Such practices have been widespread in the food industry. In 1998, FDA commissioned a partnership with the departments of agriculture in Minnesota and Wisconsin (the Partnership) to study the cross-contamination of undeclared allergen residues in selected Minnesota and Wisconsin firms.[131] The study found that less than fifty percent

[124] *See generally* FDA, Advice to Consumers, *supra* note 5 (defining "cross-contact" as "the inadvertent introduction of an allergen into a product" and explaining that cross-contact generally is the result of environmental exposure during processing or handling).

[125] The Food Allergen Partnership found that opportunities for cross-contamination during production are great:

> Product changeover presents an unintentional opportunity for product that contains an allergen to contaminate a product that does not contain that particular allergen, thus resulting in an undeclared allergen. Equipment cleaning is a critical allergen control point for the production of a non-allergen-containing product following product changeover. ... [The study found that p]roduction was frequently not scheduled or sequenced for allergen control. Bakeries would schedule production "First-in / First-out" or based on product color. ... Many firms did not have dedicated equipment for allergen and non-allergen product lines. Non-dedicated product lines were observed to be inadequately cleaned between products, rinsing equipment with water alone or only cleaning equipment at the end of the production day.

FDA, Food Allergen Partnership, *supra* note 119.

Allergy expert Dr. H.A. Sampson provides an example of the pervasive and perilous nature of cross-contamination:

> Another child allergic to milk is given a box of assorted "dairy-free" fruit-flavored popsicles. He enjoys the orange one and the red one. The blue one causes a severe reaction, requiring intervention in an intensive care unit. The physicians are aware that food dyes very rarely cause reactions. On detailed inquiry, the manufacturer explains that "we always run the blue ones after the creamsicles."

Sampson, *From Biology Toward Therapy*, *supra* note 45.

[126] *See* FDA, Food Allergen Partnership, *supra* note 119 ("In many establishments common utensils were used in production of allergen and non-allergen containing products ... . Cross-contamination also occurred when baking sheets were reused without cleaning, or when baking parchments were reused. Several firms [were] reported to reuse baking parchment six to ten times.").

[127] *See* FDA, CPG on Cross-contact, *supra* note 56.

[128] *See* FDA, Food Allergen Partnership, *supra* note 119 ("In an ideal situation there would not be rework or re-feed. Thirty-seven of the 85 firms inspected utilized rework. Of firms that utilized rework, 40 percent of Minnesota and 55 percent of Wisconsin firms had product that tested positive for undeclared allergen residues.").

[129] *See, e.g.*, Diane Eve Paley, Past President Celiac Sprue Association (CSA), Celiac Disease and Generic Drugs, Remarks Before the Digestive Disease National Coalition (DDNC) (Nov. 2004), *available at* http://www.csaceliacs.org/DDNC/CeliacDiseaseandGenericDrugs.php (mentioning that cross-contamination can occur through "flour dusting of product transfer lines" and that cross-contamination is a "major concern" of people with celiac disease).

[130] FDA, 2001 Public Meeting Transcript, *supra* note 44, at 152-54 (statements of John Hallagan, General Counsel, Flavor and Extract Manufacturers Association and the International Association of Color Manufacturers, and Ken Falci, Director, Office of Scientific Analysis and Support, CFSAN, FDA).

[131] *See* FDA, Food Allergen Partnership, *supra* note 119.

of firms inspected utilized some procedures to control cross-contamination. Ninety-six percent of firms did not use analytical testing methods to verify that cleaning and sanitation procedures eliminated allergen residues. Three-fourths of Minnesota firms did not employ Sanitation Standard Operating Procedures that were proven effective and were followed consistently, and less than four percent of the firms inspected employed personnel dedicated to allergen control.

A different study, presented at the 2004 Annual Meeting of the American Academy of Allergy, Asthma and Immunology, found that fifteen percent of products containing entirely nonwheat ingredients nevertheless contained wheat proteins, likely due to cross-contamination.[132] An Oregon Department of Agriculture study found that twenty-three percent of chocolate candies studied that were not supposed to contain peanuts, in fact, contained peanut protein. University of Nebraska researchers discovered peanut allergens in four out of nineteen packaged foods that did not list peanuts as an ingredient.[133]

In 1999, the Partnership brought together by FDA identified numerous techniques to prevent cross-contamination. These methods include dedicating certain production lines to foods containing a specific type of allergen, scheduling the processing of allergen-containing foods on separate days of the week than products that do not contain allergens, running allergen-containing products on lines after allergen-free products have been run, heightening sanitation processes, verifying sanitation before running nonallergenic products, increasing employee training about allergens, appropriately labeling food articles that previously have been processed and are being reworked into new products, and making improvements to equipment and system designs.[134]

As the Partnership study indicates, however, few manufacturers have employed such techniques fully and consistently to prevent cross-contamination. This likely is due in part to the fact that the food GMP regulations have not been revised since 1986[135]—it was not until 2005 that FDA first considered amending the food industry GMPs to specifically address cross-contamination prevention,[136] and FDA factory inspections until recently have not scrutinized allergen management.

c. *Advisory Labeling*

To compensate for the uncertainty regarding ingredients and inadequate procedures to control cross-contamination, and in an effort to help shield themselves against liability, many companies have over-labeled products by placing advisory or precautionary statements on labels. Manufacturers in recent years increasingly have utilized warning statements such as "may contain X Allergen," "processed on shared equipment," or "this product is produced in a factory that produces products containing X Allergen."

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[132] *See* Melissa Schorr, *Study: Wheat-Free Foods May Contain Wheat* (Mar. 22, 2004), http://my.webmd.com/content/article/84/98081.htm.

[133] *See* FDA, 2001 Public Meeting Transcript, *supra* note 44, at 102 (statement of Michael Jacobson, CSPI).

[134] *See* FDA, Food Allergen Partnership, *supra* note 119; *see also* FDA, 2001 Public Meeting Transcript, *supra* note 44, at 76-79 (statement of Lisa Katic, Director of Scientific and Nutrition Policy, Grocery Manufacturers of America (GMA)).

[135] *See* CFSAN, FDA, FOOD CGMP MODERNIZATION—A FOCUS ON FOOD SAFETY (Nov. 2, 2005), *available at* http://www.cfsan.fda.gov/~dms/cgmps3.html [hereinafter CFSAN, FDA, FOOD CGMP MODERNIZATION REPORT]; 51 Fed. Reg. 22,458 (June 19, 1986).

[136] *See* CFSAN, FDA, FOOD CGMP MODERNIZATION REPORT, *supra* note 135. This report contains recommendations for amending GMPs to establish, among other things, mandatory training for food production personnel with regard to allergens, requirements for a written allergen control plan, and accompanying recordkeeping requirements. FDA is seeking comments on these and other issues in anticipation of publishing a Notice of Proposed Rulemaking.

One food-allergic consumer encountered this problem of over-labeling, for instance, when she discovered that a bag of plain raisins she was about to eat stated on the label that it "may contain peanuts."[137]

A survey of FAAN members found that precautionary labeling was their number one labeling concern.[138] FDA emphasized the problems of advisory labeling in its 2001 Public Meeting on food allergen labeling, where one of three panels focused exclusively on the topic.[139]

One problem with such advisory statements is that they may be employed in place of compliance with GMPs or adequate disclosure of source ingredients, thus unnecessarily further limiting accurate consumer information and, hence, choice. Indeed, in recent years, two food industry trade associations, the Grocery Manufacturers of America (GMA) and the National Food Processors Association (NFPA), have urged their members to not use advisory labeling in lieu of following GMPs.[140]

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[137] *See* FDA, 2001 Public Meeting Transcript, *supra* note 44, at 92 (statement of Anne Muñoz-Furlong, FAAN). Similarly, a respondent to the Allergen Labeling Survey has found that manufacturers may erroneously declare the presence of an allergen even when it is well known that the ingredient in question, in fact, does not contain allergenic protein:

> [T]oday there are also "voluntary" warnings appearing all over the place. We have eliminated consuming several safe food choices because of these "warnings." A favorite broth that contains soy oil ... [that] we have consumed with no reaction for 15 years, now has a completely unnecessary "voluntary" warning below [the] ingredients that reads, "contains soy." I called the company. They were very uneducated. But, after speaking with two people I was told that the ingredient soy oil prompted the voluntary warning. I explained this only unnecessarily scares the soy allergic if the ingredient prompting the warning is only soy oil. I explained that although I appreciated the company voluntarily trying to alert consumers to allergens with the warning such as "contains soy" it was incorrect to do so for soy oil because soy oil does not contain soy protein.

E-mail from CM to Author, Response to Allergen Labeling Survey (Jan. 11, 2005).

[138] FDA, 2001 Public Meeting Transcript, *supra* note 44, at 93 (statement of Anne Muñoz-Furlong, FAAN).

[139] More than twenty years earlier, FDA had noted similar problems created by manufacturer use of "and/or" labeling in ingredient lists that gave manufacturers the flexibility to modify food ingredients without altering product labels. In 1976, FDA issued regulations (21 C.F.R. § 101.4(b)(14)) limiting the permissible use of "and/or" statements to declare fats and oils to when those ingredients are not predominant in the final food product. In 1979, FDA recognized that this treatment of "and/or" labeling still was not ideal, citing the same reasons that advisory labeling is criticized:

> There appears to be at least one problem with the present system for declaring fats and oils: it may result in the listing of ingredients that are not actually present. As a result, it may *narrow the choice of products* available to people who wish to avoid certain substances. Thus, although "and/or" labeling does not cause health problems, it *does not allow those people suffering from allergies or other medical conditions to deal most effectively with their problems*. The agencies recognize and sympathize with those individuals who may be allergic to the protein fractions in some fats and oils. ... Agencies are also aware of religious concerns and personal preferences centering on the use of certain fats and oils. However, even if the use of "and/or" labeling were eliminated, there still would be no guarantee that foods containing more desirable fats and oils would be available. Moreover, the requirement for more specific labeling could impose higher costs on all consumers by restricting manufacturers' ability to respond to marketplace factors (availability and price) without having to change their foods' labels. Finally, if there is a significant need for products containing only a specific fat or oil, the competitive marketplace is likely to make them available (usually at a premium price).

44 Fed. Reg. 75,990, 75,999 (Dec. 21, 1979) (emphasis added). In an Advanced Notice of Proposed Rulemaking, FDA stated it proposed to limit "and/or" labeling to fats and oils that constitute less than ten percent of the final product on a dry weight basis.

[140] *See* FDA, 2001 Public Meeting Transcript, *supra* note 44, at 74, 82-83 (statements of Lisa Katic, GMA and Regina Hildwine, Senior Director Food Labeling and Standards, Regulatory Affairs, National Food Processors Association (NFPA)); *see also* Food Allergy Issues Alliance, Food Allergen Labeling Guidelines (May 22, 2001), *available at* http://www.gmabrands.com/publicpolicy/docs/whitepaper.cfm?DocID=770& (on file with author) [hereinafter Alliance Voluntary Guidelines].

Over-use of advisory labeling also can perversely cause people to ignore the warnings altogether. "Because of the proliferation of 'may contain' statements," Muñoz-Furlong notes, "the integrity of all precautionary labels [is] being questioned by consumers."[141] Some physicians, in fact, have instructed patients to ignore precautionary labeling, which they view as disclaimers employed to protect manufacturers, not consumers.[142]

A food allergy consumer website that led a zealous grassroots effort to advocate for the passage of the FALCPA summarizes this dilemma of advisory labeling:

> "[M]ay contain" labeling [is] used as an "out" to relieve manufacturers of the burden of proper labeling, while protecting them from litigation. Such labeling either places all such foods off limits to those with food allergies (some large manufacturers label virtually *all* of their foods with this catch-all phrase) or leads to a reverse false sense of security that even if foods *are* so marked, they are probably safe anyway.[143]

This confusion and frustration exists because no industry-wide standards define the meaning of the various precautionary phrases employed by manufacturers, and many manufacturers themselves do not have company policies addressing what the terms signify. Consumers understandably are baffled about how to interpret these statements and gauge the potential risk of products bearing such warnings.[144] Precautionary labeling "raises more questions to the consumer than it really answers," according to Muñoz-Furlong.[145]

Food industry trade organizations noted at the 2001 Public Meeting that some amount of advisory labeling may be necessary because "the nature of the food supply and our manufacturing processes in some instances make it impossible to avoid."[146] Precautionary labeling is a valuable tool when it notifies consumers that, despite a company's best efforts to eliminate cross-contact and to identify a product's contents accurately, a given product may contain an allergen. Manufacturers too often, however, have relied on precautionary labeling in an attempt to avoid expending resources to determine a product's actual contents or to prevent cross-contamination. Without industry-wide standards addressing when the various warnings should be used by manufacturers or what those warnings signify, consumers cannot make informed decisions. The problem is not that manufacturers employ precautionary labeling—it is that precautionary labeling should *mean* something.

d. *Manufacturer Ignorance and Resistance*

For food-sensitive individuals, contacting a manufacturer directly may offer the only prospect of obtaining needed information about a product.[147] Consumers, thus, are

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[141] FDA, 2001 Public Meeting Transcript, *supra* note 44, at 92 (statement of Anne Muñoz-Furlong, FAAN).

[142] *Id.* at 93.

[143] Food Allergen Labeling and Consumer Protection, ShamrockBay.com (last updated July 20, 2004), http://www.shamrockbay.com/FA/FoodAllergenProtection.shtml#Issue (last visited Dec. 28, 2005).

[144] *See, e.g.*, FDA, 2001 Public Meeting Transcript, *supra* note 44, at 95 (statement of Anne Muñoz-Furlong, FAAN).

[145] FDA, 2001 Public Meeting Transcript, *supra* note 44, at 97-98 (statement of Anne Muñoz-Furlong, FAAN).

[146] *Id.* at 76 (statement of Lisa Katic, GMA).

[147] Obtaining information from manufacturers can be critical. Recognizing the importance of customer service representatives, one article directed to people with celiac disease advises:

continued

subject, on a manufacturer-by-manufacturer basis, to great variability in terms of manufacturers' procedures to obtain information and willingness to disclose product details and information quality.

Four out of five FAAN members surveyed in 2000 reported calling manufacturers to obtain more information about a product's contents.[148] Some manufacturers, like Kraft and General Mills, have been food industry leaders with regard to allergens and for years have employed stringent policies regarding food allergens, have maintained detailed databases on their products, and have communicated product information readily to consumers who contact their companies. Food-sensitive individuals have discovered that these companies have been the exception, however, and that contacting manufacturers often has proved more perplexing than enlightening.

Many product labels do not contain a telephone number consumers can call with questions about ingredients. Once a telephone number is located, customer service representatives may not be able to provide the missing information.[149] Typically, this is because the manufacturer itself is uncertain of ingredient details. Some manufacturers are unsure of the components of ingredients provided by their suppliers or whether the supplier has an effective allergen control program in place.[150] Because some deviations in product formulation may occur depending on the price or availability of some ingredients, a manufacturer may not know the ingredients contained in any given batch or lot.

Also, customer service personnel may know no more about a food's ingredients than what is printed on the food label. Often, personnel have not been trained to address questions about allergens, which may cause them to convey incomplete or inaccurate information.[151] As the mother of a peanut-allergic son stated at the 2001 Public Meeting,

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> [I]t's important to be polite, professional, and appreciative when you call manufacturers. Not only will you get much better service, but we need them! We need them to comprehend the gravity of our questions and to understand how important it is to be 100 percent sure that the answers they give us are accurate. We need them to realize that they can't guess at their answers, and that we very much appreciate that they understand what we're asking.

Dana Korn, *Learning to Decipher Customer Service-Speak*, 2(3) CELIAC.COM'S GUIDE TO A SCOTT-FREE LIFE WITHOUT GLUTEN 6 (Summer 2003) (on file with author), *available at* http://www.celiac.com/st_main.html?p_catid=29.

[148] *See* FDA, 2001 Public Meeting Transcript, *supra* note 44, at 141 (statement of Anne Muñoz-Furlong, FAAN).

[149] A citizens petition submitted to FDA in 2000 by nine state Attorneys General calling for improved allergen labeling summarizes these various problems consumers can encounter when calling manufacturers:

> [A]ccording to an informal survey recently conducted [in October 1999] by members of the New York Nut Allergy Awareness Group, Inc., numerous food manufacturers do not include a toll-free telephone number on their product labels. Consumers are thus left with the task of ferreting out their appropriate address or telephone number, often expending considerable time and expense in the process. When a consumer manages to track down the manufacturer of a product, there is no guarantee that knowledgeable staff will be available or possess sufficient and accurate information to answer his or her questions. Such was the case when M.A.C., a mother of two food-allergic children, attempted to obtain additional product information concerning Farina Mills® Enriched Farina Creamy Hot Wheat Cereal. Although M.A.C. made 19 telephone calls, many long-distance, she was not even able to determine who manufactured the product, much less how it was produced. It should not be this difficult to obtain necessary product information from manufacturers.

Nine State Attorneys General Citizens Petition, *supra* note 104, at 21 (internal citations omitted).

[150] *See, e.g.*, Bodendorfer et al., *supra* note 46.

[151] One website for people with food allergies warns consumers to be wary of quick answers from customer service representatives to ingredient questions. "If the person on the other end of the phone is not acquainted with food allergies, they may do no more investigating than you do. Thus they may not know what 'natural flavoring,' etc., can mean. On quite a few occasions they have 'messed up' in my case." Melissa Taylor, Petition for Clearer Food Labeling Food Allergy, An Open Letter About Food

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sometimes she speaks to a customer service representative "who reads from a written policy statement, but won't send it, and is unable to answer basic questions."[152] Few customer service representatives know the reason behind precautionary "may contain" labeling and can advise a consumer about the likelihood a given product was contaminated inadvertently or the method in which it would have been contaminated.

It can be difficult, moreover, to obtain information in a timely fashion—something important to shoppers debating whether to purchase a product, people reviewing ingredients before preparing a meal, and people who already have consumed a product and need to decide whether to seek medical help or take other action. Some manufacturers are slow to return telephone calls or never return them at all.[153] Other manufacturers demand written requests for information or a letter or telephone call from a physician documenting the food sensitivity before information will be released.[154] In some cases, an inability to obtain information from manufacturers may reflect a manufacturer's insufficient awareness about or sensitivity to the needs of people with food allergies.[155] Some

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Labeling and FAST's Role in Changes, http://www.angelfire.com/mi/FAST/food.html (last visited Feb. 25, 2006); *see also, e.g.*, Korn, *supra* note 147, at 6:

> It's a good idea to call the manufacturer to confirm that there aren't hidden sources of gluten. ... No, our product is not gluten-free: Do not interpret this as meaning, "No, our product is not gluten-free." I realize that's what they said, but it may not be what they mean. Probe deeper by asking, for example, "Can you tell me what in your product has gluten in it? I read the label and didn't see anything questionable." One time when I asked this, the woman told me it was "whey" that contained gluten. Penalty flag! Whey doesn't contain gluten! This is when you need to realize that you're talking to someone who doesn't understand the concept, and you should ask to be transferred to a quality control supervisor. ... Yes, it is gluten-free: This doesn't necessarily mean, "Yes, it is gluten-free." You have to judge for yourself whether or not they truly understand the concept.

[152] FDA, 2001 Public Meeting Transcript, *supra* note 44, at 172-73.

[153] As the mother of a peanut-allergic son who spoke at the 2001 Public Meeting explained:

> [E]ven after I call the manufacturer, I often do not get accurate information. Sometimes I leave a message on an answering machine that can go unanswered for a period of weeks, and sometimes forever. ... Often I have to make at least three calls before I even talk to an informed person.

Id.; *see also, e.g.*, Melissa Taylor, Petition for Clearer Food Labeling Food Allergy, *supra* note 151.

[154] FDA, 2001 Public Meeting Transcript, *supra* note 44, at 139-40 (statement of Anne Muñoz-Furlong, FAAN).

[155] This appears to be a popular theory among some people with food sensitivities who have grown frustrated trying to obtain information from manufacturers. As one woman with a food allergy describes her experiences calling manufacturers: "I had to call companies and actually ask people who worked there what was in their food. Some people were nice, and some laughed at me, and some were just plain rude. I didn't call about ingredients near[ly] as much as I should have ... ." Kelsey, Petition for Clearer Food Labeling Food Allergy, Personal Experiences, *supra* note 151. Another allergy sufferer expressed her dissatisfaction about what she perceived to be a lack of concern of food manufacturers for her safety:

> I do not understand why it is so difficult (or threatening) for food manufacturers to list ALL ingredients on their labels. ... Maybe if a friend or relative of the people making the labeling decisions was affected with a life-threatening allergy they would be a little more understanding (not that I would wish this on anyone!). It is a shame that we live in a country so consumed with money and greed that the very simplest things are overlooked. What's even sadder is that not only the general public but health officials sometimes think that allergy sufferers are just sick in the head and that we are making up these symptoms or over-exaggerating them. I wish we, the allergy sufferers, could get our point across that we NEED this information for our health's sake! It has already been proven that peanut allergies CAN and HAVE killed, but yet there is still resistance from manufacturers to disclose all ingredients, no matter how minute. Where are their consciences?

Denise R. Blogna, Petition for Clearer Food Labeling Food Allergy, Personal Experiences, *supra* note 151.

manufacturers may refuse to provide requested information out of liability concerns or in an effort to safeguard their proprietary interest in recipe formulas.[156] Whatever the reason, manufacturers' failure to remedy critical gaps in information has further constrained the options available to food-sensitive individuals and has contributed to ambiguity—and, therefore, fear—about eating.

3. *Food Labels Have Been Incorrect: The Problem of Mislabeling*

An increasingly common cause of food recalls is the outright mislabeling of allergen-containing food.[157] Studies also have revealed an alarming incidence of improperly labeled food. A researcher at the Food Allergy Research and Resource Program at the University of Nebraska in Lincoln found that one in five products studied that claimed to be "wheat-free" or "gluten-free" actually contained significant amounts of wheat protein.[158] The FDA Food Allergen Partnership that surveyed bakeries and ice cream and confectionary manufacturers in 1999 found:

- allergen-containing raw ingredients were omitted from product labels in twenty-five percent of the firms;
- roughly half the plants surveyed did not verify that the ingredients printed on labels matched the actual ingredients in products;
- among firms that felt they had adequate label verification procedures, fifteen percent nevertheless had label discrepancies; and
- nearly forty percent of Minnesota firms and sixty-four percent of Wisconsin firms that did not verify label accuracy manufactured products found to contain undeclared allergen residues.[159]

Mislabeling can occur when companies change product formulas or substitute similar source ingredients without updating labels,[160] labels are misprinted, products are packaged accidentally using the wrong label, labels on inner and outer packaging do not match,[161] differences in ingredients contained in different package sizes are not reflected on the label,[162] or cross-contamination or formulation mistakes occur during

[156] *See, e.g.*, *Labeling Among Allergen Issues Addressed at Labeling Conference*, FOOD LABELING & NUTRITION NEWS, Apr. 21, 1999, at 14 ("The flavor industry is wary of giving away proprietary information, but a firm should be able to indicate if a flavor additive contains an allergenic ingredient without disclosing such details [food allergy expert Susan Hefle said]."); Korn, *supra* note 147, at 6 ("Every now and then ... [the manufacturer has] an 'If we tell you what's in our product, we'd have to shoot you' mentality."); Melissa Taylor, Petition for Clearer Food Labeling Food Allergy, *supra* note 151 (stating that a common response from manufacturers is "suspicion of caller being from a rival company, trying to learn their secret ingredients, and/or claim of it being proprietary information. This has happened to us, one company was quite rude and thought we were trying to steal their ingredient list!").

[157] Recalls due to unlabeled allergens have risen steadily over the past decade. Undeclared allergens is now the leading cause of food product recalls in the United States. *See, e.g.*, Steve L. Taylor, *Food Allergens: From Chaos, Confusion, and Concern to Commitment and Control* (Oct. 28, 2004), http://fst.osu.edu/harris/lecture.htm#ALLERGENS [hereinafter Taylor, *From Chaos*]; FALCPA § 202(3)(B), 21 U.S.C.A. § 343(note) ("Nationally, the number of recalls because of unlabeled allergens rose to 121 in 2000 from about 35 a decade earlier."); *see also infra* note 222 (discussion of allergen-related food recalls).

[158] *See* Schorr, *supra* note 132.

[159] FDA, Food Allergen Partnership, *supra* note 119.

[160] *See, e.g.*, *Designing an Allergen Control Plan*, FOOD QUALITY, July/Aug. 2003, *available at* http://www.foodquality.com/Cover%20Story2.htm.

[161] *See, e.g.*, Joshi et al., *supra* note 94, at 1021.

[162] *See, e.g.*, *id.*

processing and are not indicated in labeling.[163] In some cases, manufacturers simply improperly identify a product's ingredients.[164]

4. *Food Labels Have Been Nonexistent: The Problem of Restaurants*

Eating out, while a pleasurable experience for most people, is responsible for much anxiety among food-sensitive individuals. A study published in 2001 of thirty-two fatalities caused by food allergies found that nearly thirty percent of lethal allergen exposures occurred in food establishments.[165] One study of over 5,000 people registered with the National Peanut and Tree Nut Allergy Registry found that 13.6% had experienced at least one allergic reaction while eating at restaurants.[166] Of those who experienced adverse reactions, thirty-eight percent had informed their server in advance about their allergy.[167] In response to these dangers, some people try to avoid dining out completely,[168] but many find that option impractical because school activities, work events, travel, and social interaction regularly involve or necessitate eating outside the home.

The possibility for mistakes in restaurants is high. No mandatory system comparable to packaged food labeling exists for the disclosure of food ingredients to food establishment patrons. Servers and food preparers frequently lack the level of knowledge about dish ingredients required by food-sensitive individuals, and restaurants rarely implement employee training about—and protocols regarding—how to serve individuals with food sensitivities safely. Even when food establishments take food sensitivity seriously, waiters and food preparers often have not known the ingredients in their foods, either because the original packaging was discarded or because the labels were difficult to decipher due to the absence of plain English labeling.

Cross-contamination may occur during food preparation. The sharing of utensils, pans, grills, counter space, cutting boards, and fryers to prepare multiple foods is common practice in food establishments.[169] If restaurants cook grilled cheese sandwiches on the same griddles as omelets, both dishes become contaminated with an unexpected allergen—the sandwiches with eggs and the omelets with wheat. A restaurant may grill hamburgers on the same grill that they use to grill fish or toast hamburger buns. French

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[163] *See, e.g.*, *Labeling Among Allergen Issues Addressed at Labeling Conference*, *supra* note 156.

[164] *See generally, e.g.*, FDA, Food Allergen Partnership, *supra* note 119.

[165] *See* Bock et al., *supra* note 5, at 192.

[166] *See* International Dairy Deli Bakery Association, *New Strategies for Food Labeling*, PROFITWISE™ BULL. (Oct. 2001), http://www.iddba.org/prwise4.htm (citing a study presented by Scott Sicherer to the American Academy of Allergy, Asthma and Immunology).

[167] *See id.*

[168] For example, the father of a soy-allergic teenager who participated in the Allergen Labeling Survey describes the pressure to always eat in the home:

> Dining out feels like Russian roulette. The wait staff are clueless, [they] try to help from kindness, but cannot because they are not educated. ... I am aware that my tone is one of frustration, but we have been in the game for a long time; and we have little illusion of a workable solution to the constant threat, other than eating at home all the time. As my son gets closer to young adulthood, it is unfathomable for any of us to figure out how he will cope when he goes to college, travels, etc. ... So, every potential outing/trip/travel is a puzzle as to how to make it somewhat safe and find out what and where to eat.

E-mail from CM to Author, Response to Allergen Labeling Survey (Jan. 12, 2005).

[169] As one Allergen Labeling Survey respondent described: "I have a friend who is extremely allergic to peanuts, and she ended up in the emergency room because someone had prepared her food with kitchen tools that had also been used in a food with peanuts. Somehow this needs to be taken care of." E-mail from RP to Author, Response to Allergen Labeling Survey (Jan. 10, 2005).

fries become contaminated with wheat protein when fried in the oil used to fry battered chicken strips and onion rings.

Additionally, some restaurants are reluctant to disclose food ingredients. Restaurants may be concerned about exposing themselves to liability by making representations about their food or by revealing proprietary information.

Some pioneering restaurants have designed menus to inform consumers of allergens and have designated employees trained in allergen management to handle the orders of food-sensitive individuals. These practices remain rare, however, and attention to the needs of food-sensitive consumers varies widely from one restaurant to the next.

III. HISTORY OF U.S. FOOD LABELING POLICY RELATED TO FOOD SENSITIVITY

"Our thought has been that the purchaser of food products, the one who is going to take those food products into his system, is entitled, as a matter of simple right, to know what he is eating."
Walter G. Campbell, Chief of the Food and Drug Administration (1934)[170]

"The expectation of a safe food supply for all is an American right."
H. Res. 309, 106th Cong. (1st Sess. 1999),
introduced by Representative Constance Morella (D-MD)

"Americans deserve to have confidence in the safety and labeling of the food on their tables."
H.R. 4704, 107th Cong. § 1(8) (2d Sess. 2002),
introduced by Representative Nita M. Lowey (D-NY)

The above statements—the first articulated by the Commissioner of FDA who urged the passage of the FDCA of 1938, and the latter two found in the preambles of predecessor versions of the FALCPA—in one sense articulate the principles embraced by the original food labeling law enacted in America in 1906, the spirit of which has endured until today. The statements capture the heart of FDA's mission to "protect[] the public health by assuring the safety, efficacy, and security of ... our nation's food supply" and to help the public "get the accurate, science-based information they need to use ... foods to improve their health."[171]

In another sense, however, the quotes articulate a singularly bold assertion that has never been fully adopted in the United States and is not achieved in the FALCPA. Despite some policymakers' rhetoric to the contrary, U.S. food labeling policy has never expressly recognized that Americans have a "right to know" all of the ingredients and sources of ingredients in the foods they consume, regardless of whether they desire that information for medical, ethical, religious, nutritional, or economic reasons. For consumers with food sensitivities, the absence of a right to know exactly what they are eating represents a serious health hazard.

[170] *Hearing Before the S. Comm. on Commerce*, 73d Cong. (1934) (statement of Walter G. Campbell, Chief of FDA), *reprinted in* CHARLES WESLEY DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD 1176 (1987).

[171] FDA, FDA's Mission Statement, http://www.fda.gov/opacom/morechoices/mission.html (last visited Feb. 12, 2006). When it comes to food safety, FDA has a myriad of hazards to manage, including potentially lethal food-borne pathogens such as bacteria and parasites; foods contaminated with harmful materials such as pesticides, fertilizers, and animal drugs; and bioterrorist contamination of the food supply. For an overview of FDA's immense responsibilities with regard to food safety, see generally Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61 (2000).

The idea championed by Representative Nita M. Lowey (D-NY), Senator Edward M. Kennedy (D-MA), and others who supported the FALCPA—expanding notions of "food safety" to include the safety of individuals with food sensitivities—is a radical concept, given that ingredient disclosure requirements have operated largely unchanged since passage of the FDCA nearly seventy years ago.

As FDA has stated on numerous occasions, the FDCA "does not provide a 'right to know' the ingredients of every food."[172] Nevertheless, beginning in the 1970s, FDA began a slow return to the roots of the FDCA by increasingly recognizing the importance of greater ingredient disclosure to food-sensitive individuals.[173] FDA has noted more recently that "individuals who are allergic to a specific food need to know when it is present as an ingredient in a food in order to make informed purchase decisions," and that "FDA believes that consumers have a right to be able to choose between products on the basis of the ingredients contained in the foods."[174] Until the 1990s, however, FDA fell far short of actively promoting or enforcing these ideals. Even with the great strides made by passage of the FALCPA, these ideals remain unrealized.

The FALCPA represents the product of intense congressional, regulatory, consumer, and industry efforts primarily over the past decade. This initiative came in the wake of years of ignorance and apathy: a lack of awareness and concern on the part of industry, *ad hoc* policymaking and inertia within FDA, an absence of consumer organization and mobilization, and a general dearth of medical and scientific research about and interest in food sensitivities.

The drafting and passage of the FALCPA was accomplished because the atmosphere in America surrounding food labeling has shifted dramatically over the past several decades.[175] This altered culture is due to the convergence of numerous factors, including scientific advances in diagnosing food sensitivities and detecting allergens in foods, increased public awareness about food sensitivities, the mobilization of people with food sensitivities, the prioritization of food allergy issues by FDA, and recognition by industry of the growing market for products to meet special dietary needs.

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[172] 58 Fed. Reg. 2850, 2860 (Jan. 6, 1993).

[173] In 1979, for instance, FDA in fact affirmed that consumers had some "right to know about the foods they eat" when it discussed its effort to propose changes to the food label.

> The purpose of food labeling is to enable consumers to select and use products that meet their individual needs and preferences. To achieve that purpose, labeling must provide sufficient information to enable the public to identify foods and their characteristics, including their ingredients and nutritional value. ... In their deliberations about recommending specific changes in food labeling requirements to make labels more informative and more easily understood, the [FDA, USDA, and FTC] have followed the following principles: (1). Public Health Importance. ... [A]ccurate and informative labeling about a product's nutrient content and its other characteristics has even greater public health significance now than in the past. Furthermore, disease or other abnormal physiological conditions such as allergies compel many Americans to follow special diets. These people especially need informative food labeling so they can make informed food choices. (2). The Consumer's Right-to-Know. Innovations in food processing and packaging have made it increasingly difficult for consumers to judge a product's actual contents from its appearance, even for traditional foods. The agencies have therefore concluded that law or regulation must strengthen those policies that guard consumers' right-to-know about the foods they eat ... .

44 Fed. Reg. 75,990, 75,991-92 (Dec. 21, 1979).

[174] 58 Fed. Reg. 2850, 2867 (Jan. 6, 1993).

[175] *See, e.g.*, Taylor, *From Chaos*, *supra* note 157 ("[A]wareness of food allergies as a food safety issue for the food industry began to occur in the 1980's. Both the prevalence and severity of food allergies are apparently increasing. ... Accordingly, the food industry and governmental regulatory agencies began to focus more attention on food allergies in the 1990's.").

The turn of the century witnessed greater emphasis on food sensitivity issues by FDA, improved food industry awareness and efforts to address allergen management, increasing grassroots advocacy by food-sensitive consumers and consumer groups, and a congressional push for national legislation to better address the needs of food-sensitive individuals. As described in the following sections, the combined efforts of FDA, concerned consumers, the food industry, and Congress ultimately resulted in the passage of the FALCPA.

A. *Early Statutory and Regulatory History*

"Food allergies have probably affected mankind since the dawn of time," states leading food allergy expert Steve L. Taylor. "The first well recorded case histories of food-allergic patients appeared in the early part of the 20th century. Yet, food allergies were largely ignored by the medical community and regulatory authorities until recent years."[176] Indeed, this inaction or occasional piecemeal action by lawmakers and FDA is reflected in the fact that the needs and rights of people with food sensitivities have received virtually no critical legal attention. Legal analysis as it relates to food sensitivities—the implications of food and drug laws and regulations on individuals with food sensitivities, tort and products liability claims a person might raise in response to products provoking allergic reactions, and theories of accommodation that might be argued under disability rights law—has been a desolate landscape.[177]

Until the FALCPA amended the FDCA, there were "no labeling standards ... in place for food allergies" in the United States.[178] The first federal law enacted in the United States to govern the regulation of food, the Federal Food and Drugs Act of 1906 (1906 Act),[179] reflected a conception of food products as relatively standardized and composed of straightforward ingredients. The 1906 Act's approach to preventing consumer deception was to regulate information placed voluntarily on food items by sellers, rather than to prescribe that certain information be disclosed on a label.[180] The 1906 Act was subsequently repealed in 1938 and replaced with the more comprehensive and forceful FDCA.[181]

[176] Taylor, *Emerging Problems*, *supra* note 13.

[177] One measure of legal scholarship, a Westlaw® search conducted in January 2005 for law journal articles containing some permutation of "food allergy" in the title, yielded only a single article critiquing the medical insurance industry. A Westlaw® search revealed no law journal articles even mentioning food allergies before 1982, with the exception of a brief mention of food allergies in one 1952 review of a book concerning products liability. Food allergies emerged as a topic in American legal articles only in the 1980s and 1990s, but even then discussion was limited almost exclusively to the debate about the potential for hidden allergens in bioengineered foods. Another measure of legal recognition of food allergies—a review of cases in which individuals with food sensitivities have asserted liability or disability claims—revealed scant case law concerning food sensitivities. *See, e.g.*, Jonathan Bridges, Note, *Suing for Peanuts*, 75 NOTRE DAME L. REV. 1269, 1272 (2000) (discussing various theories of liability under which peanut-sensitive individuals might bring suit, and stating that determining strategies for liability is difficult "perhaps because there is little relevant case law for guidance").

[178] H.R. REP. NO. 108-608, at 3.

[179] Federal Food and Drugs Act of 1906 (popularly known as the "Pure Foods Law"), Pub. L. No. 59-384, 34 Stat. 768 (1906), formerly codified at 21 U.S.C. §§ 1-15.

[180] The legislative history of the FDCA notes this fact as a serious weakness of the 1906 Act. *See Hearing Before the S. Comm. on Commerce*, 73d Cong. (1934) (statement of Walter G. Campbell, Chief of FDA), *reprinted in* DUNN, *supra* note 170, at 1175 ("One of the weaknesses of the present law is the fact that it is negative in character. It merely says that a product will be deemed to be misbranded if it contains any statement that is false or misleading. There is nothing affirmative in the requirements of the statutes about branding products except a declaration of net weight.").

[181] *See id.* ("Senator, we were anxious to amend the existing law. We undertook to do that when we first began to work, but the very nature of the text of the existing law made it from a drafting standpoint, almost an utter impossibility to effect the modifications that we are seeking to effect here, and have at the same time language that would be conclusive and that would not be confusing. So we finally, after a considerable period of work in preparing merely amendments to the existing law, gave that up as an utterly impossible task."); S. REP. NO. 361 (1935), *reprinted in* DUNN, *supra* note 170, at 237 ("Since the

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The FDCA's ingredient labeling requirements—the likes of which was unprecedented in the world—mandated that the name of the food, a statement of ingredients,[182] the net quantity of contents, and the name and address of the manufacturer be affirmatively declared, in a standardized format, on food labels.[183] Sections 342(a)(1) and (4) declared as adulterated any food that "bears or contains any poisonous or deleterious substance which may render it injurious to health;" however, allergens were deemed to not be "deleterious substances" within the purview of this provision.[184] These labeling requirements have been subject to little alteration over time,[185] despite substantial changes in the American diet and food processing over the past seventy years.

The FDCA's legislative history indicates that the principal health condition cited in 1934 in favor of the FDCA's ingredient disclosure requirements was the then little-known and little-understood condition of food allergies.[186] A Senate Report declared

passage of that [1906] law, profound changes in methods of manufacturing and selling foods and drugs have resulted from developments in scientific, technological, and economic fields. These changes have not been devoid of opportunities for the unscrupulous to profit, without contravening the provisions of the present law, by endangering the public health and defrauding the consumer. Court decisions have revealed textual weaknesses in the measure that were not foreseen when it was enacted.").

[182] For foods for which FDA established a standard of identity (i.e., established ingredients that must be present and relative ingredient proportions), the FDCA required only the name of the food and names of optional ingredients (with the exception of spices, flavorings, and colors) to be identified on the label. *See* 21 U.S.C.A. § 343(g). For foods with no standard of identity, the FDCA required ingredients to be declared on the label (with the exception of spices, flavorings, and colors). *See* 21 U.S.C.A. § 343(i).

[183] *See* 21 U.S.C.A. § 343(e)-(g), (i).

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> In the consideration of these provisions of the bill, much discussion has centered around the question of "allergy." ... To avoid any confusion that might possibly arise from the fact that so many persons are allergic to wholesome articles of food that can be eaten by the vast majority without harmful effect, the bill has not been drawn simply to ban food which may be harmful or dangerous but the test is predicated on whether or not the product contains a poisonous or deleterious substance. Certainly strawberries, eggs, wheat flour, and the like cannot be considered poisonous or deleterious substances and the fact that persons may be made ill by them would not authorize action under the terms of the bill.

S. REP. NO. 361 (1935), *reprinted in* DUNN, *supra* note 170, at 242-43. *See also* S. REP. NO. 646 (1935), *reprinted in* DUNN, *supra* note 170, at 478; *cf.* A petition by nine state Attorneys General argues that foods contaminated with allergens through cross-contact should be deemed adulterated. *See* Nine State Attorneys General Citizens Petition, *supra* note 104, at 26 ("The FDA, under its authority to prevent adulteration, has in the past promulgated good manufacturing practices designed to prevent the contamination of food with microorganisms, filth or other harmful substances," but has failed to do so for allergens).

[185] *See, e.g.*, Peter B. Hutt, *Regulating the Misbranding of Food*, 43 FOOD TECH. 288 (Sept. 1989) ("The statutory provisions enacted by Congress in 1938 to regulate food misbranding have remained virtually unchanged. This history therefore reflects evolving administrative policy implemented by FDA, not statutory changes adopted by Congress."); 44 Fed. Reg. 75,990, 75,991 (Dec. 21, 1979) ("Congress enacted the Federal food laws in 1906, and although it has revised them occasionally since then, the basic concepts of food labeling have remained unchanged for many years. The last major revision of the food labeling provisions of the Federal Food, Drug, and Cosmetic Act, for example, occurred in 1938.").

[186] The legislative history of the FDCA helps illuminate the newness of the concept of a food allergy in the 1930s. The following exchange occurred between the Commissioner of FDA and two Senators during a Congressional hearing in 1934 regarding proposed new food and drug legislation:

> Mr. Campbell [FDA Chief]: I do not think you heard, and I am sorry that you and the entire committee did not hear Dr. Brown, of Washington, an expert on hypersensitivity, testify yesterday afternoon. He pointed out this, that he had a child in his office who was suffering from allergy. I don't know whether the cause was eggs or milk.
> Senator Hebert: What was that word, allergy?
> Mr. Campbell: Yes; allergy.
> Senator Hebert: How do you spell it?
> Mr. Campbell: A-l-l-e-r-g-y.
> Senator Hebert: What is the definition of it? I heard the term a number of times and I admit my ignorance. Now, I ask you to explain it to me.
> Mr. Campbell: You need not feel humiliated, because it is not in the dictionary, or at least it is not in those that I have consulted. It is a medical term. It means the hypersensitivity

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that the FDCA's misbranding provisions not only promote fair dealing between the manufacturer and the consumer, but also have "distinct public-health significance":

> A surprisingly large proportion of our population is allergic to some food or other which for most people is entirely wholesome. Many people are made ill—some violently so—by common ingredients of food which most people consume with impunity. That large group of unfortunates can protect themselves from the consumption of foods to which they are allergic by the information made available to them under [these misbranding provisions].[187]

Yet, despite the FDCA's substantial benefits and excellent intentions with regard to helping food-sensitive individuals, the FDCA's ingredient disclosure requirements fell dangerously short of protecting the health and safety of people with food sensitivities. First, the FDCA did not require disclosure of ingredients in standardized foods.[188] Second, the FDCA contained problematic exceptions to its labeling scheme: the subingredients in spices, flavorings,[189] and colorings,[190] and additives at "insignificant levels" without technical effect in the product[191]—all ingredients pervasive in the food supply—did not need to be disclosed on the label. "Incidental additives" derived from spices and flavorings did not need to be disclosed at all, even by generic terminology.[192] Moreover, the sources of some ingredients did not need to be disclosed as part of the ingredient's "common name,"[193] manufacturers were permitted to use "may contain" or "and/or" labeling when formulations of a product varied from batch to batch,[194] and "common or usual" ingredient names could be highly scientific and technical.

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of certain individuals to certain protein products. It may manifest itself in the form of asthma or hives or other forms of physical distress.
Senator Copeland: What is food for one is poison for another.
Mr. Campbell: That is right.
Senator Hebert: I would like to look up the derivation of that word.
Senator Copeland: Here is a book on the subject.
Senator Hebert: All right. I suppose it is one of those $14 words that physicians coin.

Hearing Before the S. Comm. on Commerce, 73d Cong. (1934) (statement of Walter G. Campbell, Chief of FDA), *reprinted in* DUNN, *supra* note 170, at 1176.

[187] S. REP. NO. 520 (1934) (accompanying S. 2800), *reprinted in* DUNN, *supra* note 170, at 120; *see also* S. REP. NO. 361 (1935), *reprinted in* DUNN, *supra* note 170, at 247; *Hearing Before the S. Comm. on Commerce*, 73d Cong. (1934) (statement of Walter G. Campbell, Chief of FDA), *reprinted in* DUNN, *supra* note 170, at 1176-77.

[188] This was so because, in the words of then-Commissioner of FDA Walter Campbell, "we assume that there will be little contributed either economically, or from the standpoint of health of the consumer, in declaring on such products the list of ingredients." *Hearing Before the S. Comm. on Commerce*, 73d Cong. (1934) (statement of Walter G. Campbell), *reprinted in* DUNN, *supra* note 170, at 1178; *cf.* FDA, *Rare But Risky*, *supra* note 76.

[189] *See* 21 U.S.C.A. § 343(i) (providing that flavorings, spices, and colors may be declared collectively in composite foods without naming each one). Natural flavorings can include, *inter alia*, "flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, ... leaf, or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products there of." 21 C.F.R. § 101.22(a)(3).

[190] *See* 21 U.S.C.A. § 343(i); 21 C.F.R. § 101.22(h)(1)-(2).

[191] *See* 21 C.F.R. § 101.100(a)(3) (exempting incidental additives from label declaration and defining an "incidental additive" as an ingredient that has no technical or functional effect in the finished food and that is present in that food at a level that is "insignificant").

[192] *See* 21 C.F.R. § 101.22(h)(2).

[193] *See* 56 Fed. Reg. 28,592, 28,603-04 (June 21, 1991).

[194] *See* 21 C.F.R. § 101.100(a)(1); 44 Fed. Reg. 75,990, 75,998-99 (Dec. 21, 1979); 56 Fed. Reg. 28,592, 28,596 (June 21, 1991) ("[T]he agency does not find any basis to propose to revise other paragraphs in § 101.4(b) that permit 'and/or' labeling of other food categories. ... In adopting these provisions, FDA concluded that the flexibility that they provide to manufacturers is significant, and that consumers would not be deprived of necessary information by them.").

Over time, FDA on occasion attempted to address some of these deficiencies—what some involved in the debate surrounding the FALCPA referred to as "loopholes"—in the FDCA. This took place within FDA's more general shift of focus away from defining food standards toward improving labeling disclosure so that consumers themselves could make meaningful food decisions.[195] In the late 1970s, the agency began to take note of certain allergen-related hazards and considered—and in some cases issued—regulations to address disclosure of select allergens or ingredients on the food label.[196] When FDA did address food allergies, however, it did so largely on a food-by-food, allergen-by-allergen basis.[197] FDA maintained that "[t]he agency's primary tool for handling a situation where population subgroups may be at increased risk from a food ingredient that is safe for most people is to use labeling to inform those persons who need or want to avoid the ingredient."[198]

Despite FDA's asserted intention to use the food label to disclose ingredients harmful to population subgroups, FDA's actual record with regard to requiring disclosure of food allergens is more equivocal. A review of notices in the *Federal Register* during the 1980s and early 1990s reveals little FDA concern about precautionary labeling that restricted the choices of food-sensitive consumers; numerous rejections by FDA of calls for improved labeling of allergens and the extension of source ingredient declaration requirements to major-allergen-containing ingredients;[199] and FDA resistance to

[195] *See, e.g.*, Merrill & Francer, *supra* note 171, at 154.

[196] For instance, in 1985, FDA required the specific source of "gluten" be identified on the label when it issued regulations recognizing as generally recognized as safe (GRAS) "corn gluten" and "wheat gluten." 21 C.F.R. § 184.1321-.1322; 50 Fed. Reg. 8997, 8998 (Mar. 6, 1985). FDA stated it believed gluten-sensitive individuals were adequately safeguarded and rejected consumer requests calling for the mandatory identification of products as "gluten-free." FDA's stated rationale was that, because the source of gluten (wheat or corn) must be identified by name, "the labeling already required is adequate to alert the public and protect gluten-sensitive individuals." 50 Fed. Reg. 8997, 8997 (Mar. 6, 1985). Although a "gluten-free" standard was likely scientifically infeasible at the time, FDA's statement nevertheless reflects a failure to appreciate the fact that "wheat gluten" is but the tip of the iceberg in terms of ingredients that individuals sensitive to gluten must avoid, and that identification of "wheat gluten" on the label would be only a partial remedy for people with celiac disease—in contrast to "gluten-free" labeling.

[197] *See, e.g.*, 58 Fed. Reg. 29,557 (May 21, 1993) (proposing to "amend the standard of identity for canned tuna to require the term '(includes soybeans)' as part of the name used to declare the ingredient vegetable broth when soybeans are one of the vegetable extractives used to make that ingredient" because "it would be unlikely that 'vegetable broth' would be understood by consumers to be a product that has been made from soybeans"); 66 Fed. Reg. 38,591, 38,593 (July 25, 2001) ("On a case-by-case basis, FDA has used notice-and-comment rulemaking to require the declaration of individual allergenic flavorings, spices, and colors. This is a labor-intensive and time-consuming process for the agency.").

[198] 61 Fed. Reg. 22,993, 22,993 (May 13, 1996); *see also* 52 Fed. Reg. 46,968, 46,969 (Dec. 10, 1987) ("The agency recognizes the difficulty and complexity of assessing the safe use of substances that, like numerous foods, including nuts and shellfish, are generally safe for the majority of the public but that may pose acute hazards for small subpopulations. ... As a general rule, FDA's policy is to address such circumstances by requiring package labeling that will disclose the presence of the ingredient to purchasers. This general principle is reflected in previously-issued regulations governing sulfites in packaged foods ... .").

[199] *See, e.g.*, 58 Fed. Reg. 2850, 2864, 2871 (Jan. 6, 1993) (declining to require the identification of the sources of certain ingredients on the food label such as the source ingredients in "modified food starch," and rejecting consumer suggestions such as requiring "(from milk)" to appear after "sodium caseinate" on ingredient lists and requests that sweeteners derived from corn be identified as such); *see also* 56 Fed. Reg. 28,592, 28,603-04 (June 21, 1991):

> [T]here are situations in which source information is not part of the common or usual name of food ingredients. In most instances, these are ingredients that have a long history of use. For FDA to provide for declaration of the source of these ingredients, it would have to amend the common or usual names of all foods to include their source. However, for the

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requests for mandatory "plain English" labeling of allergens, because the agency presumed that food-sensitive consumers knew what terms to look for in the ingredient statement to effectively avoid harmful allergens.[200] Additionally, FDA's regulations usually targeted allergens that were manufactured chemical compounds[201] rather than "naturally" occurring allergens, such as the Big Eight. When FDA did address the labeling of allergens in specific contexts, FDA endeavored to weigh the value of consumer choice, economic feasibility to manufacturers, the agency's understanding of the limits on its authority, and FDA's determinations about consumer safety needs.[202] This difficult balancing act overall resulted in an *ad hoc*, piecemeal, and inconsistent approach to allergen disclosures over the years, despite the agency's few (unsuccessful) efforts to set general, broadly-applicable labeling policy in response to allergen concerns.[203]

FDA did not commit to pursuing a comprehensive strategy regarding food allergens until the mid 1990s, and the agency did not begin to formulate and implement such a plan until around the turn of the century. The first studies of food-induced, fatal anaphylaxis

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> agency to adopt such a requirement would require enormous resources, and the agency simply does not have such resources available. Moreover, many of these ingredients are so well known that most consumers understand the source of the ingredient from its name (e.g., raisins from grapes, sugar from sugar cane or sugar beets, whey from milk). Accordingly, FDA is not moving to provide source information in the common or usual names of all foods.

The agency did express its willingness to consider source labeling on an ingredient-by-ingredient basis when an ingredient "has a material bearing on the purchase of a food," such as "where consumers may be faced with significant adverse health consequences without this information." *Id.* at 28,604. It appears, however, that this inquiry rarely was performed in practice.

[200] *See, e.g.*, 58 Fed. Reg. 2850, 2856 (Jan. 6, 1993) ("FDA is not persuaded that requiring a descriptive or collective term to be used with the common or usual name of the sulfiting agent is necessary because the declaration of the sulfiting agent by its common or usual name will adequately inform the consumer of its presence."); *id.* at 2859, 2864 (stating that "[t]he agency does not agree that the requested statement [identifying a food as 'lactose free'] is needed because lactose intolerant consumers know to avoid milk and milk products," and rejecting a suggestion that caseinate be identified as a milk derivative on food products not identified as "nondairy" in addition to those identified as "nondairy").

[201] *See* 21 C.F.R. § 74.705(d)(2); 42 Fed. Reg. 6835 (Feb. 4, 1977); 44 Fed. Reg. 37,212 (June 26, 1979); 51 Fed. Reg. 24,519, 24,522, 24,523 (July 7, 1986) (FD&C Yellow No. 5, an ingredient to which only an estimated 50,000 to 100,000 people may be allergic and which causes mild adverse reactions not requiring medical treatment); *see also* 21 C.F.R. § 101.100(a)(4); 50 Fed. Reg. 13,306 (Apr. 3, 1985); 51 Fed. Reg. 25,012, 25,012 (July 9, 1986); 52 Fed. Reg. 46,968, 46,969-70 (Dec. 10, 1987); 58 Fed. Reg. 2850, 2856 (Jan. 6, 1993) (sulfites, an ingredient to which as many as one million people may be allergic, and which may provoke fatal reactions in sensitive individuals); *see also* 51 Fed. Reg. 41,765 (Nov. 19, 1986) (FD&C Yellow No. 6); 21 C.F.R. § 172.804(e)(2) (aspartame); 21 C.F.R. § 101.22(h)(5) (monosodium glutamate).

[202] FDA engages in this balancing whenever it proposes changes to labeling requirements. For instance, in its implementation of the NLEA, FDA restricted mandatory disclosure to clearly-delineated information that it deemed essential to consumer health decisionmaking, stressing that "not all information related to maintaining healthy dietary practices can be included on the food label" due to space limitations and the risk of losing consumers' attention if they become saturated with information. 58 Fed. Reg. 2079, 2107 (Jan. 6, 1993). FDA also wrestled with weighing the costs to industry (and, subsequently, to consumers) of greater labeling requirements. *See, e.g.*, 56 Fed. Reg. 28,592, 28,596 (June 21, 1991).

[203] *See, e.g.*, 44 Fed. Reg. 75,990, 75,990-91 (Dec. 21, 1979):

> This is the first joint effort of the three agencies with responsibility for food labeling and advertising [FDA, USDA, and FTC] to review the entirety of the food labeling laws and regulations. (Previous efforts, usually initiated by an agency on its own, have been largely ad hoc.) ... FDA, USDA, and FTC realized the need to pause and assess existing food labeling laws and policies before implementing further regulatory changes. Therefore, the agencies set out to develop an overall labeling strategy that will provide consumers with the information that they want and need about today's foods.

emerged in the late 1980s and early 1990s.[204] By the mid 1990s, international scientific consensus developed about the foods that tend to be responsible for most allergic reactions. With more scientific information about food sensitivities and the development of technological methods for testing for the presence of allergens in foods, FDA slowly grew aware that the needs of people with food sensitivities were not being addressed adequately.[205]

In 1990, Congress overhauled the food label after half a century of stasis when it called for heightened nutrition labeling on prepackaged foods by enacting the NLEA.[206] The enactment of the NLEA reflected greater national focus on nutrition; invigorated an emphasis on consumer choice through disclosure of information on product labels;[207] recognized that the FDCA's original labeling model, based on disclosing on labels only deviations from food standards of identity set by FDA regulations, was outmoded; and initiated regulations by FDA to "reestablish the credibility of the food label."[208] Though not directed at helping food-sensitive consumers,[209] the NLEA had several positive

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[204] *See* J.W. Junginger et al., *Fatal Food-Induced Anaphylaxis*, 260 JAMA 1450-52 (1988); H.A. Sampson et al., *Fatal and Near-Fatal Anaphylactic Reactions to Food in Children and Adolescents*, 327 N. ENG. J. MED. 380-84 (1992); *see also Labeling Among Allergen Issues Addressed at Labeling Conference*, *supra* note 156 ("[Food allergy expert Susan] Hefle recounted the history of attention paid to food allergies, citing the new concern to the first published literature on deaths [due] to allergens published in JAMA in 1988 and NEJM in 1992. 'The media picked up on these studies,' she said.").

[205] As CFSAN noted in 1993:

> Another public health issue expected to grow as a result of new knowledge is food sensitivities, namely allergies and intolerances. Modern medicine has long recognized the relationships between foods and physiological reactions. The biomedical sciences have now advanced to the point where links between specific food components and food sensitivities can be described with increasing accuracy. Therefore, it can be expected that as the scientific evidence of these links advances, the FDA will respond by providing consumers with new information of importance for their health.

Jane E. Henney, *Food Safety Challenges and the New Center*, 48 FOOD & DRUG L.J. 473, 477 (1993).

[206] *See supra* note 10.

[207] *See, e.g.*, 55 Fed. Reg. 29,487, 29,490 (July 19, 1990):

> Comments received by FDA as a result of the 1989 ANPRM and at the recent public hearings indicate a great desire for nutrition labeling on more foods and for more label information about food components that have been identified as important in maintaining good health. Public health concerns about the relationship between diet and health, including the role of food components in the etiology of certain chronic diseases, have grown during the last 20 years.

[208] 58 Fed. Reg. 2302, 2302 (Jan. 6, 1993).

[209] In the notice announcing FDA's 1990 proposed nutrition labeling regulations, for instance, food sensitivities are not mentioned at all. *See* 55 Fed. Reg. 29,487 (July 19, 1990). Food sensitivities received some discussion in FDA's proposed regulations to implement the NLEA and the accompanying regulatory impact analysis statement. *See* 58 Fed. Reg. 2927, 2940 (Jan. 6, 1993):

> The benefits of the 1990 amendments and the implementing regulations include decreased rates of cancer, CHD, osteoporosis, obesity, hypertension, and *allergic reactions to food.* As consumers are given more informative labeling in an improved format, uncertainty and ignorance concerning the ingredient and nutrient content of the foods they eat will decrease, and some consumers will select more nutritious, healthier foods.

(Emphasis added). FDA recognized that helping food-sensitive individuals was not the focus of the NLEA, however, and that most of the benefits of the legislation and implementing regulations would be due to nutritional benefits to the public. *See id.* at 2936 ("Although the agency agrees that the required labeling of allergens such as hydrolyzed corn protein will have some benefits for preventing allergic responses, these benefits are expected to be small relative to the nutritional benefits of the final rules.").

consequences for individuals with food sensitivities.[210] Policymakers in fact believed the 1990 nutrition amendments would help address the unmet needs of food-sensitive consumers. FDA touted that, given the NLEA's passage, "the information present in the ingredient list is adequate to enable the consumer to avoid ingredients of concern."[211] According to Elizabeth J. Campbell, Director of FDA's Center for Food Safety and Applied Nutrition's (CFSAN's) Division of Programs and Enforcement Policy, "For those with food allergies, I think it is more of a patient education problem."[212] Nonetheless, the NLEA did not significantly address the food sensitivity dimension of consumer health and consumer choice. The NLEA did not revoke other existing ingredient declaration loopholes for flavorings, spices, noncertified color additives, and other additives, nor did it attempt to remedy consumer confusion with regard to technical ingredient names.

Indicative of the persisting belief by some in the government that current laws were sufficient for people with food sensitivities, in 1996 U.S. delegates from FDA to the Codex Alimentarius Commission, an international food standards-setting body, objected to a proposal requiring the declaration of major food allergens on the food label, arguing that "complete ingredient listings"—such as that found in the United States—was a better plan.[213] This belief that U.S. laws and regulations were sufficient reflected an erroneous assumption that if food-sensitive consumers simply learned what they need to avoid and read a label, they would have adequate information upon which to base decisions.[214]

B. *Recent Consumer, Industry, and FDA Action*

Long before legislative initiatives were ever considered as a feasible possibility, food-sensitive consumers and their caregivers recognized that they had to work actively to promote their safety. By the late 1980s and early 1990s, organizations for food-allergic individuals and food-sensitivity communities were developing due to the increase in awareness of food sensitivities, diagnosis of food sensitivities, and usage of the Internet. Networks among individuals and support groups formed throughout the country.

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[210] The NLEA inaugurated increased emphasis on product content transparency and consumer choice. It marked the demise of the FDCA's dated approach of exempting standardized foods from content disclosure requirements. The NLEA also extended ingredient disclosure requirements beyond optional ingredients to mandatory ingredients in standardized foods. *See* 21 C.F.R. § 130.3(e). Additionally, the NLEA required that certified color additives be declared by their common or usual names rather than the generic term "colorings." 58 Fed. Reg. 2850, 2868 (Jan. 6, 1993).

[211] 56 Fed. Reg. 28,592, 28,615 (June 21, 1991).

[212] FDA, *Rare But Risky*, *supra* note 76.

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> The United States does not support the establishment of a positive list [of allergens] and does not believe there is a scientific basis that could justify establishing 'minimum' levels (or 'safe' levels) of potentially allergenic ingredients ... . The United States believes the issue is nullified by the distinct declaration of all ingredients by meaningful common or usual names. ... [I]n our judgment, it is not possible to develop scientifically supportable criteria or lists that would permit the identification of all potentially allergenic food ingredients, or to develop 'safe' levels of those ingredients that would not require identification on the label.

U.S. Delegation to Object to Codex Proposals on Allergens, Trans Fat Labeling, FOOD LABELING & NUTRITION NEWS, Aug. 22, 1996, at 3.

[214] *See, e.g.*, 58 Fed. Reg. 2850, 2865 (Jan. 6, 1993) ("Because the agency is not requiring declaration of the food source in the naming of these sweeteners, it encourages consumers wishing to avoid certain sweeteners for religious or other reasons to familiarize themselves with the names of these sweeteners and look for these names in the ingredient lists."); *id.* at 2321 ("A [food-sensitive] consumer should read the ingredient list on the food label to determine whether a food contains a substance he or she needs to avoid.").

Individuals with food sensitivities increasingly contacted food companies and notified FDA when products that appeared from the label to be safe caused allergic reactions. In the early 1990s, some major food producers such as Kraft, General Mills, and the Kellogg Company began taking notice of these complaints.[215] Organizations such as FAAN,[216] the Food Allergy Initiative, Peanut Allergy.org, and the American Celiac Task Force (ACTF),[217] as well as general proconsumer groups such as CSPI[218] and individual activists who created websites to mobilize food-allergic individuals, began to advocate for labeling changes to help food-sensitive consumers. Around the turn of the century, consumers submitted several petitions to FDA calling for improved allergen labeling.[219]

[215] *See, e.g., Manufacturers Stress Importance of Allergen Labeling*, FOOD LABELING & NUTRITION NEWS, Nov. 14, 1996, at 13-14. In 1998, General Mills was recognized as a leader in food allergen-related cross-contact control, training, labeling, and customer service when it was awarded the Mariel C. Furlong Award for making a difference in the lives of food allergic individuals by FAAN. *See* FOOD CHEM. NEWS, July 20, 1998, at 29, *available at* 1998 WL 10981512.

[216] FAAN was at the forefront of allergen labeling efforts. *See, e.g.*, Press Release, FAAN, 20-Year Struggle Will End With Passage of Food Allergy Bill (July 15, 2004), *available at* http://thesoydailyclub.com/Food/FAANAllergy07162004.asp ("In the years since its founding, FAAN has become the national and international leader in raising public awareness of food allergies and anaphylaxis, in providing accurate information about food allergy, and advocating for those families affected by the condition."). Throughout most of the 1990s, aside from FAAN "there was really nothing out there as far as advocating for people with food allergy," according to Chris Weiss, FAAN's Director of Legislative and Regulatory Research since 2001. "No one really knew anything about it." FAAN has been "meeting with people at FDA and various members of the food industry for years and years." Telephone Interview with Chris Weiss, Director of Legislative and Regulatory Research, FAAN (Mar. 16, 2005). FAAN was a member of the Food Allergy Issues Alliance, composed mostly of food industry trade organizations, and contributed to the creation of the voluntary guidelines. Anne Muñoz-Furlong also was a featured panelist at the 2001 Public Meeting; she and a CSPI representative were chosen to represent consumer interests in the Public Meeting's panels. FAAN worked with Representative Lowey and lobbied Congress for passage of allergen labeling legislation—even though it had consulted with the food industry in the creation of the voluntary guidelines—because with the voluntary guidelines, "no matter how you slice them, they're still voluntary." Telephone Interview with Chris Weiss, FAAN, *supra*.

[217] Most of the groups involved in advocating for the FALCPA were food allergy groups. In contrast, ACTF, which was composed of leaders of national celiac disease support groups, medical professionals, research institutions, and representatives of gluten-free food manufacturers, represented individuals with celiac disease. ACTF acted as the voice of the celiac community during the push to pass the FALCPA. It was formed in 2003 after the celiac disease prevalence study results were released by the University of Maryland Center for Celiac Research. This study "opened the doors for people paying much more attention" to celiac disease, according to ACTF Co-chair Andrea Levario. Telephone Interview with Andrea Levario, ACTF Co-chair (Jan. 27, 2005); *see also* Michelle Melin-Rogovin, *The Future of Food Labeling in the U.S. Depends on You*, 2(4) CELIAC.COM'S GUIDE TO A SCOTT-FREE LIFE WITHOUT GLUTEN 11 (Autumn 2003) (on file with author) (Melin-Rogovin is Program Director of the University of Chicago Celiac Disease Program and an ACTF representative). "Dr. Fasano [who spear-headed the research] knew that more and more people were now going to be diagnosed. The next major hurdle was going to be how are you going to feed these people? ... You couldn't read a food label and know what you're eating is safe." Telephone Interview with Andrea Levario, ACTF, *supra*. "This was a true grassroots effort," Levario says. Within the span of 18 months, ACTF was created, it mounted a lobbying effort, and it witnessed the successful passage of the FALCPA. ACTF "has no money. This was all done strictly via word of mouth, via the Internet, via e-mail. ... We were a voice in all this, and it was strictly, totally grassroots, every step of the way, which is pretty phenomenal." *Id*.

[218] *See* Press Release, CSPI, Food Industry Opposing Label Improvements (Sept. 20, 2002), *available at* http://www.cspinet.org/new/200209201.html. Other general consumer groups such as the Consumer Federation of America and Consumers Union also supported the FALCPA.

[219] The first organized consumer movement to petition FDA for more comprehensive allergen labeling began in October 1997 by Food Allergy Survivors Together (FAST), a supportive group and website for individuals with food sensitivities. *See* 66 Fed. Reg. 38,591, 38,592 (July 25, 2001); FDA, 2001 Public Meeting Transcript, *supra* note 44, at 14-15 (statement of Christine Lewis, Director of the Office of Nutritional Products and Labeling and Dietary Supplements, FDA). For a copy of the

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Several consumer groups had the ear of the FALCPA's congressional sponsors. They gave some input into the draft legislation and provided talking points regarding problems faced by food-sensitive individuals. These groups also helped generate support among members of Congress for the bill by "put[ting] a human face on this problem."[220]

FAST petition, see http://www.fda.gov/ohrms/dockets/dailys/01/Dec01/121101/99p-2148_ans0002_vol1.pdf (last visited Dec. 28, 2005). *See also* Melissa Taylor, Petition for Clearer Food Labeling Food Allergy, *supra* note 151 ("This campaign was started by Food Allergy Survivors Together in 1997—the first food allergy group to tackle this issue, due to mailing list member request. ... FAST is reportedly the first allergy group to bring this subject out in the open. ... After discussing this problem with other concerned consumers on the FAST mailing list in 1997, we decided to start a labeling campaign toward the FDA. Since then it has branched out somewhat, and is now a petition formulated by Lucy Shriver of The Gluten-Free Kitchen.").

The FAST Petition called for FDA to end the spices, flavorings, and colorings exemption completely and to require the declaration of all source ingredients contained in those generic terms. This was a collaborative effort by concerned consumers who wanted to take action regarding the labeling difficulties they were experiencing. E-mail Interview with Melissa Taylor, FAST Co-founder (Jan. 8, 2005) ("The petition came about from personal experience. I reacted to an unlabeled ingredient in a food I was eating, and went on the FDA website to research how this type of thing could be allowed. By 'talking' to people on the FAST mailing list, I learned many people did not understand that terms like 'natural flavoring' and 'spices' were potentially hidden allergens. I wanted to get the word out so people could avoid these ingredients, as well as try to influence legislation."). FDA cited this groundbreaking petition and consumer effort as one of the reasons it was calling for the 2001 Public Meeting. *See* 66 Fed. Reg. 38,591, 38,592 (July 25, 2001).

In 2000, nine state Attorneys General petitioned FDA to improve allergen labeling. *See* Nine State Attorneys General Citizens Petition, *supra* note 104. Unlike the FAST Petition, the Attorneys General Petition focused only on the Big Eight allergens. Several consumer groups spoke out in support of this petition. *See Advocacy Groups Urge FDA to Require Allergen Labeling*, FOOD CHEM. NEWS, July 31, 2000, at 9, *available at* 2000 WL 12748657 ("Four advocacy groups are urging FDA to require new labeling of allergens in foods and require companies to adopt stricter good manufacturing practices ... the Center for Science in the Public Interest, Public Citizen Health Research Group, PeanutAllergy.Com, ... and the Gluten Intolerance Group of North America ... ."). The Attorneys General Citizens Petition was a starting point for the discussion of food allergen labeling at the 2001 Public Meeting. *See* 66 Fed. Reg. 38,591, 38,592 (July 25, 2001). Catherine Tretheway, an attorney who assisted the New York Attorney General in preparing the petition, explained the petition's background at the Public Meeting:

> This is truly a document prepared by consumers for consumers. In drafting the petition, I not only drew from my own experiences as the parent of a food allergic child, but also from the experiences of the many parents with whom I have talked or corresponded with during the recent years that I have started my work on food allergy issues. ... The petition is not a wish list for food allergic consumers. Rather, it represents what consumers truly need to protect themselves and their loved ones from unintended consumption of food allergens. ... As the parent of a food allergic child, I appreciate the efforts of the Food Allergy Issues Alliance in issuing [voluntary industry] guidelines for better good manufacturing practices and labeling. However, even after all our discussion today, I can only conclude that consistency in labeling can only be achieved through regulatory reform.

FDA, 2001 Public Meeting Transcript, *supra* note 44, at 183-84 (statement of Catherine Tretheway). Another major petition to FDA calling for improved allergen labeling was sent by CSPI in October 2001. *See* CSPI, Regulatory Comments and Petitions, Petition for Rules Regarding the Labeling and Manufacture of Foods Containing Allergenic Substances (Oct. 4, 2001), *available at* http://www.cspinet.org/foodsafety/allergenic_substances.html; *see also* FDA, 2001 Public Meeting Transcript, *supra* note 44, at 28-29 (statement of Michael Jacobson, CSPI).

[220] E-mail Interview with Jean Doyle, Legislative Assistant for Rep. Nita M. Lowey (Feb. 11, 2005); *see also, e.g.*, FDA, 2001 Public Meeting Transcript, *supra* note 44, at 25 (statement of Kate Winkler, Legislative Assistant for Rep. Lowey) ("We've also been working very closely with some organizations like Food Allergy Initiative, FAAN and CSPI, and let them activate their base so that like the constituents who reached out to my boss to say that this is something that is needed, ... they can let their members of Congress know that this is important to them ... ."); 150 CONG. REC. H6100 (July 20, 2004) (statement by Rep. Lowey) ("The Food Allergy Initiative, American Celiac Task Force, Food Allergy and Anaphylaxis Network and so many others also deserve thanks for their continued dedicated advocacy.").

Given the growing numbers of individuals diagnosed with food sensitivities, their increased activism with regard to inadequately labeled products, and improved methods for testing foods for hidden allergens, FDA reinforced the importance of preventing allergic reactions in 1991 by instituting the first food product recalls due to undeclared allergens. While such recalls were at first "inconsistent,"[221] the number of allergen-related product recalls steadily rose during the 1990s—resulting in allergen-related recalls surpassing all other causes of Class I food recalls (the most serious form of product recall, reserved for products which could pose a serious risk of injury or death to consumers).[222] In 2002, recalls due to undeclared major allergens nearly doubled, rising from sixty-eight to 116.[223]

What initiated an enhanced focus on food allergens in the United States in earnest was a Notice to Manufacturers letter (Notice Letter)[224] issued by FDA in June 1996.[225] Reports from consumers about adverse reactions from undisclosed allergens in food products "prompted FDA to develop an initiative on food allergen awareness."[226] This Notice Letter demonstrated a marked change in FDA's attitude toward food allergens and a new prioritization of allergen issues.[227]

In the Notice Letter, FDA reversed its prior interpretation of the additives labeling exemption in the FDCA and declared that the specific ingredients in additives must be disclosed when the additive contains a "known allergen." FDA further asserted that advisory labeling should not be used in lieu of adherence to GMPs and that allergens

[221] *Taylor Warns Against Rework Because of Allergies*, FOOD CHEM. NEWS, Feb. 7, 1994, at 7 ("Dr. Steve Taylor, of the University of Nebraska ... alleged that the Food and Drug Administration's weekly Enforcement Report is not 'consistent,' stating that only 'dramatic adverse reactions' are listed by the agency. ... The professor also said FDA entries on the recall list are not always 'prompt.'").

[222] *See, e.g.*, Mary Ellen Butler, *Allergens, Trans Fat Labeling are FDA Priorities, Levitt Says*, FOOD CHEM. NEWS, Feb. 12, 2001, at 3, *available at* 2001 WL 12772593 ("[U]ndeclared allergens result in more Class I recalls by food companies than pathogens."); *Recalls for Undeclared Food Allergens Apparently Rising, FDA Official Says*, FOOD LABELING & NUTRITION NEWS, June 19, 1997, at 7 ("Undeclared food allergens appear to be on the rise, Lawrence Bachorik, FDA's deputy associate commissioner for public affairs, told food and drug officials earlier this month. Allergens heading the list of such recalls, he said, are eggs, peanuts, tree nuts and Yellow No. 5 food color."); FDA, CFSAN, Questions and Answers on Allergen Guides (May 3, 2001), http://www.cfsan.fda.gov/~dms/alrgpgtp.html ("A recent review of FDA food recall actions based on undeclared allergens in food revealed an increase in such recalls during the last decade. Ten years ago, there were 35 recalls per year for undeclared food allergens. From FY 1996 to FY 1999, undeclared allergen recalls averaged 90 per year. In FY-2000, the number of recalls rose to 121.").

[223] *See* FDA, Advice to Consumers, *supra* note 5.

[224] FDA, CFSAN, Notice to Manufacturers: Label Declaration of Allergenic Substances in Foods (June 10, 1996), *available at* http://www.cfsan.fda.gov/~lrd/allerg7.html [hereinafter FDA, Notice Letter].

[225] For example, prior to 1996, *Food Labeling & Nutrition News* scarcely mentioned labeling as it related to food allergens. Beginning in 1996, food allergens became a frequently discussed topic.

[226] Falci et al., *Food Allergen Awareness*, *supra* note 27, at 1 (stating further that, "In 1996, FDA issued a notice to the food industry alerting manufacturers and trade associations, requesting assistance in addressing the major public health problem of undeclared allergens in food."); *see also* FDA, Notice Letter, *supra* note 224.

[227] This change in attitude gained more strength and direction in subsequent years. According to Dr. Ken Falci, Director of CFSAN's Office of Scientific Analysis and Support:

> It wasn't very long ago, actually in 1999, that FDA first thought about being and becoming more active with food allergens, and we did have discussions and we did formulate a plan of action as far as food allergens were concerned. We formed an internal steering committee within the Center for Food Safety and Applied Nutrition, which is a center in FDA. And we also had a general committee on food allergens made up of a number of people within different offices that are in the Center for Food Safety.

FDA, 2001 Public Meeting Transcript, *supra* note 44, at 6-7 (statement of Ken Falci, FDA).

introduced to a product through cross-contamination may be considered adulterated under 21 U.S.C. § 342(a)(4). The Notice Letter also encouraged manufacturers to list allergens present in spices, flavorings, and colors, and stated that FDA might consider rulemaking to that effect, despite the exemption of those constituents from disclosure provided in the FDCA.[228] The Notice Letter marked a significant shift in FDA's approach toward allergen labeling, although the letter couched its new interpretation of the additive exception in terms that implied this had been FDA's policy all along.[229]

While a marked improvement, the Notice Letter afforded an incomplete remedy to meet the needs of food-sensitive individuals because, most importantly, the Notice Letter merely was guidance and was never codified in regulations.[230] Additionally, the Notice Letter did not:

- specify definitively which allergens require disclosure, instead listing the Big Eight allergens as "examples" of allergens;
- mandate "plain English" labeling of allergens;
- specify a standard format for allergen disclosure; or
- address the large problem of cross-contamination beyond declaring that advisory labeling could not substitute for compliance with GMPs.

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[228] At the 2001 Public Meeting on food allergen labeling, Dr. Michael Jacobson of CSPI suggested several possible ways in which FDA might accomplish such a rulemaking:

> The FDA could take several legal approaches. It could assert that the general misbranding section of the act trumps the flavoring/spices/color exemption because the ingredients can cause severe allergic reactions. Alternatively, for allergenic flavorings, spices or colors that are considered generally recognized as safe, the FDA could determine that those substances are not safe.

FDA, 2001 Public Meeting Transcript, *supra* note 44, at 134 (statement of Michael Jacobson, CSPI).

[229]

> In some of the instances of adverse reactions, failure to declare an ingredient appears to have been the result of a *misinterpretation* of the exemption from ingredient declaration provided for incidental additives in 101.100(a)(3). FDA reminds manufacturers that to qualify for the exemption from ingredient declaration provided for incidental additives and processing aids, a substance must meet both of the requirements of 101.100(a)(3), i.e., it must be present in the food at an insignificant level, and it must not have any technical or functional effect in the finished food. ... The recent adverse reaction reports indicate that some manufacturers have also *incorrectly interpreted* what constitutes an insignificant level of a substance. *Clearly*, an amount of a substance that may cause an adverse reaction is not insignificant. Because evidence suggests that some allergenic substances can cause serious allergic responses in some individuals upon ingestion of very small amounts of the substance, it is unlikely that such an allergen, when it is present in a food, can be present at an insignificant level.

FDA, Notice Letter, *supra* note 224 (emphasis added); *see also* FDA, CPG on Cross-contact, *supra* note 56 ("FDA, however, has never considered food allergens eligible for this exemption. ... The exemption under 21 CFR 101.100(a)(3) does not apply to allergenic ingredients.").

[230] *See, e.g.*, FDA, Notice Letter, *supra* note 224 ("asking" manufacturers to examine their product formulations for allergens and to amend food labels appropriately, suggesting how the "voluntary declaration" of allergens in flavors, spices, and colors could be accomplished on the label, and "urging" manufacturers to take all steps necessary to eliminate cross-contamination); 66 Fed. Reg. 38,591, 38,594 (July 25, 2001) (asking for public comment regarding, *inter alia*, whether FDA should "codify its policy to specifically state that incidental additives that are food allergens are not exempt from labeling and must be declared in the ingredient statement on the label"); Falci et al., *Food Allergen Awareness*, *supra* note 27, at 2 (stating that since the 1996 Notice Letter, FDA "recommends" that manufacturers declare allergens in spices, flavorings, and colors); Joseph A. Levitt, CFSAN, FDA, Dear Colleague Letter on Allergen Guides (May 3, 2001), http://www.cfsan.fda.gov/~dms/alrgltr2.html (stating that FDA "strongly encourages" manufacturers to declare allergens present in spices, flavorings, and colors).

Because FDA did not promulgate regulations implementing, or expend resources to enforce, its 1996 Notice Letter, FDA came "under increasing pressure from Congress, the states, and citizen groups to create labeling laws and policies for allergenic ingredients in food."[231] FDA publicly recognized these issues listed above as problems for food-sensitive individuals five years later, when the agency took the lead in allergen reform and actively pursued comprehensive improvements to allergen labeling.

The Notice Letter, which raised the specter of future FDA rulemaking addressing allergens, made food allergen management an issue for food manufacturers on a widespread scale.[232] The Notice Letter, along with increasing food recalls,[233] consumer complaints due to allergens, and a growing concern about regulation, legislation, or lawsuits,[234] led the food industry to think about and address food allergens more seriously. The food industry began to take more coordinated and comprehensive actions to regulate itself in an effort to help its customers and to stave off regulatory or legislative action.[235] Allergen management became a key issue at food industry conferences, workshops, and training programs.[236] Some companies began to individually examine their food labels and manufacturing policies with allergen issues in mind.

[231] Department of Legislative Services, Maryland General Assembly, 2001 Session, House Joint Resolution 2 (Delegate Stern), United States Food and Drug Administration—Labeling Laws and Policies Relating to Allergenic Ingredients in Food, at 2, *available at* http://mlis.state.md.us/PDF-Documents/2001rs/fnotes/bil_0002/hj0002.PDF.

[232] It is noteworthy, however, that even prior to the Notice Letter some food firms, such as Kraft, General Mills, and Kellogg Company, were aware of food allergen issues and were taking steps to address them.

[233] As Robert Humbert, Kellogg Company's manager of food safety, stated in 1996, the increased number of allergen-related recalls was due to more attention and aggressive action by FDA, not because food manufacturers were better about cross-contact and labeling prior to the 1990s: "I doubt anyone is so naive as to believe we were that much better 15-20 years ago in our manufacturing and labeling practices. ... There is obviously a change in the way industry and the agency are looking at this issue." *Allergens More Than 'Trivial Risk' to Company's Bottom Line*, FOOD CHEM. NEWS, Nov. 18, 1996, at 4, *available at* 1996 WL 14748345; *FDA Asks Food Processors for Help in Addressing Undeclared Allergens in Food*, FOOD CHEM. NEWS, Feb. 3, 1997, at 24, *available at* 1997 WL 10013252 ("[Center for Food Safety and Applied Nutrition Director Fred Shank] said the number of Class 1 recalls has increased during the 1990s in part because FDA is looking at products more closely.").

[234] *See, e.g.*, Allan E. Anderson & Gerald B. Malanga, *Clear and Present Danger*, FOOD QUALITY, July/Aug. 2003, http://www.foodquality.com/Cover%20Story2.htm:

> While many in industry focus on how new laws can subject companies to liability, existing laws commonly applied in many litigated disputes are also applied in the context of unintended exposure to litigation. ... Existing legal theories allow injured consumers or other customers to seek recovery under traditional theories, such as personal injury claims or through a breach-of-contract claim. ... The risk of exposure to litigation to a food manufacturer for damages arising from unintended food allergens is a clear and present danger.

See also Kellogg Co. v. Mattox et al., 763 F. Supp. 1369, 1384 (N.D. Tex. 1991) (denying Kellogg's motion for a preliminary injunction where a cereal was found to be marketed in violation of a *Texas state law* because, among other things, the product label failed to adequately warn consumers of the possibility of allergic reactions caused by a grain ingredient. "Because Kellogg's failure to disclose the allergenicity of Heartwise [cereal due to protein in a grain ingredient] was material, the court concludes that Heartwise is misbranded under the Texas Act.").

[235] *See, e.g.*, *Allergens More Than 'Trivial Risk,' supra* note 233, at 4 ("The growing level of awareness and concern among consumers and regulators over food allergens is prompting food companies to institute a range of operational and recordkeeping changes designed to keep undeclared allergens from turning up in products, according to speakers at a Nov. 7 food allergen meeting in Chicago sponsored by the Food Processors Institute. ... FDA has become much more aggressive about going after products with undeclared allergens ... .").

[236] *See, e.g.*, FOOD LABELING & NUTRITION NEWS, Sept. 26, 1996, at 2 (announcing a conference to be held November 7, 1996, in Chicago regarding how to identify key allergens and reduce allergen risk); *Food Allergens High on Industry Awareness*, FOOD LABELING & NUTRITION NEWS, June 26, 1997, at 5 (stating that the National Confectioners Association and Chocolate Manufacturers Association will be sponsoring a seminar on food allergens for its members in 1997, and that "[c]hocolate and candy manufacturers are becoming much more aware of the need to prevent peanuts or their residues from turning up in non-peanut products"); FDA, 2001 Public Meeting Transcript, *supra* note 44, at 150 (statement of John Hallagan, Flavor and Extract Manufacturers Association) (stating that the Flavor and Extract Manufacturers Association sponsored an educational workshop for its members on allergens for the first time in 1997).

Additionally, a major coalition of food industry representatives known as the Food Allergy Issues Alliance (the Alliance),[237] with input from the consumer group FAAN and an allergen expert, formed after the issuance of the Notice Letter to discuss the industry's response to food allergen-related concerns and to help the food industry "be proactively out front of and address this allergy issue."[238] In 1999, the Alliance produced voluntary guidelines to help the industry regulate itself—to manage food allergens during food processing and to identify major allergens in labeling.[239] The Alliance assured FDA that "the guidelines would address food allergen issues their member companies would be implementing soon without requiring FDA to amend or issue regulations."[240] Also, that same year, NFPA issued a Code of Practice describing voluntary GMPs and improved sanitation practices to address cross-contact.[241] Industry officials asserted that the voluntary guidelines were "sufficiently flexible to suit various situations" and argued that a mandatory approach to allergen labeling would "necessitate FDA revising a number of rules for standards of identity and other labeling rules," which would "complicate a labeling approach that can be done, and [] is now being done on a voluntary basis."[242] The Alliance anticipated that the marketplace and a desire to protect consumers would drive manufacturers to follow the guidelines.[243]

These efforts by industry ultimately, however, proved to be too little, too late. The shortfalls of the voluntary guidelines were several and substantial. The principal drawback was that the guidelines were purely voluntary, rendering any benefits of the guidelines subject to the extent to which manufacturers across the nation, large and small, prioritized compliance. The guidelines permitted four different formats in which allergens could be declared on the label, which provided for less clear and consistent labeling than the scheme later proposed by the FALCPA. And although the guidelines went further than the FALCPA in limiting the circumstances under which manufacturers could employ advisory labeling, the guidelines did not ask companies to test for allergenic ingredients (visual inspection was sufficient to deem a product not cross-contaminated). Although FDA used the voluntary guidelines as its "starting point" for discussion regarding allergen labeling in the 2001 Public Meeting,[244] the limits of the guidelines also were extensively discussed. In the words of a representative from CSPI at the 2001 Public Meeting, "the time has long past for all this total voluntary flexible action on the part of industry."[245]

In the wake of the results of FDA's 1998 partnership with the departments of agriculture in Minnesota and Wisconsin[246] that found that incidents of mislabeling, cross-contamination, inadequate label verification, and inadequate recall procedures in food firms were

[237] Industry members of the Alliance included the American Bakers Association, the American Frozen Food Institute, General Mills, GMA, NFPA, and the International Dairy Foods Association (IDFA).

[238] FDA, 2001 Public Meeting Transcript, *supra* note 44, at 42 (statement of Lisa Katic, GMA).

[239] Alliance Voluntary Guidelines, *supra* note 140.

[240] 66 Fed. Reg. 38,591, 38,592 (July 25, 2001).

[241] *See, e.g.*, Formanek, *supra* note 11; FDA, 2001 Public Meeting Transcript, *supra* note 44, at 15 (statement of Christine Lewis, Director of the Office of Nutritional Products and Labeling and Dietary Supplements, FDA).

[242] FDA, 2001 Public Meeting Transcript, *supra* note 44, at 36-37, 41 (statement of Regina Hildwine, NFPA).

[243] *See, e.g., id.* at 163 ("[N]othing is quite as effective in the food industry as what we call peer pressure or the competitive marketplace, and certainly we know from the experience of food allergic consumers that they very much appreciate when food companies go to the trouble of putting food allergen information on their labels on a voluntary basis.").

[244] *See* 66 Fed. Reg. 38,591, 38,592 (July 25, 2001).

[245] FDA, 2001 Public Meeting Transcript, *supra* note 44, at 102 (statement of Michael Jacobson, CSPI).

[246] *See generally* FDA, Food Allergen Partnership, *supra* note 119.

widespread, FDA held a series of workshops to raise awareness of these issues within the food industry and to educate manufacturers about allergen control techniques.[247] CFSAN added improved food allergen labeling to its "priority list" in 2000,[248] where it remained in 2001[249] and 2002.[250] CFSAN launched several initiatives to improve industry awareness of the need for improved allergen control mechanisms, to better understand food allergies and the concerns of consumers, to help develop allergen test kits, to learn more about allergenicity thresholds, and to prepare guidance documents on allergen management.[251] With the promulgation of two *nonbinding* advisory documents in early 2001, FDA made cross-contact management an aspect of GMPs and a subject of food firm inspections, and provided guidance to industry and regulators on how to manage allergens through appropriate manufacturing and labeling practices.[252]

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[247] *See* FDA, Food Allergen Partnership, *supra* note 119 ("Industry workshops were conducted to provide feedback on the Partnership findings with a goal of increasing awareness of undeclared food allergen issues. Representatives of the partnering agencies summarized inspection and sample results, and discussed the potential sources of food safety, allergy risks, and preventive steps to minimize risk of food borne illness in food products."); Formanek, *supra* note 11.

[248] *See, e.g.*, Falci et al., *Food Allergen Awareness*, *supra* note 27, at 2:

> Beginning in 2000, CFSAN made increasing consumer and industry awareness to the presence of allergens in foods a high priority. In meeting the 2000 goal of increased awareness, CFSAN representatives held meetings at 14 locations in which they made presentations on allergen risks and labeling requirements. ... The agency also sought to gain insight into industry allergen management practices and control methods. As part of the 2000 effort, FDA and state health departments began working cooperatively to establish uniform inspection procedures for food allergens.

See also Kenneth J. Falci, FDA, The FDA, Food Allergens, and You (Nov. 2, 2000) (PowerPoint presentation), *available at* http://www.cfsan.fda.gov/~comm/vltaller.html (discussing FDA's priority issues related to food allergens).

[249] *See, e.g.*, Dennis E. Baker & Joseph A. Levitt, CFSAN, FDA, "Dear Colleague" Letter About the "Food Allergen Partnership" (Mar. 26, 2001), *available at* http://www.cfsan.fda.gov/~dms/alrgltr.html ("For the last two years the Agency has been actively involved in a process of increasing allergen awareness within the food industry. This year, more attention is being paid to the allergen issue in response to these recent findings, and allergens are on the 'A' list of activities in the Center for Food Safety and Applied Nutrition Program Priorities."); Falci et al., *Food Allergen Awareness*, *supra* note 27, at 2 ("Continuing these efforts with the 2001 CFSAN priorities, CFSAN plans to proceed with consumer and industry education efforts and to develop a strategy for clearer labeling of food allergens on the food label. Priorities include publishing a draft Compliance Policy Guide on manufacturing and labeling practices, issuing a field allergen inspection guide and providing training for FDA field offices."); Butler, *supra* note 222, at 3 ("Levitt plans to focus on allergens this year, he said, because it is an area that poses a public health hazard, but is also an area where FDA can make some progress.").

[250] *See* Falci, The FDA, Food Allergens, and You, *supra* note 248 (stating that CFSAN's "A" List Priorities regarding allergies include: continuing consumer and industry outreach, developing and implementing an allergen enforcement strategy for cross-contamination, reporting to Congress on plans to regulate to prevent cross-contamination by undeclared allergens, conducting training of field investigators, and reporting to Congress on food handling latex allergies).

[251] *See generally* Falci et al., *Food Allergen Awareness*, *supra* note 27.

[252] FDA issued two food allergen guidance documents—a Compliance Policy Guide: Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens (updating the Notice Letter by announcing FDA's internal enforcement priorities concerning undeclared food allergens, describing FDA's current thinking on allergens, and outlining policy and actions that the agency "may or may not" take under the law) and a Guide to Inspection of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients (providing guidance to FDA investigators and inspectors to assist them in evaluating conditions that may result in the introduction of undeclared allergens in foods). *See generally* FDA, Dear Colleague Letter on Allergen Guides, *supra* note 230. *See also* FDA, CPG on Cross-contact, *supra* note 56; FDA, Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients (Aug. 2001), *available at* http://www.fda.gov/ora/inspect_ref/igs/Allergy_Inspection_Guide.htm; CFSAN, Q&A on Allergen Guides, *supra* note 222.

In August 2001, FDA held a key public meeting (2001 Public Meeting) regarding food allergen labeling—the first public meeting on the topic and the first effort by FDA to gather comments on a large scale in preparation for rulemaking addressing allergen labeling. Reflecting the agency's new attitude toward allergens, FDA expressly acknowledged that food-sensitive consumers (as first publicly recognized in the 1996 Notice Letter) continued to not receive sufficient information from food labels to protect their safety:

> Each year FDA receives reports of consumers who experience adverse reactions following exposure to allergenic substances in foods. ... Most consumers are aware of their specific sensitivities and rely on the food label to avoid foods that might result in an allergenic reaction. However, adverse reactions often occur when an allergen-sensitive consumer consumes an allergenic substance that has not been declared on the food label. ... Thus, *in some cases food labels may not provide consumers with food allergies with information about all the ingredients that are in the foods that they eat.* The undeclared presence of allergens in foods is a *serious public health issue* because the ingestion of food allergens is potentially life-threatening to sensitive individuals. Therefore, as part of its public health mission to keep food safe, FDA has been focusing increased attention and activity on issues relating to food allergens, especially the proper labeling of products containing such allergens and the control of food allergens in products not intended to contain such allergens.[253]

Then, at the end of 2003, FDA took a tremendous step forward to address food allergen concerns: the agency issued a notice of proposed rulemaking calling for Big Eight allergens to appear on product labels "in plain English terms that clearly identif[y] the presence of these ingredients," including disclosure of Big Eight allergens contained in spices, flavors, noncertified colors, and incidental additives.[254] The rule was never codified, however, because the FALCPA was passed before the comment period expired.[255]

C. *Congressional Action*

Around the end of the century, as FDA, industry, and public attention to food allergen-related problems improved, so did congressional awareness. Legislative efforts to improve allergen labeling spanned six years and three Congresses. The FALCPA's passage was the result of truly bipartisan, bicameral efforts.

In the House of Representatives, allergen labeling advocacy was spearheaded by Representative Lowey. Beginning in 2000, she persistently introduced legislation proposing improved allergen disclosure on food labels each year, encouraging national attention and debate on the issues surrounding food sensitivities. Despite years of introducing bills that never left the committee phase of the lawmaking process, Representative Lowey persisted. She was joined by Senator Kennedy who, along with Senator Judd Gregg (R-NH), led allergen labeling initiatives in the Senate.[256]

[253] 66 Fed. Reg. 38,591, 38,591-92 (July 25, 2001) (emphasis added).

[254] 68 Fed. Reg. 72,889, 72,890 (Dec. 22, 2003).

[255] *See* 69 Fed. Reg. 73,147, 73,149 (Dec. 13, 2004) ("FDA initially intended to issue a proposed rule to establish requirements for labeling foods that contain common food allergens. ... Subsequently, on August 2, 2004, the President signed into law the Food Allergen Labeling and Consumer Protection Act of 2004 ... . FDA is now in the process of determining the approach it intends to take in light of the new statutory requirements.").

[256] Rep. Lowey also credits Senator Judd Gregg of New Hampshire, Rep. James Greenwood of Pennsylvania, and members of the Administration with helping facilitate the passage of the FALCPA. E-mail Interview with Jean Doyle, Ass't to Rep. Lowey, *supra* note 220.

Senator Kennedy introduced sister bills to those introduced in the House and helped work out a compromise amendment that was critical to the enactment of the FALCPA.[257] Improved allergen labeling slowly developed momentum on Capitol Hill and gained policy prominence on a national scale, such that food allergen labeling even became an issue in the 2004 Presidential election.[258]

Why at the turn of the century was legislative activity pursued to address food allergen issues? Only a few years earlier FDA had issued the Notice Letter and had begun in earnest to make improved allergen disclosure and management a priority. FDA reinforced this newfound prioritization with manufacturer inspections for undeclared allergens, product recalls, and the threat of enforcement action for violation of FDA's policy guidance regarding allergens. Furthermore, major players in the food industry had vowed to reform themselves—by 2001, many manufacturers had begun to implement the Alliance's voluntary guidelines and expressed their commitment to educating smaller manufacturers about allergens to encourage full industry-wide compliance.

Why then, after over sixty years of inaction regarding allergens, and just as serious action was being taken on the regulatory front and by the private sector, did Congress feel the need to step in and amend the FDCA to address food allergens?

The answer to this question appears to be that the same forces at work driving FDA and the food industry to seek reform—a larger and more vocal food-sensitive consumer population, heightened public awareness of food sensitivities, and improved information regarding the dangers and prevalence of confusing and incomplete labeling—also were at work on Capitol Hill, lending support for legislative action to improve allergen labeling.[259]

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[257] Proposed bill S. 2499 became "stymied" in the Senate Health, Education, Labor and Pensions (HELP) Committee, which Senator Kennedy chaired, as "key Republicans" on the committee "sided with the food industry, which generally opposes any labeling changes." CSPI Press Release, *supra* note 218. About four months after Senator Kennedy introduced S. 2499, he "offered a substitute amendment as modified that was considered as original text by the committee" in an executive session. S. REP. NO. 107-322, at 5. In October 2002, the Help Committee by unanimous vote favorably reported the amended S. 2499. The amended S. 2499, "in a bid to appease Senate GOP concerns," made several compromises with the food industry. *Kennedy Floats Amendment to Mandatory Allergen Labeling Bill*, FDA WEEK, Aug. 9, 2002, at 6, *available at* www.InsideHealthPolicy.com. *See infra* text accompanying note 271. These compromises were crucial to the FALCPA's passage. The compromise language remained largely intact in later proposed bills, essentially serving as the basis of S. 741—the final version of the FALCPA.

[258] *See, e.g.*, Volunteers for John Kerry for President, John Kerry for President Talking Points, http://www.infoimagination.org/ps/kerry/docs/TalkingPoints.pdf (last visited Feb. 21, 2006) ("John Kerry has a three-point plan to make kids safer and healthier and assure they enter school ready to learn. His plan includes a new Kids Safety Effort requiring safety labels for food allergens ... ."); George G. Olsen & Karina V. Lynch, *Legislative Watch: A Comparison of the Health Care Proposals of the Presidential Candidates*, REHAB MANAGEMENT: THE INTERDISCIPLINARY J. REHABILITATION (Oct. 2004), http://www.rehabpub.com/rehabec/102004/2.asp.

[259] For instance, Rep. Constance Morella (D-MD), who introduced a resolution in the House regarding allergen labeling in 1999—the first proposed legislative action to improve allergen labeling—cited as an impetus for the resolution the fact that she had "a number of constituents" who had experienced life-threatening reactions to food because insufficient protections were in place to ensure their safety, "and I am sure that all of my colleagues will find the same in their districts." 145 CONG. REC. H9239 (Oct. 1, 1999) (statement by Rep. Morella). Rep. Lowey similarly cited as her motivation for promoting improved labeling the fact that several constituents told her that they or their children "had food allergies and had a hard time avoiding foods that could cause reactions because of unclear or inexact labeling." It seemed to Rep. Lowey that "we could easily create a common sense solution by merely requiring that everyday terms for the eight major allergens are also used on labels." E-mail Interview with Jean Doyle, Ass't to Rep. Lowey, *supra* note 220. Rep. Bill Shuster (R-PA), who urged his colleagues to support the FALCPA, stated on the floor of the House that he learned of the frustrations of food sensitivities when a member of his staff was diagnosed with celiac disease. 150 CONG. REC. HR6099, 6100 (July 20, 2004).

Legislation afforded an opportunity to make significant improvements over FDA and private industry action. Legislation gave teeth to FDA's current allergen policies, which were not codified and were insufficiently enforced,[260] it could be enacted faster than the slow process of FDA rulemaking, and it allowed for the inclusion of provisions calling for action outside the scope of FDA's authority (e.g., provisions to promote allergen-related research and data collection and the requirement that major allergens in spices, flavorings, and colors be disclosed). Jean Doyle, a Legislative Assistant in Representative Lowey's office, noted these benefits of congressional, as opposed to FDA, action: "while the FDA has the authority to accomplish certain portions of the bill, on their limited budget and reduced staff, it would have been difficult for them to complete a rulemaking on such a vital issue in a timely fashion," and "FDA would not have had the authority to close the flavoring loophole—an important element to the success of this new manner of labeling."[261] Importantly, legislation also could provide FDA with the resources to enforce the new law.

A year after the Alliance issued the voluntary guidelines, FAAN's Muñoz-Furlong observed that FAAN was "surprised and disappointed that not all of the food industry has embraced" the guidelines, with small and midsized manufacturers, in particular, resisting compliance unless Congress requires it.[262] And even if eighty percent of the food industry was prepared to comply with the voluntary guidelines, as GMA asserted in a letter to the *New York Times* in 2003,[263] Representative Lowey contended "[i]t's just not enough to completely and accurately label some of the food some of the time."[264] Representative Lowey believed that voluntary compliance, while a "good start," nevertheless was dangerously insufficient: "with so many children suffering from food allergies, the Federal Government is obligated to respond."[265]

Hundreds if not thousands of individuals with food sensitivities or their caregivers made telephone calls and sent letters to the offices of their congressional representatives to support legislative proposals to improve labeling. Individuals with celiac disease testified in May 2004 before the House Appropriations Subcommittee on Labor, HHS, and Education—the first time people with celiac disease had testified before a congressional committee about the disease and the need for improved research, educa-

[260] As Congress noted: "Although additives that are, or that contain, a major food allergen are not considered to be incidental, these ingredients are nonetheless sometimes inadvertently left off of the food label." S. REP. NO. 108-226, at 3 (2004); *see also* FDA, 2001 Public Meeting Transcript, *supra* note 44, at 103-04 (statement of Michael Jacobson, CSPI):

> The FDA has already stated in its April 19 Compliance Policy Guide that undisclosed cross-contamination may cause the food to be considered adulterated. Seizures of contaminated products would protect consumers and send a clear signal to the industry that the FDA is truly concerned about food allergens and will vigorously enforce its compliance policy. Currently, FDA inspectors rarely visit factories that make cookies, pastries and other foods that may contain dangerous and unlabeled allergens. The FDA simply lacks the funds and so companies don't even have to worry about inspections. We urge the FDA to use some of its budget increases to hire additional inspectors. In addition, we urge the FDA to seek new funding on the order of roughly $10 million a year for more inspectors, more tests, educational efforts, and research to develop quick reliable testing methods.

[261] E-mail Interview with Jean Doyle, Ass't to Rep. Lowey, *supra* note 220.

[262] *Allergen Legislation Gains Approval of Senate HELP Committee*, 12(2) GUIDE TO U.S. LABELING LAW MONTHLY BULL. 6 (Nov. 2002).

[263] *See* Laura Gilcrest, *Allergen Labeling Compliance at Issue in Controversial* New York Times *Editorial*, FOOD CHEM. NEWS, June 9, 2003, at 17, *available at* 2003 WL 11733081.

[264] Greg Winter, *Calls Increasing for Clarity on Food Labels*, N.Y. TIMES ON THE WEB, July 2, 2002, www.nytimes.com.

[265] E-mail Interview with Jean Doyle, Ass't to Rep. Lowey, *supra* note 220.

tion of the medical community, and food labeling.[266] Individuals organized writing campaigns to Congress. For instance, two parents of peanut-allergic children "launched a postcard campaign to educate members of Congress about the FALCPA" and "printed over 3000 postcards for various parents, with photos of their food allergic children on one side and information about the bill on the other" that people could send to their members of Congress.[267]

At first the food industry opposed legislative action outright, asserting that the voluntary guidelines and FDA's current policies effectively dealt with allergenicity problems.[268] This position of the food industry was short-lived. As FDA and Congress became more active in pressing for the codification of allergen labeling rules and these efforts gained momentum, the food industry gradually recognized the need to become a part of the creation of these new standards.

The food industry worked closely with Congress in 2003 and 2004, therefore, to develop the final version of the FALCPA. A legislative assistant in Representative Lowey's office explained that, "From the beginning the food industry had concerns with the legislation. But Congresswoman Lowey worked with her colleagues for years to take the food industry's concerns into consideration."[269] One key compromise involved setting the effective date for labeling changes to coincide with the new transfat regulations, thereby minimizing costs and disruption to the food industry because firms would need to change labels only once. The food industry additionally worked to retain some flexibility in the format of allergen disclosure. Ultimately, the FALCPA gave industry the choice between two formatting options that had been endorsed in the voluntary guidelines and were the "most popular with both consumers and the food industry." The FALCPA, thus, did not "penalize those [manufacturers] that have been good players by voluntarily providing information" under the voluntary guidelines.[270]

Other compromises that the food industry worked with Congress to achieve included:

- the elimination of requirements regarding gluten identification on food labels;
- the elimination of the requirement that allergens appear in bold font on the label;
- the elimination of manufacturer recordkeeping and data collection requirements;
- the elimination of fines for manufacturers that fail to adequately label allergens;
- the elimination of the printing of a telephone number on labels;
- the elimination of a provision requiring the use of GMPs to minimize cross-contamination;

[266] *See* Allison Herwitt, ACTF Co-chair, Congress Hears First Ever Testimony on Celiac Disease (May 25, 2004), http://www.celiac.com/st_prod.html?p_prodid=971 ("The celiac community has waited a very long time for this incredible opportunity.").

[267] Press Release, Food Allergy Action, Food Allergy Mom Forms Grassroots Advocacy Group (July 23, 2004), *available at* http://foodallergyaction.org/pr072304.html.

[268] *See, e.g.*, Press Release, CAIMA, NFPA Stresses Need for Cooperative Efforts on Food Allergen Labeling, Rather Than New Legislation (Apr. 30, 2001), *available at* http://www.caima.net/research_reports.htm#NFPA%20STRESSES%20NEED%20FOR%20COOPERATIVE%20EFFORTS%20ON%20FOOD%20ALLERGEN%20LABELING,%20RATHER%20THAN%20NEW%20LEGISLATION; *Kennedy Floats Amendment to Mandatory Allergen Labeling Bill*, *supra* note 257, at 6 ("But the food industry source says that even though the amendment goes in the right direction, the food industry continues to oppose the bill on the grounds that a mandatory approach is not appropriate or needed, and that instead the food industry should be allowed to continue to implement its voluntary guidelines."); *NFPA Responds to Labeling Petition*, FOOD INGREDIENT NEWS, Sept. 1, 2001, *available at* 2001 WL 12422524; *see also* IDFA, Food Industry Coalition Letter to Senate, Regarding Allergen Labeling Legislation (June 2002), *available at* http://www.idfa.org/leg/alllabel.cfm; Gilcrest, *Allergen Labeling Compliance at Issue*, *supra* note 263.

[269] E-mail Interview with Jean Doyle, Ass't to Rep. Lowey, *supra* note 220.

[270] *Id.*

- the elimination of specifications for when advisory labeling may permissibly be employed;
- the elimination of language placing restrictions on advisory labeling; and
- the addition of an exemption from the FALCPA's labeling scheme where an allergen already is stated in plain English elsewhere in the ingredient list.[271]

The efforts of FDA, industry, consumers, and Congress converged in 2004. Just as FDA was about to issue a notice of proposed rulemaking to impose labeling requirements for major allergens, Congress—in consultation with FDA (and relying heavily on information documenting the need for improved labeling gathered by FDA), food industry representatives, and consumer groups—passed the FALCPA. Ultimately, it was Congress that forged new ground in food labeling to address the long-neglected issue of labeling for food allergens, just as it had in 1990 when it broke fifty years of relative food labeling inertia to amend the FDCA to legislate comprehensive nutrition labeling requirements.[272]

Legislative efforts to improve allergen labeling, unprecedented before 1999, went through several iterations and adaptations over the course of six years until the FALCPA eventually was passed.[273] During that time, legislative initiatives frequently were stymied, and numerous bills died in committee. As one publication noted in 2004, the FALCPA, which had been "lingering in 'provision purgatory' ... finally did see the light of day."[274] After "much hard work and incredible efforts"[275] to reach compromises, language was drafted with which the food industry, Republicans, and Democrats all finally could agree.

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[271] *Compare* H.R. 4704, 107th Cong. (2d Sess. 2002) *with* S. 2499, 107th Cong. (2d Sess. 2002) (as introduced in the Senate) §§ 3, 5, and 6; S. 2499, 107th Cong. (2d Sess. 2002) (as reported in the Senate); *and* S. REP. NO. 107-322 (2002); *see also* IDFA, Chip Kunde, IDFA Senior Vice President, Washington Week: Dairy Updates From Capitol Hill and the Campaign Trail, Allergens Legislation (July 12, 2004), http://www.idfa.org/news/stories/2004/07/legisoverview.cfm; IDFA, Senate Approves Food Allergen Labeling Bill (Mar. 14, 2004), http://www.idfa.org/news/stories/2004/03/allergens.cfm; Laura Gilcrest, *Senate Bill Limits Readability Rules to Allergen Labeling*, FOOD CHEM. NEWS, Sept. 30, 2002, at 25-26, *available at* 2002 WL 11879913; *Substitute Pulls Mandatory Gluten Declaration: Senate Panel Passes Watered-Down Food Allergen Labeling Bill*, FDA WEEK, Sept. 27, 2002, at 5, *available at* www.InsideHealthPolicy.com; IDFA, Senate Committee Approves Compromise Allergen Labeling Bill (Sept. 26, 2002), http://www.idfa.org/news/stories/2002/09/allergenbill.cfm; *Kennedy Floats Amendment to Mandatory Allergen Labeling Bill*, *supra* note 257; *see also supra* note 257 for information regarding compromises made.

[272] The parallels between the circumstances surrounding the passage of the FALCPA and the NLEA are striking. In 1973, FDA issued regulations requiring certain nutrition information to appear on the food label that only applied when a manufacturer added nutrients to a food or made claims about a food's nutritional value. *See generally* 38 Fed. Reg. 2125 (Jan. 19, 1973). In 1990, FDA issued a notice announcing a "major initiative to reform the nation's food labeling system" and proposing mandatory nutrition labeling. *See* 55 Fed. Reg. 29,487, 29,487 (July 19, 1990). These regulations were never codified because just three months later Congress enacted the NLEA, formally amending the FDCA. Perhaps this confluence of legislative and regulatory initiative reflects a general altering of public and governmental attitudes with regard to these labeling issues such that change was viable at these points in time through either legislative or regulatory means.

[273] *See* H.R. Res. 309, 106th Cong. (1st Sess. 1999); H.R. 5532, 106th Cong. (2d Sess. 2000); H.R. 1356, 107th Cong. (1st Sess. 2000); H.R. 4704, 107th Cong. (2d Sess. 2002); S. 2499, 107th Cong. (2d Sess. 2002); S. 741, 108th Cong. (1st Sess. 2003); H.R. 467, 108th Cong. (1st Sess. 2003); H.R. 3684, 108th Cong. (1st Sess. 2003).

[274] Allissa Hosten, *2004: A Year of Postponements, Procrastination ... and Progress*, FOOD CHEM. NEWS, Dec. 20, 2004, at 17, *available at* 2004 WL 67505546; *see also Winners and Losers of 2004*, FOOD CHEM. NEWS, Dec. 20, 2004, at 21, *available at* 2004 WL 67505548 ("The theme for this year's winners seems to be, 'The best comes to those who wait,' as groups that had been waiting indefinitely for key legislation to make its way down the political pipeline made the biggest gains. ... In another legislative leap, the reincarnated Food Allergen Labeling and Consumer Protection Act finally passed this year, after dying in the House in 2003.").

[275] Press Release, Rep. Nita M. Lowey, Lowey Statement on Food Allergy Labeling Law (Aug. 5, 2004), http://www.house.gov/apps/list/press/ny18_lowey/foodallergylaw080504.html.

By the time the FALCPA was voted on in 2004, the legislation had received broad co-sponsorship and wide, bipartisan support.[276] The FALCPA unanimously passed the Senate on March 8, 2004, and passed in the House on July 20th by such a large margin that only a voice vote was needed, indicating at least a two-thirds majority in favor of the bill.[277] Thus, remarkably, over the course of just a few years, the concept of requiring the identification of food allergens on product labels transformed from being radical to virtually noncontroversial. Consumer groups,[278] FDA,[279] members of Congress,[280] and several industry trade organizations[281] praised the passage of the FALCPA.

Chris Weiss, FAAN's Director of Legislative and Regulatory Research, described the coming together of these various forces and interests in this way: "Over the course of a couple years through meetings and exchanges, all of the parties eventually found the same page, and that was the [FALCPA]. ... All the efforts just paid off. All the cosmic tumblers clicked into place."[282] In the words of Representative Lowey: "There is no doubt that this bill becoming law is cause for celebration. It isn't often that we achieve true bipartisan, bicameral victories on Capitol Hill these days."[283]

D. Changing Perception of Food Ingredient Disclosure in the United States and Internationally

As the dietary preferences and needs of Americans continue to expand, nutrition and obesity concerns increase, and information about food ingredients has improved,

[276] Co-sponsors of the legislation were roughly split evenly between political parties.

[277] *See* S. 741, Bill Summary and Status, Thomas.loc.gov (last visited Feb. 20, 2006).

[278] *See, e.g.*, Food Allergy Initiative, Food Allergy Initiative Celebrates the Food Allergen Labeling & Consumer Protection Act Becoming Law (Aug. 6, 2004), http://www.medicalnews service.com/fullstory.cfm?storyID=2444&fback=yes ("The Food Allergy Initiative celebrates a major victory in its public policy campaign as President George W. Bush signed the Food Allergen Labeling and Consumer Protection Act (S. 741)."); Press Release, FAAN, President Bush Signs Food Allergen Labeling and Consumer Protection Act: Historic Day for the 11 Million Americans With Food Allergies (Aug. 3, 2004), *available at* http://www.foodallergy.org/press_releases/falcpasign.html; Press Release, CSPI, Senate Passes Food Allergen Labeling Bill (Mar. 9, 2004), *available at* http://www.cspinet.com/new/200403091.html ("'This bipartisan legislation could be a real life-saver for people with food allergies,' said CSPI executive director Michael F. Jacobson.").

[279] *See, e.g.*, Press Release, FDA, FDA Commends Passage by the House of Representatives of S. 741, A Bill Providing Improved Consumer Protection and Incentives for Animal Drug Development (July 20, 2004), *available at* http://www.cfsan.fda.gov/~lrd/fpfalcpa.html ("FDA applauds the passage of the Food Allergen Labeling and Consumer Protection Act. It will be of great help to consumers that are prone to allergies. We welcome this legislation which is consistent with FDA's initiatives to provide consumers with the information they need to make healthy choices.").

[280] *See* 150 CONG. REC. HR6099, 6100 (July 20, 2004).

[281] *See, e.g.*, Press Release, NFPA, NFPA Applauds Passage of Food Allergen Labeling Legislation by U.S. House of Representatives (July 21, 2004); Press Release, Food Marketing Institute, Supermarket Industry Commends Congress for Passing Plain-Language Allergen Labeling Bill (July 21, 2004), *available at* http://www.fmi.org/media/mediatext.cfm?id=659.

[282] Telephone Interview with Chris Weiss, FAAN, *supra* note 216; *see also* FAAN Press Release, *supra* note 278:

> FALCPA is the result of years of hard work and a cooperative effort involving the food industry, the Food and Drug Administration (FDA), FAAN, other consumer advocacy groups, concerned families nationwide, and bi-partisan efforts by federal legislators such as Senators Judd Greg (R-NH) and Edward Kennedy (D-MA), Representative Joe Barton (R-TX), Chair of the House Committee on Energy and Commerce Representative Michael Bilirakis (R-FL), Chair of the House Subcommittee of Health, Representative Jim Greenwood (R-PA) and Representative Nita Lowey (D-NY), who originally introduced the legislation.

[283] Lowey Statement, *supra* note 275. On the day of the vote on S. 741 in the House, Rep. Lowey thanked many colleagues for their support of the FALCPA: "We spent a few years and many hours hashing out the bill before us, committed to crafting a noncontroversial, bipartisan product. And I believe we accomplished our goal." 150 CONG. REC. HR6099 (July 20, 2004) (statement by Rep. Lowey).

consumer expectations about the right to know what they are eating have changed. The once far-fetched claim that Americans deserve to have confidence in the labeling of the food on their table no longer appears quite as controversial. This trend of increasing public expectations regarding food transparency was reflected in 2004 in numerous successful initiatives, in addition to the FALCPA, that called for greater information disclosures on the food label, including an agreement by several produce and meat industry groups to employ country-of-origin labeling and FDA's mandating disclosure of the trans fat content of foods.[284]

The growing emphasis on food sensitivities in the United States at the turn of the twenty-first century also was experienced internationally. In significant ways, the United States undeniably has been an international leader in terms of food safety in general and food labeling in particular.[285] When it came to food allergen labeling, however, the United States was behind several other countries and international groups. Canada became active—and an international leader[286]—in addressing food sensitivity issues as early as the 1980s. In 1997, the Canadian Food Inspection agency was formally established and charged with implementing allergen control activities.[287] By 2001, Canada had implemented guidelines for allergen-related food product recalls, increased the number of allergen-related recalls, and adopted requirements to ensure that ten major allergens are fully and consistently labeled.[288] The Codex Alimentarius Committee,[289] an international body that develops worldwide food standards, adopted voluntary labeling standards for major allergens in 1999—the result of over a decade of discussions about whether and how to improve allergen labeling.[290] And the European Union (EU) enacted mandatory allergen labeling requirements just one year before the United States.[291]

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[284] *See, e.g.*, Valerie Philips, *Obesity, Carbs Are Hot Dietary Topics of 2004*, DESERT MORNING NEWS, Dec. 29, 2004, *available at* 2004 WL 104366747.

[285] *See, e.g.*, FDA, Notice Letter, *supra* note 224 ("While packaged foods sold in the U.S. are among the most comprehensively labeled foods in the world (some countries provide broader exemptions from ingredient declaration), FDA is studying its labeling requirements, and considering whether rulemaking is necessary, for the labeling of allergenic ingredients.").

[286] *See, e.g.*, Taylor, *From Chaos*, *supra* note 157 ("Internationally with the notable exception of Canada, the response of the food industry to food allergies has been more uneven due to a continuing lack of knowledge and training.").

[287] *See* Canadian Food Inspection Agency, Health Canada, Paper on the Allergen Control Activities Within the Canadian Food Inspection Agency (2003), *available at* http://www.hc-sc.gc.ca/fn-an/securit/allerg/cfia-acia/allergen_paper-evaluation_allergene-01_e.html.

[288] *See id.*; Alex Binkley, *CFIA [Canadian Food Inspection Agency] Improves System to Monitor Food Supply; Food Recalls Increase*, FOOD CHEM. NEWS, Apr. 17, 2000, at 11-12, *available at* 2000 WL 12748067.

[289] The Codex Alimentarius is a set of international food standards established to protect the health of consumers and facilitate fair international trade. *See* JOINT FAO/WHO FOOD STANDARDS PROGRAMME OF THE CODEX ALIMENTARIUS COMMISSION, CODEX ALIMENTARIUS: FOOD LABELLING COMPLETE TEXTS iii (2001) [hereinafter JOINT FAO/WHO FOOD STANDARDS PROGRAMME].

[290] *See Allergen Labeling Policy Considered by Codex Committee*, FOOD LABELING & NUTRITION NEWS, May 6, 1993, at 15-17; *see also* FAO, REPORT OF THE FAO TECHNICAL CONSULTATION ON FOOD ALLERGIES, Annex 4: Consideration by Codex of Food Allergies and Hypersensitivity 4 (Nov. 13-14, 1995) [hereinafter FAO CONSULTATION]:

> The current deliberations of the [Codex Committee on Food Labeling] in respect of the problem of food allergens dates from the nineteenth session in 1987 when the Committee took note of the availability of a reliable method for the determination of gliadin, which had been identified as the causative agent of gluten intolerance in celiac disease, and agreed that this and similar problems of food allergy and intolerance and their relationship to the adequacy of the ingredient listing requirements in the General Standard should be considered at a future meeting.

[291] *See generally* European Union Council Directive 2003/89, 2003 (L 308), *available at* http://europa.eu.int/eur-lex/lex. These labeling regulations did not go into effect, however, until November 25, 2005. *See, e.g.*, Anthony Fletcher, *EU Strengthens Allergen Labelling* (Nov. 30, 2005), *available at* http://www.foodnavigator.com/news/ng.asp?n=64224-eu-directive-label.

IV. SUMMARY OF THE FALCPA

"At present, there is no cure for food allergies, and a food allergic consumer must avoid the food to which the consumer is allergic."
FALCPA § 202(2)(B)-(C)

This section of the article analyzes the FALCPA's provisions. It first discusses the ways in which the FALCPA amends the FDCA's food labeling requirements to help make the presence of major food allergens "easily visible to consumers."[292] The FALCPA's provisions that attempt to address several safety concerns not remedied by the new labeling requirements and improve knowledge about food sensitivities are then summarized.

A. *Amendments to the FDCA: New Labeling Requirements*

The FALCPA applies to packaged food[293] sold in the United States[294] that is *labeled* on or after January 1, 2006.[295] The FALCPA requires that the labels of such food that contains the protein of one of eight "major food allergens"[296] must disclose the presence of the allergen in "plain English."[297] Section 203(a) of the FALCPA creates a new subsection (w) in 21 U.S.C. § 343 that expands the FDCA's definition of misbranding to include a failure to identify the presence of major food allergens in a product. Explicitly closing the incidental additives and the spices, flavorings, and colorings loopholes, the FALCPA states that "notwithstanding ... any other law, a flavoring, coloring, or incidental additive that is, or that bears or contains, a major food allergen shall be subject to the labeling requirements of this subsection."[298] Like other labeling requirements of the FDCA, these new misbranding provisions have preemptive effect over state and local food labeling laws.[299]

[292] H.R. REP. NO. 108-608, at 7.

[293] "Raw agricultural commodities" are exempt from allergen labeling. FALCPA § 203(a), 21 U.S.C.A. § 343(w)(1).

[294] "FALCPA's requirements apply to all packaged foods sold in the U.S. that are regulated under the Federal Food, Drug & Cosmetic Act, including both domestically manufactured and imported foods. FDA regulates all foods except meat products, poultry products, and egg products." FDA, Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (2d ed. Dec. 14, 2005), *available at* http://www.cfsan.fda.gov/~dms/alrguid2.html [hereinafter FDA, Food Allergen Guidance for Industry].

[295] *See* FALCPA § 203(d), 21 U.S.C.A. § 321(note). Companies may continue to sell products labeled before January 1, 2006. The FALCPA does not require food products labeled before this date to be removed from the marketplace and relabeled. *See* S. REP. NO. 108-226, at 9; *see also* FDA, Food Allergen Guidance for Industry, *supra* note 294 ("FALCPA does not require any action with respect to products labeled before January 1, 2006); FDA, Advice to Consumers, *supra* note 5 ("FDA cautions consumers that there will be a transition period of undetermined length after January 1, during which it is likely that consumers will see packaged food on store shelves and in consumers' homes without the revised allergen labeling."); Amy Ratner, *New Year, New Labels*, GLUTEN-FREE LIVING 15 (Summer 2005). The fixed date encouraged timely industry action, as well as informed consumers when they could expect to begin trusting the accuracy of food labels. This timeframe also helped minimize the burden on industry by corresponding to the original deadline for new trans fat labeling requirements issued by FDA and by giving manufacturers time to exhaust label supplies and develop new labels.

[296] Congress deemed these eight allergens the "most significant" food allergens, S. REP. NO. 108-226, at 5, because they account for "over 90% of food allergies in the United States," H.R. REP. NO. 108-608, at 3.

[297] *See* H.R. REP. NO. 108-608, at 3. The legislation "ensure[s] that the food source from which a major food allergen is derived is clearly labeled in plain English."

[298] FALCPA § 203(a), 21 U.S.C.A. § 343(w)(4).

[299] *See* FALCPA § 203(a), 21 U.S.C.A. § 343(w)(4), (x).

1. *"Major Food Allergens" Defined*

Section 203(c) of the FALCPA adds to the FDCA section 321(qq)(1), which defines the eight major food allergens as milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, and any protein derived from these foods. Tree nuts, fish, and crustacean shellfish must be labeled by their specific type of nut or species of fish or shellfish (e.g., almonds, pecans, or walnuts; bass, flounder, or cod; crab, lobster, or shrimp, respectively).[300] Identification of tree nuts, fish, and shellfish by their specific name averts the problem of overgeneralized labeling that would preclude individuals allergic to only certain types of those foods to partake of numerous products that they otherwise could safely enjoy.

The FALCPA provides three exceptions to the definition of "major food allergen." First, the FALCPA exempts from its allergen labeling requirements highly-refined oils and ingredients derived from highly-refined oils.[301] The term "highly-refined oils" refers to bleached, deodorized oils,[302] of which the oil that poses the greatest allergenicity concern is peanut oil. Studies have shown that the amount of offending proteins present in highly-refined oils is not significant enough to cause an allergic response in most allergic individuals.[303] Highly-refined oils, nonetheless, must continue to be labeled by their common or usual name (such as peanut oil) under the FDCA's preFALCPA labeling standards.[304]

Second, any person can *petition* FDA to challenge the "major allergen" designation of ingredients they believe do not produce allergic reactions.[305] The petitioner has the burden to provide scientific evidence that demonstrates that the ingredient when derived using the method described in the petition "does not cause an allergic response that poses a risk to human health."[306] Thus, a company that is able to remove an allergenic protein from an ingredient (e.g., through distillation) could petition the Secretary of HHS ("Secretary")[307] for an exemption. If the Secretary does not affirmatively approve the petition within 180 days, it is deemed denied.[308]

Lastly, the FALCPA establishes a *notification process* whereby ingredients derived from the eight major allergens that do not contain allergenic protein or do not cause allergic reactions (as demonstrated by a manufacturer) can be exempt from the FALCPA's labeling requirements.[309] For example, if FDA determines that a certain amount of a particular allergen is required to trigger an allergic response, companies could file a notification stating that their products contain less than the established threshold

[300] In guidance issued over a year after the FALCPA's passage, FDA clarified how it will interpret some of the FALCPA's provisions for compliance purposes. FDA elaborated that other specified terms may be used to disclose certain major allergens. *See* FDA, Food Allergen Guidance for Industry, *supra* note 294 (stating that the terms "soybean," "soy," and "soya" may be used to disclose the allergen "soybeans"; the singular term "peanut" may substituted for the plural term "peanuts"; and singular terms [e.g., almond, pecan, or walnut] may be used for specific types of "tree nuts" [e.g., almonds, pecans, or walnuts]).

[301] *See* FALCPA § 203(c), 21 U.S.C.A. § 343(qq)(2)(A).

[302] *See* S. REP. No. 108-226, at 7.

[303] *See, e.g.*, Hefle & Taylor, *supra* note 19, at 73.

[304] *See* S. REP. No. 108-226, at 7.

[305] *See* FALCPA § 203(a), 21 U.S.C.A. § 343(w)(6); *see also* FALCPA § 203(c), 21 U.S.C.A. § 343(qq)(2)(B).

[306] FALCPA § 203(a), 21 U.S.C.A. § 343(w)(6).

[307] In practice, the responsibilities and authority of the Secretary of HHS will be delegated to FDA.

[308] *See* FALCPA § 203(a), 21 U.S.C.A. § 343(w)(6)(B).

[309] *See* FALCPA § 203(a), 21 U.S.C.A. § 343(w)(7); *see also* FALCPA § 203(c), 21 U.S.C.A. § 343(qq)(2)(B).

amount.[310] The notification provision also exempts from "major allergen" status ingredients that the Secretary previously has determined, under section 409 of the FDCA, do not cause an allergic response that poses a risk to human health (the generally recognized as safe (GRAS) notification process is not included).[311] It is presumed that the Secretary has approved the exemption unless the Secretary specifically notifies the company of the contrary within ninety days of receipt of the notification.[312]

Significantly, the FALCPA confers upon the Secretary the discretion to require by regulation that other food allergens, in addition to the Big Eight, be declared when present in a spice, flavoring, coloring, or incidental additive.[313] The Secretary can determine via regulation the manner in which non-Big Eight allergens shall be disclosed. Section 203 of the FALCPA also states that the FALCPA does not alter FDA's discretionary authority to require the labeling under the FALCPA's labeling scheme of other food allergens that are not major food allergens.[314]

2. *Labeling Format*

Manufacturers may choose between two options for identifying the presence of a major food allergen. First, following or adjacent to the list of ingredients, a manufacturer may print in type size no smaller than the other items in the ingredient list the word "Contains" followed by the plain English name of the food source from which the allergenic ingredient was derived.[315] For example, on a box of cereal a statement such as the following may appear at the end of a list of ingredients:

Contains wheat, milk, and tree nuts.

Alternatively, the manufacturer may print the plain English name of the allergenic protein in an ingredient in parenthesis directly following the ingredient that contains the allergen.[316] The list of ingredients on the cereal box thus might be printed as follows:

Durum (wheat), evaporated cane juice, salt,
whey (milk), nut flavoring (peanuts, almonds).

The FALCPA provides two nuances to the parentheses presentation format. The FALCPA states that companies need not declare a major allergen where the manufacturer uses the parentheses presentation and the common or usual name of an ingredient already listed incorporates the plain English name of the food source.[317] This provision

[310] *See* H.R. REP. NO. 108-608, at 17 ("While the Committee recognizes that thresholds for the eight major allergens have not yet been established by the scientific community, if they are established, ingredients containing allergenic proteins below the established threshold would be eligible for the notification procedure.").

[311] *See* FALCPA § 203(a), 21 U.S.C.A. § 343(w)(7)(A)(ii); S. REP. NO. 108-226.

[312] *See* FALCPA § 203(a), 21 U.S.C.A. § 343(w)(7)(B).

[313] *See* FALCPA § 203(a), 21 U.S.C.A. § 343(x).

[314] *See* FALCPA § 203(b), 21 U.S.C.A. § 343(note); *see also* S. REP. NO. 108-226, at 10.

[315] *See* FALCPA § 203(a), 21 U.S.C.A. § 343(w)(1)(A). FDA has stated that a "Contains" statement may be worded more than one way in order to "more accurately describe the presence of any major food allergens," so long as: 1) the word "Contains" (with a capital "C") is the first word to begin the statement; 2) the names used to declare the allergens are those permitted by the FALCPA and FDA guidance; and 3) the statement identifies the names of the food sources for all major allergens that are contained in the food. *See* FDA, Food Allergen Guidance for Industry, *supra* note 294.

[316] *See* FALCPA § 203(a), 21 U.S.C.A. § 343(w)(1)(B).

[317] See FALCPA § 203(a), 21 U.S.C.A. § 343(w)(1)(B)(i).

was designed to alert consumers to the presence of major allergens while helping to limit label clutter. For example, as explained in a Congressional Report, if "milk casein" is stated in the ingredients list then a manufacturer does not need to additionally indicate the presence of milk in parentheses beside the ingredient.[318] FDA clarified in guidance issued in December 2005 that this exception does not apply to the "Contains" statement presentation. A "Contains" statement must include the names of all allergens in a food, whether or not the name of the allergen is stated already in the ingredient list using FALCPA-approved, plain English terminology.[319]

Also, the FALCPA allows a manufacturer that chooses the parentheses presentation format to not declare the same allergen after any additional ingredients in which the allergen is present.[320] For instance, if "milk casein" or "whey (milk)" appears on the label, the manufacturer is not required to indicate the presence of milk in parentheses after the ingredient "caseinate."[321]

New section 343(w)(5) introduces some flexibility—and consequently, uncertainty—to this labeling scheme. This clause provides that the Secretary may modify the two options for the format of allergen declarations or eliminate either (but not both) options if the Secretary determines that such modification or elimination "is necessary to protect the public health."[322]

One further provision gives manufacturers a different, third option for presenting allergen information in rare circumstances, but it is unlikely to be applied much in practice. Allergen information may be placed on another form of labeling other than the ingredients label "if the Secretary finds that such other labeling is sufficient to protect the public health."[323]

B. *Other Provisions: Regulations, Restaurants, Reports, Research, and Resource Sharing*

The FALCPA contains a number of provisions designed to address food allergen safety concerns not met by the labeling requirements and to improve scientific, medical, and public knowledge about food allergies.

The FALCPA directs that within two years after its enactment, the Secretary must issue a proposed rule to define and permit voluntary use of the term "gluten-free" on food labels.[324] The FALCPA directs FDA to issue a final rule by August 2008. The House Committee Report on the FALCPA states that, "[g]iven the devastating nature of celiac disease, the Committee urges the Secretary to move expeditiously in implementing the requirements of this section."[325] Currently, there is no standard definition of "gluten-free" in the United States and studies have found that some products proclaiming themselves "gluten-free" may contain gluten. The FALCPA calls for the Secretary to consult with experts and stakeholders when drafting the rule.[326] The Senate Committee

[318] See H.R. REP. No. 108-608, at 16.

[319] FDA, Food Allergen Guidance for Industry, *supra* note 294.

[320] *See* FALCPA § 203(a), 21 U.S.C.A. § 343(w)(1)(B)(ii).

[321] *See* H.R. REP. No. 108-608, at 16.

[322] FALCPA § 203(a), 21 U.S.C.A. § 343(w)(5).

[323] FALCPA § 203(a), 21 U.S.C.A. § 343(w)(3).

[324] *See* FALCPA § 206, 21 U.S.C.A. § 343(note). The claim "gluten-free" is not intended to be a claim for special dietary use, a nutrient content claim, or a health claim, with their associated requirements for use. S. REP. No. 108-226, at 11.

[325] H.R. REP. No. 108-608, at 18.

[326] FDA has begun to do so. In the summer of 2005, FDA held a Food Advisory Committee Meeting to evaluate FDA's draft report on allergen thresholds and criteria for the term "gluten-free" and also held a Public Meeting addressing gluten-free labeling. *See generally* CFSAN, FDA, THRESHOLD WORKING GROUP, DRAFT REPORT, *supra* note 78; FDA, Public Meeting on: Gluten-Free Food Labeling (transcript) (Aug. 19, 2005), http://www.cfsan.fda.gov/~dms/glutran.html.

Report on an earlier version of the FALCPA had clarified that "the committee intends that, under the regulation, foods that are ordinarily gluten-free may be appropriately identified as a gluten-free food in food labeling."[327] Therefore, all products without gluten—even products not specifically formulated to not contain gluten (e.g., milk, butter, raisins, or orange juice)—may be labeled "gluten-free."

The FALCPA addresses the problem of cross-contamination on three fronts. First, section 209[328] provides that the Secretary, through the Conference for Food Protection and after consulting with the recommendations of public and private entities, shall "pursue revision" of the Food Code to provide guidelines for preparing allergen-free foods in food establishments. The FALCPA clarifies that the term "food establishments" nonexclusively includes restaurants, grocery store delicatessens and bakeries, and elementary and secondary school cafeterias.[329] This provision appears to be directed at preventing cross-contamination resulting from the use of common grills, common fryers, and common utensils when preparing foods with and without the eight major allergens.[330] Although private guidelines have been instrumental in helping some food establishments better serve food-allergic customers, this provision acknowledges the need for explicit revision of the Food Code to "better alert the food establishments to the problem food allergies pose to public health and make distribution of such information more widespread."[331]

Second, to help manage cross-contamination the FALCPA adds to FDA's current inspection duties the responsibility of checking food manufacturing, processing, and packaging facilities for compliance with practices to reduce inadvertent major food allergen contamination with products not otherwise containing allergens.[332] FDA inspectors also are charged with examining food labels to ensure the appropriate declaration of allergen information.

Third, the FALCPA provides that within eighteen months of the act's enactment the Secretary shall submit to Congress a report analyzing unintentional contact between nonallergenic and allergenic foods during manufacturing and processing. The report must address an array of issues, including: the prevalence of cross-contact, ways to mitigate the occurrence of cross-contact, how manufacturers use advisory labeling to warn consumers of cross-contact, how consumers would like information about cross-contact to be communicated, and the extent to which the Secretary and the food industry have effectively addressed cross-contact issues.[333]

Section 207[334] of the FALCPA aims to help alleviate the problem of the relative scarcity of and conflicting information about basic food allergy data in the United States.[335] This section calls for CDC and FDA to collect and publish data on the prevalence of food allergies, the incidence of food-allergy-induced serious adverse events, and the

[327] S. REP. NO. 107-322, at 9 (accompanying S. 2499, as reported in Senate).

[328] 42 U.S.C.A. § 243(note).

[329] *See* FALCPA § 209, 42 U.S.C.A. § 243(note).

[330] *See* H.R. REP. NO. 108-608, at 19 (stating that section 209 directs the Secretary to consider guidelines and recommendations "preventing unintentional cross-contact with major food allergens.").

[331] S. REP. NO. 107-322, at 4.

[332] *See* FALCPA § 205, 21 U.S.C.A. § 374a.

[333] *See* FALCPA § 204; *see also* H.R. REP. NO. 108-608, at 18 ("[I]t is the Committee's intention that the Secretary focus on which types of advisory labeling are effective in alerting consumers with food allergies or their caregivers about the risk of cross-contact.").

[334] 42 U.S.C.A. § 242r(note).

[335] *See, e.g.*, S. REP. NO. 108-226, at 10 ("The committee is concerned that the prevalence of food allergies is uncertain and the incidence of clinically significant and serious adverse events is not being systematically monitored.").

use of different techniques to treat and prevent allergic reactions.[336] Coordinating and expanding information about allergic reactions to foods will provide valuable information to people studying food allergies and working to improve diagnosis, treatment, and prevention methods.

The FALCPA further instructs NIH to convene a panel of allergy and immunology experts to review current food-allergy-related research efforts and make recommendations for "enhancing and coordinating" research activities.[337] The House Committee Report indicates that Congress intended for this panel also to analyze existing data on whether safe consumption levels of the eight major allergens for allergic individuals exist, which FDA may find helpful as it reviews scientific data on reaction thresholds as part of the FALCPA's petition and notification processes.[338]

Finally, the FALCPA directs the Secretary to provide technical assistance regarding the treatment and prevention of food allergic reactions to state and local agencies as part of HHS' general provision of emergency medical services-related technical assistance pursuant to section 1202(b)(3) of the Public Health Service Act (42 U.S.C. § 300d-2(b)(3)).[339] The Senate Committee Report accompanying an earlier version of the FALCPA explains the impetus behind this provision: because "not all states and localities provide emergency medical technicians with adequate training to treat successfully a patient undergoing a food allergic response," the government should provide assistance "to enhance their preparedness to address emergencies caused by food allergens."[340]

V. THE FALCPA'S UNFULFILLED PROMISES AND POTENTIAL

"Since there is currently no cure for food allergies, consumers need to be empowered to know whether or not food allerg[ens] are present in the food they consume."
House Committee Report on the FALCPA[341]

Passage of the FALCPA is a remarkable achievement that will benefit millions of Americans. The FALCPA's requirements for plain English labeling of major allergens, mandatory declaration of hidden ingredients, the coordination and publication of food sensitivity-related research, and the encouragement of the promulgation of guidelines for preparing allergen-free foods in food establishments represent significant advances that will improve the daily lives of people with food sensitivities.

The FALCPA may produce considerable positive secondary effects as well. As one participant in the Allergen Labeling Survey observed, the very fact that allergy issues "gained national attention and made it onto the national policy agenda itself is a victory."[342] Media attention generated by the FALCPA's passage, and the fact that as of

[336] In this effort, CDC is expected to analyze existing data, educate healthcare providers about the documentation and publication of this information, increase the precision of surveys of healthcare providers regarding food reactivity, add laboratory tests to the National Health and Nutrition Examination Survey (NHANES), and implement an automated system to help healthcare providers more accurately record food allergy-related deaths. *See* H.R. REP. NO. 108-608, at 8.

[337] FALCPA § 208, 42 U.S.C.A. § 242r(note).

[338] *See* H.R. REP. NO. 108-608, at 19.

[339] *See* FALCPA § 210, 21 U.S.C.A. § 300d-2(note).

[340] S. REP. NO. 107-322, at 4-5. While the preferred treatment for food allergy-induced anaphylaxis currently is injectable epinephrine, the FALCPA does not specify a particular treatment, thereby allowing the Secretary to promote new treatments that may be developed in the future. *See* S. REP. NO. 108-226, at 10.

[341] H.R. REP. NO. 108-608, at 3.

[342] E-mail from MD to Author, Response to Allergen Labeling Survey (Jan. 26, 2005).

January 1, 2006, all consumers will find information concerning major allergens on their food products, will continue to enhance industries' and the public's awareness of the seriousness of food sensitivities. The FALCPA has also reenforced—and contributed to—a growing emphasis at FDA on taking public action against companies manufacturing misbranded food products.[343] As a result of this increased attention, food establishment personnel, physicians, teachers, and travel industries may become more responsive to the concerns of people with food sensitivities. As food manufacturers become more aware of the market for allergen-free products, they may choose to develop new products to meet this niche or may voluntarily improve disclosure of nonmajor allergens.[344] Manufacturers may even seek to reformulate current products for which nonallergenic ingredients can be substituted for allergen-containing ones.[345]

In various ways, the FALCPA offers greater protection to food-sensitive individuals than international allergen labeling initiatives implemented prior to the FALCPA. In 2003, the European Union issued the most stringent allergen labeling rules at that time in the form of an Amending Directive[346] mandating that manufacturers identify on the food label certain "common food allergens" and their derivatives that are present in a final

[343] *See, e.g.*, Deborah Caulfield Rybak, *Feds Seize 30,000 Loaves of Bread* (Jan. 11, 2006), http://www.startribune.com/462/story/175831.html ("More than 30,000 loaves of French Meadow Bakery bread were temporarily declared 'toast' Tuesday when federal officials seized them, claiming that the popular organic bakery in south Minneapolis has been mislabeling nine varieties of bread as wheat-free, when they aren't. ... Under the new [Food and Drug Administration labeling rules], bread containing spelt and Kamut cannot carry labels describing them as 'wheat-free' or 'wheat-alternative.'").

[344] Increased attention to gluten in recent years already has resulted in a rise in the development and production of gluten-free products. According to recent estimates, the number of gluten-free food products in the United States has more than tripled since 2001. *See* Just-food.com, USA: 2006 Seen Busy With New Product Launches (Nov. 30, 2005), http://www.just-food.com/news_detail.asp?art=62574. Also, some companies have begun listing non-Big Eight allergens such as sesame seeds and gluten-containing grains on their product labels. *See, e.g., id.* (stating that Walmart is requiring suppliers to identify foods that contain gluten); Ratner, *supra* note 295, at 14 ("[C]onsumer demand for information about gluten-containing ingredients is causing other label changes not mandated by law. Some companies now list barley, rye and oats, even though they are not one of the top eight allergens.").

[345] Some companies already have begun to substitute ingredients that do not contain major allergens for ingredients that do. *See, e.g.*, Ratner, *supra* note 295, at 15 (A spokesman for the Flavor and Extract Manufacturers Association of the United States said that some flavor makers "are specifically looking for flavors that are free of allergens.").

[346] *See generally* EU Council Directive 2003/89. This Amending Directive principally added provisions to Article 6 of the 2000 Labeling Directive, 2000/13 2000 O.J. (L 109), *available at* http://europa.eu.int/eur-lex/en/consleg/pdf/2000/en_2000L0013_do_001.pdf. The Amending Directive revises previously-instituted labeling exemptions that allowed certain ingredients, such as those found in additives and processing aids, to not be included on labels.

> In order to achieve a high level of health protection for consumers and to guarantee their right to information, it must be ensured that consumers are appropriately informed as regards foodstuffs, *inter alia*, through the listing of all ingredients on labels. ... When used in the production of foodstuffs and still present, certain ingredients or other substances are the cause of allergies or intolerances in consumers, and some of those allergies or intolerances constitute a danger to the health of those concerned. ... Even if labelling [sic], which is intended for consumers in general, is not to be regarded as the only medium of information acting as substitute for the medical establishment, it is nevertheless advisable to assist consumers who have allergies or intolerances as much as possible by providing them with more comprehensive information on the composition of foodstuffs. ... In order to provide all consumers with better information and to protect the health of certain consumers, it should be made obligatory to include in the list of ingredients all ingredients and other substances present in the foodstuff.

Council Directive *supra* note 291, at 1.

food product in any quantity.[347] Unlike the FALCPA, however, the Amending Directive does not provide for uniform terms that must be employed to identify allergenic ingredients,[348] research about food allergies, or the improvement of restaurant food preparation practices. Furthermore, the Amending Directive exempts an ingredient statement from allergen labeling if the name under which a food is sold "clearly refers" to the allergenic ingredient,[349] introducing inconsistency about where a consumer should look to obtain allergen information.

The FALCPA also provides more heightened requirements in some respects than the Codex Alimentarius—a set of internationally-adopted, voluntary food standards developed by a Commission of the Food and Agriculture Organization of the United Nations and World Health Organization Food Standards Programme to help facilitate international trade.[350] In 1999, the Codex Alimentarius incorporated standards for allergen labeling that require the declaration on the food label of any ingredients containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, tree nuts, and sulphites in concentrations of 10 mg/kg or more.[351] In contrast with the FALCPA, the Codex's food standards are merely voluntary, do not require the identification of allergens in easy-to-understand terms, and exempt from allergen labeling "small units" of "spices and herbs."[352]

For many food-sensitive individuals for whom the FALCPA was designed, however, the FALCPA disappoints in several significant ways. As Chris Weiss, FAAN's Director of Legislative and Regulatory Research states, FAAN is "pleased in that [the FALCPA] got passed. We're very pleased. It does mark a significant step in the right direction. It is progress. However, there is still a lot the bill doesn't do."[353]

The nineteen food-sensitive individuals or their caregivers who participated in the Allergen Labeling Survey[354] gave the legislation an average rating of 2.7,[355] where 0 (zero) meant the participant found the legislation "not helpful" (i.e., they are "no better

[347] In contrast, components of compound ingredients *not* containing common allergens need only be listed if they constitute two percent or more of the final product. EU Labeling Directive, *supra* note 346, at 9, Art. 6, § 8. Prior to the Amending Directive, compound ingredients needed to be listed only if they exceeded a twenty-five-percent-of-the-final-product threshold.

[348] The Amending Directive requires that labels display "a clear reference to the name" of the allergenic ingredient. *Id.* at 10, Art. 6, § 10. The Amending Directive falls short of requiring a single, consistent term be used to identify a common allergen. It also does not require manufacturers to "clearly refer" to the specific name of the type of fish or crustaceans in a product, unnecessarily restricting the options of consumers sensitive to proteins found in a specific food within a given general category. *See id.* at Annex I, Annex IIIa.

The British Food Standards Agency has issued best practice advice to manufacturers regarding the types of terms to employ because "there is no official guidance regarding terms that should be used in every case." *See* Food Standards Agency, Guidance Notes on the Food Labelling (Amendment) (No. 2) Regulations 2004 (Nov. 15, 2004), 10, § 11.1, *available at* http://www.food.gov.uk/multimedia/pdfs/labelamendguid2004.pdf.

[349] EU Labeling Directive, *supra* note 346, at 10, Art. 6, § 10.

[350] *See* JOINT FAO/WHO FOOD STANDARDS PROGRAMME, *supra* note 289, at iii.

[351] *See id.* at 4. Allergenic foods can be added or removed from this list. *Id.* at n.1. Compound ingredients not containing these known allergens need only be listed on the food label if the ingredient constitutes over five percent of the food. *Id.* Before it was amended in 1999, the Codex Alimentarius required mandatory ingredient declaration only of compound ingredients constituting over twenty-five percent of a food product. *See generally* FAO CONSULTATION, *supra* note 290.

[352] JOINT FAO/WHO FOOD STANDARDS PROGRAMME, *supra* note 289, at 11.

[353] Telephone Interview with Chris Weiss, FAAN, *supra* note 216.

[354] This informal survey involved a limited, non-random sample of participants. These numerical results of the survey are provided only to underscore the range of reactions to the Act among people directly affected by FALCPA. For further explanation of the Allergen Labeling Survey, see *supra* note 1.

[355] The median result was 3 and the mode was 4.

off than before the Act was passed, or worse off now that the Act has passed") and 5 meant the participant found the FALCPA "extremely helpful." Scores ranged from 0 (three responses) to 5 (two responses).

All respondents—even those who rated the legislation a 5—suggested recommendations for further improvements related to allergen labeling. In fact, some of the respondents who expressed the most satisfaction with the FALCPA on the rating scale also were the most critical of the FALCPA's drawbacks when elaborating on the reasons behind their rating choice. This may reflect a general appreciation among food-sensitive individuals who are aware of how much the FALCPA fails to do that, at least, legislation finally has acknowledged the serious problem of food allergens; that the FALCPA constitutes a victory for food allergy awareness; that any incremental improvement is preferable to the status quo;[356] and that, while the FALCPA may not benefit the respondent directly, it helps others struggling with food sensitivities.

What can account for survey respondents' varied assessments of the FALCPA? What do the survey's results suggest about the reform priorities of various food-sensitive consumers? This section explores the extent to which the FALCPA meets its avowed intention to empower consumers to know whether food is safe for consumption. By highlighting several significant shortcomings of the FALCPA, areas ripe for future allergen labeling reform are suggested. Drawing a rough distinction between two somewhat overlapping categories of limitations, subpart A discusses drawbacks related to what the FALCPA's provisions affirmatively provide and subpart B explores important issues that the FALCPA neglects.

A. *Drawbacks of the FALCPA's Provisions*

The FALCPA's wording raises concerns that its labeling scheme, in some ways, may backfire on consumers and creates uncertainty about the implementation of some of its provisions.

1. *Ways the FALCPA Backfires Against Consumers: Diminished Consumer Diligence and Deficiencies of the Label Formatting Scheme*

In some ways, with increased consumer trust in food labels may come increased risks. The FALCPA also may contribute to over- as well as under-inclusive labeling. If the plain English name of an allergen were listed after each allergen-containing ingredient, consumers could be more empowered to make informed decisions about a food and accept their own level of risk.[357]

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[356] For example, one Allergen Labeling Survey respondent stated that "any piece of legislation that improves labeling is always a plus." E-mail from EK to Author, Response to Allergen Labeling Survey (Jan. 25, 2005).

[357] One Allergen Labeling Survey respondent elaborated on her feeling of lack of power given the FALCPA's labeling scheme and exemption provisions:

> I'm not comfortable with the threshold aspect of the law. Just because a trace amount may not pose a risk to human health, a person should have the right to know what they are eating. I want to make the decision whether or not I feel comfortable eating a certain ingredient, as opposed to a manufacturer deciding for me that it's ok to eat an ingredient that I would otherwise avoid.

Id.

a. *The Problem of Diminished Consumer Diligence*

At their basic level, labeling requirements are helpful only if they actually make food labels more accurate. An unavoidable consequence of any codification of stricter labeling requirements for allergens is that consumers then will place more trust in those labels. As trust increases, risk increases. People who have been vigilant researchers will now more readily accept labels at face value. This result—which is the FALCPA's purpose and key benefit—potentially increases allergen dangers because reduced consumer caution heightens the risks associated with noncompliance with the FALCPA, accidental mislabeling, or inadvertent cross-contamination.

The FALCPA imposes requirements only on products labeled on or after January 1, 2006. Because the date a product is labeled triggers the FALCPA's provisions (rather than the date of its sale or introduction into interstate commerce), consumers may not receive the full benefits of the FALCPA for months or even years because inventories of products labeled before January 1, 2006, will need to be exhausted. FDA has warned consumers to expect a "transition period of undetermined length after January 1, 2006, during which it is likely that consumers will see packaged food on store shelves and in consumers' homes without the revised allergen labeling." The agency advises consumers to "always read a product's ingredient statement in conjunction with any 'contains' statement."[358]

In addition, after this undefined "transition period," label inaccuracy may pose greater problems than before the FALCPA went into effect. One Allergen Labeling Survey respondent stated that mislabeling was her biggest worry about the legislation. "I read ingredients very carefully right now, and if I begin to rely solely on the new labels, and they're wrong, I would be in trouble."[359] The full benefits of the FALCPA thus depend on consistent and complete participation on the part of the food industry and effective enforcement by FDA.

b. *Deficiencies of the FALCPA's Label Formatting Scheme*

The FALCPA's label format provisions may backfire against consumers by creating the dual problems of under- and over-inclusive labeling of allergens, thereby threatening the safety of highly-sensitive consumers, limiting the choices of many food-sensitive consumers, and resulting unnecessarily in lost sales for manufacturers and retailers.

The FALCPA could become a "nightmare" for food-allergy sufferers, asserts leading allergen expert Steve Taylor of the Food Science and Technology department at the University of Nebraska. "Congress didn't get this 100 percent right."[360] The following three subsections will use soy lecithin to illustrate the dual problems of over- and underlabeling created by the FALCPA's label format provisions.

i. *The Problem of Overinclusivity*

At least until certain ingredients or quantities of allergens are exempted through the FALCPA's petition and notification processes (and manufacturers update their food

[358] FDA, Advice to Consumers, *supra* note 5.

[359] E-mail from B to Author, Response to Allergen Labeling Survey (Jan. 22, 2005).

[360] Martha Filipic, *Food Law Confusing the Allergic*, CINCINNATI POST, Nov. 10, 2004, *available at* http://www.cincypost.com/2004/11/10/allerg111004.html; *see also* Ratner, *supra* note 295, at 14 ("Steve Taylor, PhD, an allergen expert and director of the Food Allergy Research and Resource Program at the University of Nebraska, called the [FALCPA] a 'mixed bag.' He said celiacs and those with food allergies 'are better off because there is more label clarity, but they are worse off because they may have considerably less food choices.'").

labels to reflect such changes), the FALCPA poses the problem of overinclusivity. Unless FDA exempts an ingredient, the FALCPA calls for "zero tolerance" of major food allergens—that is, any amount of allergenic protein triggers the FALCPA's labeling requirements.

Taylor notes that the FALCPA, in some cases, may significantly, and unduly, burden consumer choice because it does not account for threshold tolerances. Evidence suggests that glucose syrup, citric acid, and vinegar distilled from wheat, for instance, are so highly processed that even though they are derived from wheat they no longer contain allergenic protein by the time they are included in food products.[361] The FALCPA nevertheless forces manufacturers to disclose extremely trivial amounts of allergens that would be safe for the majority of food-sensitive individuals to consume:

> The [identification and disclosure of allergens in food] situation has recently become more chaotic just when real progress was being made. The legislative arm of government weighed in with the passage of the Food Allergen Labeling and Consumer Protection Act of 2004. While most of the provisions of FALCPA are commendable, FALCPA will require the labeling of all ingredients derived from commonly allergenic foods regardless of the amounts present in the finished product. This will lead to the declaration of many more such ingredients on the product label thereby decreasing food choices and the quality of life for food-allergic consumers. Many of these ingredients are present at such miniscule levels that allergic consumers would not likely react to them, and most of these products have been safely consumed by food-allergic individuals for years. Thus, the food industry once again finds itself in the midst of chaos. The distinction is that many of the forthcoming changes will do little to further protect food-allergic consumers and the focus will switch from consumer protection to label compliance.[362]

For example, most people allergic to soy can safely consume soy lecithin. Soy lecithin, nevertheless, currently requires a "soy" declaration under the FALCPA. The FALCPA's labeling scheme prevents a soy-allergic individual from determining that a product containing soy lecithin nonetheless is safe for consumption by sometimes making it impossible for a consumer to be certain which ingredient is responsible for an allergen declaration.

If the manufacturer chooses to disclose the name of an allergen at the end of the ingredient list, the manufacturer does not identify which particular ingredient(s) contains the allergen.[363] For instance, a soy-allergic individual who can consume soy lecithin safely would be unable to know whether he can safely consume a product that employs an appropriate "Contains' statement, such as the following:

Flour, soy lecithin, hydrolyzed vegetable protein. Contains wheat, soy.

The soy-allergic consumer who can consume soy lecithin safely cannot determine if this product is harmful because the label does not indicate whether the hydrolyzed

[361] Ratner, *supra* note 295, at 13; *see also* Cynthia Kupper, Gluten Intolerance Group of North America, What's New With the Gluten-Free Diet, Presentation at Making Tracks for Celiacs: A Patient Education Day (conference sponsored by the Center for Celiac Research, University of Maryland, on July 9, 2005) (copy of presentation slides on file with author) (discussing how the FALCPA's labeling scheme is problematic unless FDA exempts certain ingredients, and stating that FDA as of July 2005 did not have criteria established for making exemptions).

[362] Taylor, *From Chaos*, *supra* note 157.

[363] *See* FALCPA § 203(a), 21 U.S.C.A. § 342(w)(1)(A).

vegetable protein ingredient contains soy. The declaration of soy at the end of the ingredient list fails to inform the consumer whether the declaration is due to the lecithin or the hydrolyzed vegetable protein.

If, instead, the manufacturer decides to place the plain English name of an allergen in parentheses after an allergen-containing ingredient, the consumer still may not know that the allergen is in that ingredient alone because of the following exception: if the plain English name of the allergen already appears elsewhere in the ingredient list, the FALCPA states it *need not be declared again after subsequent allergen-containing ingredients.*[364] Imagine the same ingredient statement using the parentheses presentation method:

Flour (wheat), soy lecithin (soy), hydrolyzed vegetable protein.

The appearance of "(soy)" after "lecithin" obviates the manufacturer's need to disclose whether the hydrolyzed vegetable protein contains soy. The soy-allergic consumer who can consume soy lecithin safely again cannot determine the safety of the product.

Therefore, regardless of which format the manufacturer chooses to disclose allergens, the consumer may not know which particular ingredient(s) contains the allergen. The unnecessary restriction posed by this scheme is particularly troubling with regard to ingredients such as soy lecithin that are pervasive in the food supply. Individuals wishing to not be so restricted will have to resort to the preFALCPA techniques of learning the complex terms for potentially allergenic ingredients and calling manufacturers. Some people fear overinclusivity may lead consumers to again distrust labels, or worse, ignore them.[365]

To avoid the overinclusivity problem, manufacturers simply would need to be required to state the name of an allergen in parentheses after each ingredient containing the allergen—this would ensure precision. An optional "Contains" statement would contribute to readability. An Allergen Labeling Survey respondent who is the parent of a soy-allergic teen urged the adoption of this more precise labeling format:

> [P]roducts which are fine for soy allergic [individuals] but contain soy lecithin—products that have been consumed with no adverse affect to date—will suddenly [after the FALCPA goes into effect] have the scary warning below the ingredient list that says "contains soy." For the regular person to understand the inability for anyone who has anaphylaxis to overcome visceral fear prompted from those words "contains soy" and continue to consume the product despite the warning based on the ingredient list which displays soy lecithin, try to imagine a favorite product suddenly containing under ingredients the words "contains arsenic." You could not get past that if you have spent your life looking for such warnings and heeding them. ... It is of major concern then for us as to what ingredient they are referring to. Is it saying the item is processed with other soy protein containing products, or can we relax and "assume" the "contains soy" warning is referencing the harmless ingredient soy lecithin? If we could go back to the ingredient list and observe the ingredients that prompted the allergy "warning" we can then say for ourselves that soy lecithin ... is not going to cause a life threatening event. So many of the products we buy contain soy lecithin. ... It is very hard to explain that this

[364] *See* FALCPA § 203(a), 21 U.S.C.A. § 342(w)(1)(B)(ii).

[365] Ratner, *supra* note 295, at 14.

> makes it worse for us. We will be looking for information that is true and finding warnings that are inappropriate. This condition makes you nervous enough; so having warnings flashing at you as you peruse the shelves at the store that mean life and death for yourself or your child, but are not true, is cruel.[366]

The FALCPA's problematic formatting design first appeared in a proposed compromise bill introduced by Senator Kennedy and reported in the Senate in October 2002.[367] The Food Allergy Issues Alliance voluntary industry guidelines promulgated in 2001, in contrast, list five ways in which manufacturers can declare the presence of major allergens on the food label, and only one of these options (identifying the allergen following the ingredient list) did not require the identification of *each* allergen-containing ingredient.

ii. *The Problem of Underinclusivity*

The petition and notification processes by which ingredients can be exempted from the FALCPA's labeling requirements may create the reverse dilemma for some consumers: that of underinclusivity. The absence of scientific information about the threshold amounts of allergenic protein needed to trigger adverse reactions, and the fact that thresholds differ among allergy sufferers, means that some people will be disserved by certain allergen declarations and by certain ingredient exemptions from allergen declarations.

On the one hand, as Taylor observed, unless a given ingredient is exempted from the FALCPA's labeling requirements through the petition or pre-approval procedures, manufacturers will be forced to declare that some ingredients contain an allergen even if the ingredient contains such minuscule amounts of the allergenic protein that the ingredient is not harmful to most food-allergic individuals.

On the other hand, if an ingredient *does* receive an exemption from FDA, thereby relieving manufacturers of any obligation of disclosing the ingredient's (albeit slight) allergenic potential, individuals highly sensitive to the allergen will be unable to discern whether the absence of the name of the allergen on the label means the product actually is safe for consumption. These individuals, thus, will be little better off than they were before the FALCPA's passage; they will be forced to guess at whether a product that *appears* to be safe actually is safe for them. For these individuals, the FALCPA's scheme is underinclusive and fails to alert them to hazardous allergenic protein.

For example, several food industry trade associations have worked to develop proposals for an exemption for soy lecithin.[368] While this would benefit people like CM's soy-allergic son, the exemption may harm individuals with acute food sensitivity who do experience reactions to soy lecithin. A predicament thus is created by the difficulty of identifying tolerances of food-sensitive individuals, the FALCPA's allowance of exemptions, and the FALCPA's formatting provisions that do not require the identification of each allergen-containing ingredient.

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[366] E-mail from CM to Author, Response to Allergen Labeling Survey (Jan. 11, 2005).

[367] *See* Food Allergen Labeling and Consumer Protection Act of 2002, S. 2499 (reported in Senate), 107th Cong. § 3(a) (2d Sess. 2002). Proposed bills related to allergen labeling prior to this did not specify how allergens should be declared on the label. *See* H.R. 5532, 106th Cong. § 2 (2d Sess. 2000) (requiring labels to simply "bear[] a statement with appropriate prominence" identifying the name of a known allergen); H.R. 1356, 107th § 3 (1st Sess. 2001) (requiring labels to "bear[] a statement with appropriate prominence on the information panel" providing the name of the known food allergen); H.R. 4707, 107th Cong. §§ 3, 5(c) and S. 2499 (introduced in Senate), 107th Cong. § 3 (2d Sess. 2002) (requiring only that the label bear, in bold font, the name of the food allergen, and authorizing the Secretary of HHS to determine specific formatting requirements).

[368] *See* Susan L. Hefle & Steve L. Taylor, Expert Opinion: Soybean Lecithin, University of Nebraska-Lincoln, Institute of Agriculture and Natural Resources, FARRP 1 (Sept. 24, 2004), http://www.farrp.org/articles/feolecithin.pdf [hereinafter Expert Opinion: Soybean Lecithin].

iii. *The Inevitable Dilemma*

This dilemma is not easily resolved and may be unavoidable. For the petition process to have its greatest effect, ingredients would have needed to be exempted before manufacturers produced new labels to meet the January 1, 2006, enforcement deadline. As of December 7, 2005, however, FDA had received no petitions and had received notifications regarding only two ingredients—extensively hydrolyzed casein (milk) and a starter growth media (soy).[369]

Moreover, exemptions granted by FDA are permissive only; manufacturers may continue to label an exempted ingredient as if it were allergenic to avoid relabeling products or to err on the side of caution. This result generates even more confusion because, given the FALCPA's formatting scheme, consumers will not be able to discern whether an allergen declaration is due to the presence of an exempted ingredient or another ingredient.

The mixed response of food allergy experts to the FALCPA illustrates these inherent, and perhaps inevitable, tensions. Although Taylor has criticized the FALCPA for requiring the disclosure of extremely slight amounts of allergens, he also has advocated against an exemption for soy lecithin from the FALCPA's scheme, despite its safety for most soy-allergic individuals.[370]

Identifying the presence of an allergen after each offending ingredient would clear up this confusion. Consumers could then evaluate for themselves the reason for the declaration of an allergen and make an informed decision.

iv. *Other Examples of the Backfire Problem: Highly-refined Oils and Oats*

This backfire problem also occurs in relation to the FALCPA's explicit exemptions from the definition of "major food allergen" those ingredients derived from highly-refined oils. Studies have shown that most allergenic proteins are removed during processing and these oils rarely provoke allergic reactions in food-sensitive individuals.[371] Nevertheless, some people do react to trivial amounts of protein in these ingredients. As one peanut-allergic Allergen Labeling Survey respondent explained, "I am one of those

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[369] *See* FDA, CFSAN, Inventory of Notifications Received Under 21 U.S.C. 343(w)(7) for Exemptions from Food Allergen Labeling (Feb. 26, 2006), http://www.cfsan.fda.gov/~dms/falnoti.html; FDA, Advice to Consumers, *supra* note 5. By comparison, the European Food Safety Authority's Scientific Panel on Dietetic Products, Nutrition and Allergies already has published opinions analyzing twenty-seven requests for the exemption of ingredients from allergen labeling. These opinions are available electronically at http://www.efsa.eu.int/science/nda/nda_opinions/catindex_en.html. The Panel has provisionally excluded numerous ingredients from the EU's allergen labeling requirements.

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> The soybean allergens are found in the protein fraction. The vast majority of this protein is removed in the soy lecithin manufacturing process. Soy lecithin does contain trace levels of soy protein. However, apparently, *soy lecithin does not contain sufficient soy protein residues to provoke allergic reactions in the majority of soy-allergic consumers.* Many allergists do not even advise their soybean-allergic patients to avoid soybean lecithin when it is included as an ingredient on food products. From this practical standpoint, we can surmise that most soybean-allergic individuals do not react adversely to the ingestion of soybean lecithin. Yet, there is, of course, the possibility that some of the more sensitive soybean-allergic consumers might react to ingestion of soybean lecithin, so *we do advocate the source labeling of lecithin when it is used as a direct food ingredient.*

Expert Opinion: Soybean Lecithin, *supra* note 368, at 1 (emphasis added).

[371] *See, e.g.*, 56 Fed. Reg. 28,592, 28,603 (June 21, 1991) ("The American Academy of Allergy and Immunology's Committee on Adverse Reactions to Foods concluded that oils are *probably infrequently* responsible for *significant* allergic reactions, and that, accordingly, 'avoidance of these oils and foods containing them is *probably* not necessary.'") (emphasis added).

folks who go into anaphylaxis with the slightest contact with peanuts. Pure peanut oil is distilled in such a way without particulate matter. I have had [it] and it caused less of [sic] reaction. The tiniest peanut has done me in."[372] Given the still-evolving and preliminary scientific knowledge about threshold amounts of protein necessary to trigger reactions, it is likely any exemption will be disadvantageous for the extremely sensitive consumer.

An analogous problem also may arise in relation to the FALCPA's mandate for the creation of a standard to define and control use of the term "gluten-free" on food products. Controversy has long surrounded the question of whether oats contain gluten.[373] Definitive studies have demonstrated the safety of oats for the vast majority of individuals with celiac disease. Nevertheless, several notable authorities[374] continue to include oats among the grains people with celiac disease must avoid, and the oats controversy persists.[375] Dr. Alessio Fasano, head of the Celiac Research Center of the University of Maryland, has stated that despite the safety of oats for most people with celiac disease, he is not confident recommending oats to all celiac individuals until more studies are conducted about the effect of oats and the problem of cross-contact between oats and wheat.[376]

When formulating the standard for "gluten-free" labeling, if FDA considers oats a gluten-carrying grain, people with celiac disease may be tremendously disserved. Oat flour is one of the most common substitutes for wheat flour, and many products that otherwise are gluten-free contain oats. The largest and most scientifically rigorous study on oats published in 1995 notes that:

> Adherence to a strict gluten-free diet is difficult. Therefore, any relief of dietary restrictions, such as those on oats, could make the diet more acceptable to

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[372] E-mail from JK to Author, Response to Allergen Labeling Survey (Jan. 10, 2005).

[373] *See generally* E.K. Janatuinen et al., *A Comparison of Diets With and Without Oats in Adults With Celiac Disease*, 333 N. ENG. J. MED. 1033-37 (Oct. 19, 1995):

> [T]he place of oats in the diet of patients with celiac disease is controversial. ... We found that the use of oats by patients with celiac disease as part of a gluten-free diet had no unfavorable effects on adult patients in remission and did not prevent symptomatic and mucosal healing in patients with newly diagnosed disease. ... Our data suggest that most patients with celiac disease, whether in remission or newly diagnosed, can add moderate amounts of oats to their otherwise gluten-free diets without any harmful subjective side effects or laboratory abnormalities.

(Internal citations omitted). *See also* Parveen J. Kumar & Michael G.J. Farthing, *Oats and Celiac Disease*, 333 N. ENG. J. MED. 1075-76 (1995):

> Whether to include oats in the diet for patients with celiac disease has been debated at length for the past 30 years. It is therefore surprising that so few studies have assessed the effect of dietary oats on the small-intestinal mucosa. Studies have usually involved only small numbers of patients (primarily children) and have been open and uncontrolled. Often the effect of adding oats has been assessed only for short periods. ... The comprehensive study by Janatuinen and colleagues in this issue of the Journal is therefore welcome and will come as a relief to patients with celiac disease who enjoy foods containing oats.

[374] *See, e.g.*, JOINT FAO/WHO FOOD STANDARDS PROGRAMME, *supra* note 289, at 4 (requiring the declaration of cereals containing gluten, defined as "wheat, rye, barley, oats, spelt or their hybridized strains and products of these").

[375] *See generally, e.g.*, Tricia Thompson, *Oats and the Gluten-Free Diet*, 103(3) J. AM. DIETETIC ASS'N 376 (2003) ("Since 1995, results of several additional investigations have been published, including those of the first study to evaluate the safety of long-term consumption of oats. The present article examines the continuing controversy over the use of oats as well as the mounting evidence suggesting that oats are safe to include in a gluten-free diet."); *see also* H.R. 4704, 107th Cong. § 3 (2d Sess. 2002) (including in a list of allergens requiring declaration on the label "other grains containing gluten (rye, barley, *oats*, and triticale).") (emphasis added).

[376] Fasano Remarks, *supra* note 51.

> patients. ... Adding oats to the celiac diet could increase compliance with a gluten-free diet by providing patients with more alternatives and reducing the otherwise high cost of gluten-free foods.[377]

Some believe it is unlikely that oats would be included as a gluten-containing grain not eligible for the "gluten-free" designation. Andrea Levario, co-chair of the ACTF, an organization that lobbied for the passage of the FALCPA and that will work to influence the development of the "gluten-free" standard, believes avoidance of oats will not be considered part of a gluten-free diet.[378] An authoritative consensus statement issued by a panel of celiac disease experts convened by NIH[379] in June 2004 did not list oats as a gluten-containing food.[380] Division still exists, however, among the three major American celiac disease support groups with regard to oats.[381]

2. *Implementation Uncertainties: Label Format Ambiguities, Exemptions of Certain Ingredients, and Ambiguous Provisions*

How effectively the FALCPA will benefit food-sensitive individuals will to a large extent depend on how the agencies charged with implementing the FALCPA interpret and execute their obligations. Much of the FALCPA's power to improve the lives of people with food sensitivities thus hinges on how FDA, CDC, and NIH apply FALCPA's broad, well-intentioned provisions.

a. *Label Format Ambiguities*

The FALCPA permits some uncertainty regarding labeling format that may undercut the act's purported ability to make food labels consistent and easy to decipher.

First, the Secretary of HHS can allow allergen information to appear "in labeling in lieu of appearing on the label" if the Secretary finds that such other labeling is "sufficient to protect the public health."[382] Given the FDCA's definition of "labeling," allergen information can, at the Secretary's discretion, appear on any label or other written, printed, or graphic matter that appears on a food's container *or that accompanies the food*.[383] The Secretary's decision to allow allergen information to appear outside the food label is effective once the Secretary publishes in the *Federal Register* that decision and the name of the food product involved.[384]

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[377] Janatuinen et al., *supra* note 373.

[378] Telephone Interview with Andrea Levario, ACTF, *supra* note 217.

[379] The consensus statement was the product of a conference to improve awareness, diagnosis, and management of celiac disease in the United States sponsored by NIH's Office of Medical Applications of Research and the National Institute of Diabetes & Digestive & Kidney Diseases. The National Cancer Institute, National Institute of Allergy and Infectious Diseases, National Institute of Child Health and Human Development, USDA, and FDA cosponsored the conference. *See* NIH Consensus Development Conference Statement, *supra* note 35.

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> The management of celiac disease is a gluten-free diet for life. A gluten-free diet is defined as one that excludes wheat, rye, and barley. These dietary grains contain the peptides or glutens known to cause celiac disease. Even small quantities of gluten may be harmful. Oats appear to be safe for use by most individuals with celiac disease, but their practical inclusion in a gluten-free diet is limited by potential contamination with gluten during processing.

Id.

[381] Telephone Interview with Andrea Levario, ACTF, *supra* note 217 (discussing how the Celiac Disease Foundation and Gluten Intolerance Group believe oats are safe, but CSA still is reluctant to accept the research findings about oats).

[382] FALCPA § 203(a), 21 U.S.C.A. § 343(w)(3).

[383] *See* 21 U.S.C.A. § 321(m).

[384] *See* FALCPA § 203(a), 21 U.S.C.A. § 343(w)(3).

While this provision likely will provide the Secretary valuable flexibility to adjust the FALCPA's requirements for atypical products and situations, it introduces an element of variability in labeling, the effects of which will be determined by how sparingly this provision is invoked in practice and by the specific alternative manifestations of allergen declaration that are utilized in the standard scheme's stead. This exception to the uniform labeling format that consumers will come to rely on may pose special difficulties for children and caregivers trained simply to identify allergens by reading the ingredients list. Publication in the *Federal Register* will do little to put most consumers on notice that a given product will deviate from the traditional labeling system.

Second, another broad delegation of authority to the Secretary that may complicate the FALCPA's labeling scheme is provided in the new 21 U.S.C. § 403(w)(5). This section states that the Secretary may modify the allergen labeling formatting scheme as necessary "to protect the public health." The Secretary may *modify* the requirements that a major allergen be declared either in parentheses after a food containing the allergen or adjacent to the ingredients statement following the word "contains," or the Secretary may *eliminate* one of those options entirely.

The Secretary's freedom to adjust the format scheme over time allows the Secretary to respond to consumer input about label clarity and ultimately may promote greater consistency (such as if the Secretary were to eliminate one of the options) or precision (if the Secretary were to require that allergens be declared in plain English after *each* allergen-containing ingredient). The provision, nonetheless, introduces the potential for further labeling variation that could confuse consumers, depending on how frequently and in what ways this provision is employed. Recognizing this drawback, Congress drafted this provision in a way to narrow the possible options for variability and to encourage FDA to use its authority sparingly.[385]

b. *Exemptions of Certain Ingredients From the Labeling Requirements*

The petition and notification processes provided in the FALCPA to exempt certain ingredients from the act's labeling requirements have evoked serious concern among some food-sensitive individuals. These exemptions have the potential to encourage needed research about the allergenicity of questionable ingredients and about the extent to which allergenic proteins are removed during various chemical and manufacturing processes. The exemption provisions may promote further study of tolerance levels and may encourage manufacturers to develop innovative new techniques to eliminate or significantly reduce the allergenicity of certain ingredients. One disadvantage, however, is that the exemption processes invite FDA to make case-by-case judgments about what threshold levels of an allergen can be present in a food before requiring an allergen declaration—determinations that invariably will be over- and underinclusive, as discussed in the prior section concerning the FALCPA's potential to backfire against consumers. The deleterious potential of these exemption provisions is heightened by the fact that, because of the FALCPA, consumers will become more trusting of food labels and take fewer precautions.

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> First, FDA may modify one or both labeling options. Second, FDA may not eliminate all major food allergen labeling by eliminating both labeling options; rather, FDA may eliminate only one of the approaches. Third, and most significantly, FDA must demonstrate in the regulation that modification or elimination of an allergen labeling requirement is necessary to protect public health. The committee considers this standard to impose a *high burden* on the Secretary to justify changing these requirements of the legislation.

S. REP. No. 108-226, at 9 (emphasis added).

It is difficult to predict how the petition and notification provisions will be executed by FDA. The FALCPA's language, like most legislation authorizing administrative agency action, leaves the agency with many interpretive gaps to fill. Manufacturers can seek to have ingredients exempted from the FALCPA's labeling scheme if they provide "scientific evidence (including the analytical method used to produce the evidence)" that "demonstrates that such food ingredient, as derived by the method specified in the petition" does not contain allergenic protein or does not cause an allergic response that "poses a risk to human health."[386] The FALCPA does not clarify, for instance, whether all allergic responses pose a "risk" to human health, or only more "severe" reactions.

The Senate Committee Report's guidance to FDA about these exemption provisions leaves FDA wide implementation latitude and raises more questions about how FDA should execute the exemption provisions than it answers:

> The committee encourages FDA to adopt a *reasonable standard* for determining whether a food ingredient 'does not contain an allergenic protein.' ... The committee intends that the Secretary will provide guidance to industry on the *information that would be useful* for making a determination that foods that contain protein derived from one of the eight food allergens do not cause an allergic response that poses a risk to human health. The committee also intends that the Secretary provide an *appropriate process* for providing such information to the Secretary that *minimizes the burden on the food manufacturer*.[387]

FDA has been working to operationalize the FALCPA's petition and notification processes and to establish the data manufacturers must supply to the agency.[388] As of December 7, 2005, FDA had received two notifications and no petitions. How liberally FDA will interpret and implement the exemption provisions—what sort of "scientific evidence" is needed, what FDA considers a sufficient "risk to human health" to justify allergen declaration, and how many and how frequently ingredients are exempted—casts uncertainty over the FALCPA's entire labeling scheme.[389]

Some people with food sensitivities argue that there should be no exemptions allowed for any ingredients derived from an allergenic food source. As one highly-sensitive peanut-allergic individual contends, "the threshold provision is a bad idea. Disclosure must be complete. Allergies vary from person to person and the idea that it is less severe in a number of people does not rule out that in a few people the threshold is so low as to be negligible."[390] Some people with food sensitivities are nervous about the

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[386] FALCPA § 203(a), 21 U.S.C.A. § 343(w)(6)-(7).

[387] S. REP. No. 108-226, at 7 (emphasis added).

[388] Telephone Interview with Catherine Copp, Policy Advisor to the Director of the Office of Regulations and Policy, CFSAN, FDA (Mar. 10, 2005) (stating that an FDA working group was working to establish guidance to the industry about the petition and notification processes, as well as the substantive legal standards manufacturers must meet); *see also* CFSAN, FDA, THRESHOLD WORKING GROUP, DRAFT REPORT, *supra* note 78. The Threshold Working Group is the interdisciplinary group formed by CFSAN to assess scientific knowledge about food allergies and celiac disease and to apply that knowledge to the goal of establishing thresholds. Determinations made about threshold levels will affect what information should be submitted to FDA under the FALCPA's petition or notification processes.

[389] The FALCPA's exemption processes are significantly more specific and detailed, however, than the first provisions in proposed allergen labeling legislation that permitted exemptions of certain ingredients. H.R. 4704 and S. 2499, introduced in the House and Senate in May 2002, provided the Secretary of HHS with unfettered discretion to exempt a substance derived from a major allergen so long as the Secretary determined the substance did not "cause an allergic response that poses a risk to human health." H.R. 4704, 107th Cong. § 3(a) (2002); S. 2499, 107th Cong. § 3(a) (2002). It was almost a year later, in the version of S. 741 reported in the Senate at the end of March 2003, that the more elaborate exemption processes found in the FALCPA was first included in a proposed allergen labeling bill. *See* S. 741, 108th Cong. § 203(a) (2003).

[390] E-mail from JK to Author, Response to Allergen Labeling Survey (Jan. 10, 2005).

petition process itself, whereby FDA makes exemption decisions based on data provided only by manufacturers advocating for an ingredient's exclusion from the labeling requirements. And one Allergen Labeling Survey respondent articulated a broad view of consumers' interest in knowing what they are consuming, regardless of safety concerns: "just because a trace amount may not pose a risk to human health, a person should have the right to know what they are eating."[391] This "zero tolerance" approach was adopted by early food allergen labeling bills.

A strict "zero tolerance" policy that would require automatic allergen declarations for derivatives of major allergen-containing food is not practical, however, given the reality that the FALCPA does not mandate the identification of each allergen-containing ingredient on the food label so that consumers can make informed, independent decisions about what particular ingredients they can tolerate. Such a policy also is not desirable because some ingredients like highly-refined oils and hydrolyzed ingredients contain virtually no allergenic protein and are believed to be safe for the vast majority of food-sensitive individuals; under a zero tolerance regime, even those ingredients whose safety could be demonstrated scientifically would prompt allergen declarations, causing undue confusion and anxiety for most food-sensitive individuals.[392] Furthermore, a zero tolerance policy would be unable to adapt to evolving technologies that may eliminate offending proteins from food or to new information about tolerances and food allergenicity. Recognizing the importance of being able to adapt labeling requirements as information improves, the European Union also included an exemption provision in its labeling scheme for allergens.[393]

It is troubling that the people most in need of allergen labeling—those who are the most sensitive and, hence, at risk for unexpected, severe reactions—will be most harmed by the FALCPA's exemption provisions that authorize FDA to draw lines regarding acceptable threshold levels of allergens. The House Committee Report on the FALCPA reveals the Committee's acknowledgment of threshold concerns and its cautious ap-

[391] E-mail from EK to Author, Response to Allergen Labeling Survey (Jan. 25, 2005).

[392] This argument is premised on the assumption that certain ingredients can, in fact, be scientifically demonstrated to be safe for consumption by the vast majority of food-sensitive individuals. It is doubtful any current research has so demonstrated. Even soy oil—which along with peanut oil are the only two ingredients explicitly exempted from allergen labeling by the FALCPA and about which the tolerance of allergic individuals has been studied—remains somewhat controversial. *See, e.g.*, Joshi et al., *supra* note 94, at 1020 ("Although there are *no large, definitive studies*, soy oil in particular has generally been found to be safe and tolerated by soy-allergic individuals.") (emphasis added).

Two Allergen Labeling Survey respondents argued, moreover, that from their personal experience, some peanut-allergic individuals *do* experience adverse reactions to peanut oil. They emphasized that each person's ability to tolerate allergens differs, sometimes even depending on the specific food involved or what else the person has eaten that day, thereby making it impossible for FDA to effectively determine safety thresholds. E-mail from MP to Author, Response to Allergen Labeling Survey (Jan. 10, 2005) ("Oils should be included as requiring labeling as many, though not all, allergy sufferers will react to oils as well. ... Also it is not feasible to set a minimum threshold for allergens as every person is different. I have found my threshold for different foods is also affected by my overall health and stress level on that particular day, and the percentage of the food that is allergen in relation to the total meal."); E-mail from JK to Author, Response to Allergen Labeling Survey (Jan. 10, 2005) ("This seems to me an area that, particularly as with me, life and death are at stake; some lobbyist for food companies should not be allowed any negotiation room on this.").

[393] *See* EU Labeling Directive, *supra* note 346, at 10 (stating that the list of allergen-containing ingredients requiring allergen declarations "shall be systematically re-examined and, where necessary, updated on the basis of the most recent scientific knowledge."). The European Food Safety Authority has the power to exempt from allergen labeling those ingredients for which it has been "scientifically established that it is not possible for them to cause adverse reactions." *Id.*; *see also* Sara Lewis, *EU Panel Says Evidence Supports Mandatory Allergen Labeling*, FOOD CHEM. NEWS, Apr. 5, 2004, at 26-27, *available at* 2004 WL 67505064.

proach to the notification procedure. "The Committee recognizes that thresholds for the eight major allergens have not yet been established by the scientific community;" however, "*if* they are established, ingredients containing allergenic proteins below the established threshold would be eligible for the notification procedure."[394] As FDA concludes in a draft report addressing allergen thresholds issued June 15, 2005, any approach used to establish a threshold should be re-examined periodically to consider new knowledge, data, and approaches.[395]

The hard decisions FDA will have to make in determining threshold levels and balancing the dual problems of over- and underinclusivity seem to be unavoidable. How FDA resolves these issues—and, importantly, conveys those decisions to consumers—will significantly affect how helpful the FALCPA will be to food-sensitive individuals.

c. *Ambiguous Provisions*

The impact of the Food Code revision and food allergy-related research provisions of the FALCPA could be substantial or trivial, depending on how those provisions are executed.

i. *Food Code Revision*

With regard to developing guidelines for preparing allergen-free foods in food establishments, the FALCPA's language is equivocal. The act merely instructs the Secretary vaguely to "*pursue* revision" of HHS' Food Code.[396] No particular outcome, thus, is needed to satisfy this provision.

In 2005, FDA released a new edition of the Food Code. FDA made several amendments in light of the FALCPA, such as including a definition of "major food allergen," requiring that a person in charge of a food establishment be able to describe the foods that are major food allergens and the symptoms of allergic reactions, mandating that food packaged in a food establishment be labeled in compliance with the FALCPA, and updating information regarding food allergens.[397] Although the revised Food Code states that major allergens can be controlled through the use of "a rigorous sanitation regime to prevent cross-contact between allergenic and non-allergenic ingredients,"[398] the Food Code does not provide specific guidelines for preventing cross-contact or preparing allergen-free foods. It does not address employee training regarding allergens or standardized procedures for safely serving food-sensitive consumers. The FALCPA's failure to mandate what revisions must be made to the Food Code means that the FALCPA's Food Code provision may yield few results, depending on FDA's initiation of further revisions at the agency's discretion.

ii. *Food Allergy Research*

Besides the immediate benefit of an enhanced labeling system for major allergens, the provisions of the FALCPA with the greatest potential to benefit food-sensitive individuals arguably are those that call for HHS to conduct and support relevant research.[399]

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[394] H.R. REP. NO. 108-608, at 17 (emphasis added).

[395] CFSAN, FDA, THRESHOLD WORKING GROUP, DRAFT REPORT, *supra* note 78.

[396] FALCPA § 209, 42 U.S.C.A. § 243(note) (emphasis added). As a food restaurant trade publication characterizes the provision, the FALCPA asks the federal government to "consider revising" the Food Code to provide allergen-free food preparation guidelines for food establishments. Erica Duecy, *Food Allergies Nothing to Sneeze At, Chains Say*, NATION'S RESTAURANT NEWS, Sept. 20, 2004, at 143, *available at* 2004 WL 93664798.

[397] *See* FDA, FOOD CODE 2005, §§ 1-2, 2-102.11(c)(9), 3-602.11-.12, Annex 2 1-201.10, Annex 4, *available at* http://www.cfsan.fda.gov/~dms/fc05-toc.html.

[398] *See id.* at Annex 4.

[399] *See* FALCPA §§ 207, 208, 210; 42 U.S.C.A. § 242r(note); 42 U.S.C.A. § 243(note).

Knowledge about food allergies, to a large extent, remains uncertain and has been expanding in an *ad hoc* fashion. The FALCPA finally has made food allergy research a part of the national health agenda and, importantly, is helping to finance the effort.[400] Better documentation and coordination of findings about the prevalence of food allergies, adverse events, treatment methods, and current clinical research efforts, as well as the provision of federal assistance to local first responders to treat adverse reactions, could improve the identification of allergies and the treatment of adverse reactions. It has the potential to lead to the discovery of prophylactic remedies, to the relief of millions of people diagnosed with known food allergies, not yet diagnosed, or currently misdiagnosed.

Whether and to what extent the FALCPA's research provisions actually make a positive impact will turn entirely on the priorities and budgets of the implementing agencies.[401] The FALCPA's research provisions themselves speak in ambiguous generalities. CDC and FDA, for instance, are asked simply to "improv[e] ... the collection of ... national data" and to "educat[e] physicians and other healthcare providers" about the prevalence, diagnosis, and treatment of food allergies.[402] An *ad hoc* panel of allergy experts convened by NIH shall "make recommendations" to the Secretary of HHS for "enhancing and coordinating research activities concerning food allergies."[403] The House Committee Report does elaborate somewhat, however, on its expectations in its discussion of the cost of financing the information gathering and dissemination effort. The report expects CDC, among other things, to increase the precision of surveys of healthcare providers regarding food reactivity, to add allergy-identification laboratory tests to the National Health and Nutrition Examination Survey, and to implement an automated system where care providers can record food allergy-related deaths.[404]

B. *The FALCPA's Insufficient Scope*

In several significant ways, the FALCPA falls short of the ideal for food-sensitive individuals. Due to the realities of political compromise, the FALCPA fails to address several key issues that would empower food-sensitive individuals to know exactly what is in the foods they consume. This subsection discusses some of the FALCPA's major deficiencies due to its narrow scope and, in so doing, notes areas in need of further legislative, regulatory, or voluntary reform.

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[400] *See* FALCPA § 207(b), 42 U.S.C.A. § 242r(note) ("For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.").

[401] As an editor of the Allergy and Asthma Disease Management Center's website notes, "[t]his legislation sounds very important but also quite ambitious to me, requiring a lot of effort on the part of food allergy experts, the food industry and the DHHS regulatory/enforcement apparatus." Allergy and Asthma Disease Management Center, American Academy of Allergy Asthma & Immunology, Food Allergen Labeling and Consumer Protection Act (Sept. 29, 2004), *formerly available at* http://www.aaaai.org/aadmc/inthenews/wypr/2004archive/labeling.html (last accessed Jan. 20, 2005). One Allergen Labeling Survey respondent stated that, based on her work experience on Capitol Hill, she was skeptical about how much the FALCPA's research provisions could accomplish without the continued oversight of the act's congressional sponsors and some prioritization by the federal agencies charged with executing them: "Food allergen labeling just can't compete with the likes of flu vaccine shortages, arthritis medicine scares, or bioterrorism threats when it comes to prioritizing the major public health challenges of our time. Allergen labeling won't get the [Secretary's] (or the media's) serious attention." E-mail from MD to Author, Response to Allergen Labeling Survey (Jan. 26, 2004).

[402] FALCPA § 207, 42 U.S.C.A. § 242r(note).

[403] FALCPA § 208, 42 U.S.C.A. § 242r(note).

[404] *See* H.R. REP. No. 108-608, at 8.

1. *Beyond the Big Eight Allergens: The Neglected Food Allergy Sufferers*

By far the most common criticism of the FALCPA among Allergen Labeling Survey respondents[405] was the confinement of its labeling requirements to only eight allergens—milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soy. The FALCPA's failure to require the declaration of more allergens is a serious weakness of the legislation.

The FALCPA purports to benefit ninety percent of Americans with food allergies and the roughly two to three million people who have celiac disease.[406] Are ninety percent of Americans with food allergies actually helped by clearer labeling of the Big Eight allergens? To what extent are people with celiac disease truly empowered by the FALCPA to know what is in the foods they consume? And what about the plight of the other ten percent of people with food allergies? This subsection explores these questions and the missed opportunity to more widely benefit individuals with food sensitivities.

a. *The Desirability of Labeling More Than Just the Big Eight Allergens*

Numerous Allergen Labeling Survey respondents explained that the FALCPA would have been more helpful if it had required the declaration of more allergens. Allergens besides the Big Eight similarly can provoke a range of adverse reactions, including intestinal distress, nausea, vomiting, migraines, hives, breathing difficulties, and life-threatening anaphylaxis. The same problems of complex ingredient terminology and lack of disclosure of subingredients in spices, flavorings, colorings, and additives thwart the efforts of individuals attempting to maintain other avoidance diets.[407] In the words of a survey respondent allergic to garlic, "It amazes me that we have a government that wants to dabble in our every day lives, make us wear seatbelts and helmets, but won't [allow] us [to] find out if a substance that could kill us is in our food."[408] As the co-founder of Food Allergy Survivors Together notes on her website for food-sensitive individuals, "If we have just one allergen not in the 'big eight,' this legislation is virtually useless to us. I know it will help some people with food allergies, but not all of us. Many (er, most!) ingredients will still be able to hide under guises."[409]

Non-Big Eight foods to which several Allergen Labeling Survey respondents are allergic include sesame seeds, celery, corn, onion, strawberries, bananas, apples, grapes,

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[405] Of the nineteen survey respondents, fourteen criticized the limited list of allergens subject to the FALCPA's labeling requirements.

[406] *See* FALCPA § 202(2)(a),(6), 21 U.S.C.A. § 343(note).

[407] For instance, one Allergen Labeling Survey respondent described the FALCPA's limited benefits in this way:

> My obvious failure or limitation [of the FALCPA] is that it doesn't list my allergy. ... I am extremely allergic to sesame, whether it comes in seeds or oil. Crushed sesame seeds are often in middle eastern foods and listed in their ingredients as "tahini" which I learned the hard way was simply crushed sesame seeds. There are other names for sesame byproducts on labels, some with different spellings or other confusing factors. I'm fine with checking for most of these myself at the grocery store but asking waiters to check for several different possible ingredients doesn't always work.

E-mail from EK to Author, Response to Allergen Labeling Survey (Jan. 25, 2005).

[408] E-mail from JJ to Author, Response to Allergen Labeling Survey (Mar. 7, 2005).

[409] Melissa Taylor, Petition for Clearer Food Labeling Food Allergy, *supra* note 151 (also recognizing that the FALCPA is nevertheless "a huge victory, especially for those who have just the big eight and especially for those with life-threatening food allergies").

plums, coconut, garlic, ginger, and cinnamon. The food most frequently urged for inclusion within the FALCPA's mandatory declaration scheme was corn.[410] A corn allergy is particularly debilitating. Adverse reactions to corn include life-threatening anaphylaxis and some reactions can require hospitalization. Corn is present in most processed foods. It can be the source of, or involved in, the processing of over 170 different ingredients that do not mention the word "corn" on the label (e.g., alcohol, artificial sweeteners, baking powder, bleached flour, brown sugar, citric acid, dextrose, fructose, fruit juice concentrate, honey, hydrolyzed vegetable protein, iodized salt, maltodextrin, saccharin, vanilla, xanthum gum, and yeast).[411] Much of the wheat supply is cross-contaminated by corn. Adequate identification of the actual source foods in compound ingredients is imperative for these individuals to have any food choice freedom at all.[412]

Representative of some Allergen Labeling Survey respondents' sentiments in favor of more widespread coverage of the FALCPA was one respondent's entreaty that, when it comes to sources of ingredients, companies should be required to "*list everything*" on food labels.[413]

Food manufacturers and FDA understandably balk at such an idea. Any food has the potential to cause allergic reactions in some individuals. To identify every single source ingredient in plain English could clutter the food label, overwhelming consumers and impeding the ability of children and caregivers to locate the information they need.[414] Some product packaging may not be large enough to support full declarations. Manufacturers would need to expend resources to research all of the ingredients and to ensure accurate labeling. Also, although complete formula recipes would not be dis-

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[410] The following two responses are typical of those wishing corn would be required to be identified on labels. "I would especially love to see Corn added as a labeled food. Right now it is the most hidden ingredient in most processed foods." E-mail from MB to Author, Response to Allergen Labeling Survey (Jan. 10, 2005). "I need labeling for corn in all food products in order for new laws to benefit me. It is a nightmare to avoid!" E-mail from DE to Author, Response to Allergen Labeling Survey (Jan. 14, 2005).

[411] *See* Corn Allergens, Corn Allergen List, http://www.cornallergens.com/list/corn-allergen-list.php (last visited Feb. 20, 2006).

[412] *See, e.g.*, Corn Allergens, Corn Allergens As Ingredients, http://www.cornallergens.com/list/corn-allergen-ingredients.php (last visited Feb. 20, 2006) ("The hardest part is not knowing the ingredients of ingredients. For example, sour cream lists cream as an ingredient, but if you read the ingredients of cream, it can contain sodium citrate, which can be derived from corn and cause an allergy reaction (yes, this has happened to me).")

[413] E-mail from SS to Author, Response to Allergen Labeling Survey (Jan. 23, 2005).

[414] FDA discussed the problem of label overcrowding in 1979 when it stated its intention (which ultimately received little attention) to seek or support legislation to require that all subingredients of colors and spices—but not flavorings—be declared on food labels:

> The general position of the [FDA and USDA] is that most ingredients should be declared by specific names on food labels. This position appears to present no significant problems with respect to spices and colors. Most products that include spices contain no more than four or five. ... The same is true of colors: only a few are used in any one food, and listing them should present no practical problem. ... Label declaration of flavors does present a problem, however. There are about 1,700 flavors, and as many as 125 flavors can be used in a single processed food. The average number of flavors used in a processed food (excluding meat, poultry, and egg products) is about 40. Not only are there numerous flavors, but there are also an overwhelming number of substances that can be combined to form a single flavor ingredient. Since one food may contain many flavors, it would be impractical to identify them fully on the label, and it would be difficult for the government to establish an all-inclusive labeling policy for these ingredients. ... Industry has argued that mandatory disclosure of all colors, flavors, and spices would be an onerous burden because it would overload labels, making them incomprehensible to consumers.

44 Fed. Reg. 75,990, 75,997-98 (Dec. 21, 1979).

closed, manufacturers may plausibly worry about harm from the release of their proprietary information.[415] Full disclosure, moreover, might take industry focus away from the Big Eight allergens, diluting industry efforts to address the allergens that affect the most Americans.

On the other hand, with regard to consumer confusion, for most food-sensitive label readers, a label with more information and plain English declarations probably would save them time (allowing them to bypass calling manufacturers and mulling over ambiguous ingredients), as well as suffering. Many ingredient lists already are quite lengthy and contain perplexing terminology; plain English labeling would help children and caregivers overcome the added difficulties of reading a longer ingredient list. Label crowding would not harm the average consumer who is uninterested in ingredient content, and it would not deter a consumer interested in nutrition information from viewing the unaltered nutrition information panel. People who read ingredient lists, not surprisingly, want to know the ingredients in a product. Consumers with medical, religious, ethical, and other dietary needs also have been pressing for more detailed product information. They likely would welcome full disclosure.

Labeling-space concerns could be addressed by requiring manufacturers to print on labels their company's website address or a well-staffed customer service number, and by requiring firms to make full ingredient information available through those media. Some socially-responsible food firms already engage in this practice.

Even if manufacturers had a full disclosure obligation, cross-contamination management efforts could continue to focus on the eight major allergens. Consumers with allergies to non-Big Eight foods, nevertheless, might be able to more easily obtain information from manufacturers regarding cross-contact of products with non-Big Eight allergens because manufacturers would have gone through the process of carefully determining all of the ingredients in their product lines.

Is it so fantastic and impractical to require food manufacturers to know what is in their products and to be able to disclose that information? Undoubtedly, in some instances on a product-by-product basis, full disclosure may raise substantial proprietary concerns.[416] But it is not self-evident that full disclosure usually would work a considerable detriment to manufacturers. Manufacturers already need to determine ingredient sources to comply with the FALCPA, and it is doubtful that significantly greater expense and effort would be required to discover all source ingredients as part of these current efforts. Under current labeling laws, competitors already have access to the vast majority of ingredients that compose food products.[417]

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[415] *See, e.g.*, 44 Fed. Reg. at 75,998:

> Manufacturers also have contended that label declaration of the specific colors, flavors, and spices used in a food will divulge trade secrets. In the case of colors and spices, the [FDA and USDA] have concluded that labeling specific ingredients would not reveal trade secrets and that the benefits to consumers of knowing the identity of these ingredients would be substantial.

[416] *See, e.g.*, *Manufacturers Stress Importance of Allergen Labeling*, *supra* note 215 (quoting a Kellogg Company representative as saying that "tracking allergens in flavorings is a real challenge due to the diversity of flavor ingredients and the proprietary nature of their formulas").

[417] Manufacturers raised concerns about the disclosure of product formulas and proprietary information when Congress deliberated regarding the FDCA. FDA and Congress rejected these arguments. FDA stated that competitors already can discern most product ingredients, and product preparation method, which can significantly impact flavor, need not be disclosed. *See Hearing Before the S. Comm. on Commerce*, 73d Cong. (1934) (statement of Walter G. Campbell, Chief of FDA), *reprinted in* DUNN, *supra* note 170, at 1177-78:

> But against [the argument that ingredient disclosure will require the release of proprietary information], it seems to me, is the fact that [the manufacturer's] secret is not so profound

continued

Uneasiness about disclosure often may be rooted in a manufacturer's concerns about the costs associated with determining what is in its product and incorporating that information on the label, rather than reflect the manufacturer's interest in protecting business secrets. Revealing all product information might produce an overall boon to manufacturers as people who cautiously avoided all ambiguous ingredients would be free to purchase more products after the ambiguity has been resolved.

How many allergens and which ones potentially should be subjected to mandatory disclosure was debated at the 2001 Public Meeting. When FAAN's Muñoz-Furlong was asked whether the eight major allergens should be the appropriate focus of labeling or whether additional efforts should be placed on less common allergens, she stated, "My belief is that if we focus on the eight major allergens, we've covered 90 percent of the problem, and once we clear that up, we should start looking in other areas, but keep it to the eight so that we can focus there."[418] In contrast, Dr. Michael Jacobson, co-founder and Executive Director of CSPI, advocated for more expansive allergen disclosure. "We urge FDA to require disclosure not just of the major eight allergens but others as well. To someone with an allergy to corn or carmine, it's no satisfaction that wheat and shrimp are disclosed."[419]

Indeed, FDA's own rationale for requiring manufacturers to identify known allergens on food labels—outlined in its 1996 Notice Letter to manufacturers—applies equally to all allergens, not just the Big Eight. In its Notice Letter, FDA states that, although regulations exempt incidental additives present in insignificant levels from disclosure,

> Clearly, an amount of *a substance that may cause an adverse reaction* is not insignificant. Because evidence suggests that some allergenic substances can cause serious allergic responses in some individuals upon ingestion of very small amounts of the substance, it is unlikely that such an allergen, when it is present in a food, can be present at an insignificant level.[420]

> as he himself frequently imagines it is, that the character of the ingredients used can be and usually are determined. ... The flavor, the taste of ingredients may be the result of the technique of the individual who is preparing them. ... There are secrets in the preparation of food products. We certainly do not want [the manufacturer] to disclose that particular secret. That is the manufacturer's asset. Let him retain it.

In dismissing concerns about the disclosure of product formulas, however, FDA also relied in part on the fact that the specific ingredients in spices, colorings, and flavorings did not require declaration under the FDCA. S. REP. NO. 520, at 120 (1934) (accompanying S. 2800), *reprinted in* DUNN, *supra* note 170.

> This provision [requiring the listing of the common or usual names of ingredients in order of predominance by weight for foods without standards of identity] is essential if the consumer is to obtain reasonable information regarding the composition of the food he buys. ... It should be noted that this provision does not compel the disclosure of the formulas of such foods since no exact information as to proportions is required and flavors, spices, and colors need not be specifically named.

FDA did not realize at this time the dangers of allergic reactions posed by flavors, spices, and colors. Given the concern for food-allergic individuals apparent in the FDCA's legislative history, it thus is difficult to speculate as to how FDA would have weighed manufacturer proprietary interests against the public health benefits from disclosure of specific ingredients in spices and flavors.

[418] FDA, 2001 Public Meeting Transcript, *supra* note 44, at 106 (statement of Anne Muñoz-Furlong, FAAN); *see also id.* at 158 (statement of Anne Muñoz-Furlong, FAAN):

> I know that there's a study that's been done that looked at the foods that had been implicated in reactions, and there were somewhere around 160 foods on that list. That's an enormous task. What we would recommend again is to stay focused on the 90 percent of that problem. Once we figure out what the solutions are there, we can hopefully then quickly come by and address some of these other issues.

[419] FDA, 2001 Public Meeting Transcript, *supra* note 44, at 135 (statement of Michael Jacobson, CSPI).

[420] FDA, Notice Letter, *supra* note 224 (emphasis added).

FDA's 1996 Notice letter further states that it has not formally defined "allergens," and that a nonexhaustive list of allergens "commonly known to cause serious allergic responses" includes mollusks and legumes, in addition to the Big Eight allergens.[421]

In terms of legislative proposals for allergen labeling reform, requiring the disclosure of all food ingredients was a nonstarter politically. None of the allergen labeling proposals introduced in Congress since 1999 advocated for the complete disclosure of all food ingredients in spices, flavorings, and additives. Some drafts did call for more expansive labeling, however, than the FALCPA provides.[422]

Although the FALCPA rejects a full disclosure approach, the act makes clear that it does not preclude FDA from expanding via regulation the list of major allergens requiring identification under the FALCPA's labeling scheme.[423] The FALCPA's new labeling requirements "do not prevent the Secretary from requiring labels or labeling changes for other food allergens that are not major food allergens."[424]

While it is too early to speculate as to the frequency with which FDA actually may expand the list of allergens that must be declared, significant expansion of the list appears doubtful. The effort and expense that updating the allergen list would impose on the food industry, FDA's historical fixation on the Big Eight allergens, and FDA's belief that only ten percent of people with food allergies are not helped already by the FALCPA all weigh against FDA exercising its power to expand the allergen list.

One FDA insider stressed the fact that the law covers all but ten percent of allergic reactions. Catherine Copp, Policy Advisor to CFSAN's Director of the Office of Regulations and Policy, explained in March 2005 that whether FDA would include other allergens depends on establishing a scientific basis for designating another food as a major allergen. Several practical difficulties associated with conducting the requisite research exist, including variation in sensitivity between individuals and even within a given individual, and the fact that people likely to experience severe adverse reactions are less likely to be willing to participate in experiments. In her assessment, "We've got enough to deal with right now with the eight major allergens."[425] It is possible that resistance by the food industry and the inertia and limited resources of FDA may never be overcome.

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[421] *Id.*

[422] H.R. 5532, introduced by Rep. Lowey in October 2000, included in the list of "known allergens" requiring disclosure on the label: mollusks, "other legumes" in addition to peanuts and soybeans, and "such foods as the Secretary may by regulation determine cause a serious allergenic response." H.R. 5532, 106th Cong. § 2(a) (2d Sess. 2000). In May 2002, Rep. Lowey introduced a bill that also called for the labeling of gluten-containing grains and "any food that the Secretary by regulation determines causes an allergic or other adverse response that poses a risk to human health." H.R. 4704, 107th Cong. § 3 (2d Sess. 2002).

[423] *See* FALCPA § 203(b), 21 U.S.C.A. § 343(note); FALCPA § 203(a), 21 U.S.C.A. § 343(x). The Senate Committee Report states that it intends for any regulations issued by FDA requiring the identification of additional allergens to prescribe disclosure in "a manner consistent with" the FALCPA. S. REP. NO. 108-226, at 10.

[424] H.R. REP. NO. 108-608, at 18.

[425] Telephone Interview with Catherine Copp, FDA, *supra* note 388. As CFSAN's 2005 Program Priorities reflect, FDA indeed has its hands full implementing the FALCPA's requirements and pursuing additional allergen-related initiatives. *See* FDA, CFSAN, CFSAN 2005 Program Priorities (Dec. 1, 2004), http://www.cfsan.fda.gov/~dms/cfsand04.html (last visited Feb. 20, 2006) (stating that by September 30, 2005, CFSAN aims to implement training, guidance, and outreach activities to industry and field staff regarding the FALCPA; obtain an expert consultation on gluten-free labeling; develop for publication a proposed rule for gluten-free labeling; publish a proposed rule to require the declaration of carmine/cochineal extract, a color additive, on the ingredient statement of food, drug, and cosmetic products containing it; issue draft guidance on the use of test kits to detect the presence of peanut protein; complete a study for immunochemical peanut protein test kits; initiate validation of egg and milk test kits; issue an allergen Compliance Program and implement an enforcement strategy; and issue a report on allergen inspections.).

b. *The FALCPA's Impact on People With Celiac Disease*

The FACLPA is the first bill to become law that addresses celiac disease and the issue of gluten labeling.[426] It provides a much-needed first step toward providing celiac disease with national recognition and improving the lives of people with celiac disease. Nevertheless, the FALCPA leaves much to be desired for individuals with the disorder. As Dr. Alessio Fasano, Director of the Celiac Research Center at the University of Maryland, describes the FALCPA, it is an important start—but more remains to be done.[427]

Unlike the EU Labeling Directive,[428] the international labeling standards promulgated in the Codex Alimentarius,[429] and an earlier proposed U.S. allergen labeling bill,[430] the FALCPA does not require the labeling of grains containing gluten on food products. This is so, even though, according to some allergy experts as late as 2001, gluten-containing grains—not just wheat—are included in lists of the Big Eight allergens.[431] Although the FALCPA mandates that wheat be disclosed on food labels, other grains toxic to individuals with celiac disease (e.g., rye and barley) need not be disclosed in plain English or when present in spices, flavorings, colors, or additives.[432] Several Allergen Labeling Survey respondents noted this deficiency. According to one survey responder, "The labels will note the presence of wheat and that is extremely helpful. Yet without including the term gluten, the legislation falls short of allowing me to feel totally empowered. I will still have to call manufacturers to ensure that the products I buy do not contain any gluten."[433] At least one of the three national celiac disease support groups, the Celiac Sprue Association (CSA), supported the FALCPA but advocated for the further labeling of all gluten-containing source ingredients.[434] A provision in a 2002 bill that called for the inclusion of all gluten-containing grains in an allergen labeling scheme was dropped as a part of compromises reached while the bill was in committee.[435]

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[426] *See, e.g.*, Press Release, UMD Medical Center, UM Center for Celiac Research Supports Food Labeling Laws to Protect People with Celiac Disease and Food Allergies (Mar. 11, 2004), *available at* http://www.umm.edu/news/releases/food_labeling.html.

[427] Fasano Remarks, *supra* note 51 (noting that cross-contamination is a problem inadequately addressed by the FALCPA).

[428] EU Labeling Directive, *supra* note 346, at 23, Annex IIIa.

[429] JOINT FAO/WHO FOOD STANDARDS PROGRAMME, *supra* note 289, at 4; *see also* FAO CONSULTATION, *supra* note 290.

[430] H.R. 4704 explicitly included "grains containing gluten" among the "allergens" within the scope of the legislation's mandatory labeling scheme. H.R. 4704, 107th Cong. § 3 (2d Sess. 2002). The bill listed oats among its examples of gluten-containing grains. *Id.*; *see also* 148 CONG. REC. S4163-64 (May 9, 2002) (statement of Senator Kennedy).

[431] *See* Hefle & Taylor, *supra* note 19, at 71 tbl. 2.

[432] *See, e.g.*, Taylor, *Emerging Problems*, *supra* note 13 ("As with IgE-mediated food allergies, the cereal grains involved in celiac disease can be 'hidden' in foods as a result of the lack of source labelling [sic] of certain ingredients ... and various inadvertent errors made by food manufacturers."). Moreover, the 2001 FDA Public Meeting regarding the labeling of food allergens was purposefully limited to a discussion of food allergies and not celiac disease. FDA, 2001 Public Meeting Transcript, *supra* note 44, at 165 (Dr. Christine Lewis, Director of the Office of Nutritional Products, Labeling, and Dietary Supplements, FDA, stated that the meeting would not concern latex allergies, celiac sprue, or restaurant labeling.).

[433] E-mail from GS to Author, Response to Allergen Labeling Survey (Jan. 16, 2005).

[434] CSA, S.741-Food Allergen Labeling and Consumer Protection Act, CSA Notes (2004), http://www.csaceliacs.org/LabelingLegislation.php (last visited Feb. 20, 2006).

[435] H.R. 4704, 107th Cong. § 3 (2d Sess. 2002). Critics of the bill "charged that scientifically, gluten is an intolerance not an allergen." *Kennedy Floats Amendment to Mandatory Allergen Labeling Bill*, *supra* note 257, at 6. *See also Substitute Pulls Mandatory Gluten Declaration*, *supra* note 271, at 5 ("This week the Senate health committee passed without objection a watered-down version of a bill that would require food processors to label the eight most common types of food allergens in plain English. The substitute version, unlike the underlying bill, would give food firms two options for labeling these allergens and would not require the declaration of gluten."). The subsequent compromise bill served as the basis of S. 741, the FACLPA.

The clear labeling of wheat under the FALCPA, in fact, may have the perverse effect of harming those who must avoid gluten. A gluten-free product always is wheat-free, but the reverse is not true. Children or caregivers of children with celiac disease may assume incorrectly that a wheat-free product is gluten-free if they are not familiar with or do not remember the various terms for gluten-containing ingredients (e.g., rye, barley, and malt) besides wheat.

The FALCPA's petition and notification processes through which an ingredient may be exempt from the act's labeling requirements produce uncertainty regarding the level of protection that the FALCPA will provide individuals with celiac disease in practice. The law discusses these processes within the context of food allergies, not celiac disease. It is unclear therefore whether FDA will take into consideration adverse reactions suffered by individuals with celiac disease, not just individuals with food allergies, when making exemption determinations. If the amount of wheat that causes intestinal damage to a person with celiac disease is less than the amount that triggers an adverse reaction for an individual with a wheat allergy, ingredients containing wheat could be exempted from declaration that nevertheless may harm people with celiac disease.

The FALCPA does call for the development of a definition of the claim "gluten-free."[436] This involves identifying the grains that cannot be used in gluten-free foods, the amount of gluten that may be present in a food product and nevertheless be labeled "gluten-free," and the tests that may be used to identify the amount of gluten in a product. The FALCPA mandates that FDA issue a proposed rule by August 2006 and a final rule by August 2008. "Given the devastating nature of celiac disease, the Committee urges the Secretary to move expeditiously in implementing the requirements of this section," the House Committee Report stresses.[437] In August 2005, FDA held a public meeting to obtain comments from experts and stakeholders to help the agency as it develops a regulation to define the term "gluten-free."[438]

Canada, Australia, Europe, and the Codex Alimentarius all have standards for what constitutes a "gluten-free" product,[439] but the United States has yet to develop its own.[440] In 1993, FDA stated that manufacturers could use the term "gluten-free" on packaging, despite the lack of a definition of that term, so long as the phrase was not used in a "false or misleading" way[441]—needless to say, a difficult standard to apply without a definition of the meaning of "gluten-free."

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[436] *See* FALCPA § 206, 21 U.S.C.A. § 343(note).

[437] H.R. REP. No. 108-608, at 18.

[438] *See generally* FDA, Public Meeting on Gluten-Free Food, *supra* note 326; *see also* FDA, Advice to Consumers, *supra* note 5 ("Information presented during and following the meeting provided FDA important and relevant data regarding current industry practices in the production of foods marketed as 'gluten-free,' challenges faced by manufacturers of 'gluten-free' foods, and consumer perceptions and expectations of what 'gluten-free' means to them.").

[439] Telephone Interview with Andrea Levario, ACTF, *supra* note 217; *see also* Andrea Levario, *Food Allergen Labeling—What Happens Next?*, 3(4) CELIAC.COM'S GUIDE TO A SCOTT-FREE LIFE WITHOUT GLUTEN 2-3 (Autumn 2004) (on file with author) (stating that the Codex Alimentarius gluten-free standard is 20 ppm for naturally gluten-free foods, and 200 ppm for foods with ingredients that normally contain gluten but have had the gluten removed, whereas Canada's gluten-free standard is a more stringent 20 ppm for all foods). In 2005, the Codex Committee was in the process of reviewing its standard for the term gluten-free. *See* CFSAN, FDA, THRESHOLD WORKING GROUP, DRAFT REPORT, *supra* note 78.

[440] *See, e.g.*, NIH Consensus Development Conference Statement, *supra* note 35 ("The strict definition of a gluten-free diet remains controversial due to the lack of an accurate method to detect gluten in food products and the lack of scientific evidence for what constitutes a safe amount of gluten ingestion."); Schorr, *supra* note 132 ("There is no single standard for defining a gluten-free product.").

[441] 58 Fed. Reg. 2850, 2864 (Jan. 6, 1993).

The unregulated use of the term "gluten-free" has caused confusion and has placed people with celiac disease at risk.[442] NIH's 2004 Consensus Statement on celiac disease emphasizes that a definition of standards for gluten-free foods is necessary to "lay the foundation for rational food labeling."[443] As Representative Lowey, the principal congressional supporter of improved food allergen labeling, stated in a press conference celebrating the passage of the FALCPA, the act finally will "give those with celiac disease the green light to consume foods without hesitation by setting guidelines for the use of the term 'gluten-free.'"[444]

While this provision to define "gluten-free" is a significant step in the right direction, use of this declaration by manufacturers merely is voluntary rather than mandatory.[445] Although people with celiac disease will be able to trust "gluten-free" declarations beginning in 2008, the degree to which safety and convenience will improve for those with celiac disease depends on how widespread voluntary usage of the "gluten-free" claim becomes. Earlier legislative allergen labeling efforts included provisions requiring the Secretary of HHS to assess, after a "gluten-free" standard is defined, whether additional labeling of gluten is necessary on the label.[446] This provision was cut from the FALCPA.

Although the lack of mandatory gluten labeling has been criticized by some consumers with celiac disease, some celiac disease advocacy groups believe these limitations of the FALCPA with regard to gluten were unavoidable. According to ACTF co-chair Levario, it was not possible for legislation to require the declaration of gluten-containing cereal grains on food labels given the current state of disagreement about what constitutes a "gluten-free" food. Indeed, even people within the food allergy and celiac communities could not agree on a definition for "gluten-free."[447] Consensus has not yet developed regarding the amount of gluten that may be consumed safely by people with celiac disease. Only recently, moreover, have tests of sufficient accuracy become available to test food products to determine how much gluten is in a food product.

Thus, when an allergen labeling bill initiated in the 107th Congress called for the mandatory declaration of gluten on food labels, the food industry demanded that this

[442] *See generally* Schorr, *supra* note 132 (discussing findings that one out of five products labeled "gluten-free" in fact contained wheat protein and the study's conclusion that "[c]aution must be taken when eating foods labeled gluten-free").

[443] NIH Consensus Development Conference Statement, *supra* note 35.

[444] Lowey Statement, *supra* note 275.

[445] *See* FALCPA § 206, 21 U.S.C.A. § 343(note) (stating that the Secretary of HHS shall issue a rule to define and "permit use of" the term "gluten-free" on food labels).

[446] Bills introduced in the 107th Congress, in addition to requiring the promulgation of a standard for "gluten-free," called for the Secretary of HHS to assess "whether additional requirements for the labeling of gluten are warranted and necessary to better inform individuals with celiac disease, and if other labeling is warranted and necessary, identif[y] the types of such labeling." S. 3001 and H.R. 5747, 107th Cong. § 6(d) (2d Sess. 2002); *see also* S. 2499, 107th Cong. § 6(d) (2d Sess. 2002); S. REP. No. 107-322, at 8 (accompanying S. 2499, as reported in Senate) ("The committee also expects the Institute of Medicine report to inform a report by the Secretary to Congress on whether additional requirements for the labeling of gluten in food associated with celiac disease are warranted and necessary to better inform individuals with celiac disease. If the Secretary finds that other labeling of gluten in food associated with celiac disease is warranted and necessary, the report is to identify the types of such labeling and should describe why the different types of labeling are warranted and necessary.").

[447] Some national celiac groups believe oats should not be allowed in a "gluten-free" product. Additionally, the food allergy community expressed reluctance about allowing a standard for "gluten-free" that permitted any amount of gluten, no matter how slight, to be present in a food. "The food allergy community was a tight ally [with us in lobbying for] the legislation. For them, zero is zero—once you provide for leeway, you're setting yourself up for allergic reactions." Telephone Interview with Andrea Levario, ACTF, *supra* note 217.

provision be removed due to concerns about liability given the dearth of scientific knowledge about gluten tolerance levels.[448] When the bill was reintroduced in the 108th Congress, the starting point for the bill was the earlier compromise legislation that did not require the labeling of gluten. There was "no way to get the term back in. We weren't in a position to get the ideal," Levario said of the FALCPA. "We don't have some of the research behind us to get us there."[449]

Some celiac disease advocacy groups believe the FALCPA will benefit people with celiac disease significantly, despite the FALCPA's failure to require the identification of rye and barley in its labeling scheme. Several celiac disease groups praised the enactment of the FALCPA.[450] Levario explained the FALCPA's welcomed reception within the celiac community by the fact the act addresses most of the labeling needs of celiacs. "Eighty percent of the problem [for people with celiac disease] is in wheat or a wheat derivative," she explained.[451] Rye is "virtually never" used as a spice, flavoring, or additive. Barley usually is listed plainly as a key ingredient or, if hidden, is hidden in the term "malt," in which case a person with celiac disease should avoid the food or inquire further about its contents. It was difficult to justify the inclusion of rye and barley from the food allergy (not celiac disease) perspective, Levario noted, because rye and barley are not among even the most common twenty allergens for people with food allergies.[452]

The FALCPA's four-year deadline for the establishment of a standard definition of "gluten-free"[453] and its requirement for the mandatory disclosure of wheat will do much to help people with celiac disease. It is clear, however, that including gluten-containing grains besides wheat in the FALCPA's allergen labeling scheme, expressly requiring FDA to consider celiac disease in its ingredient exemption decisions, and requiring the "gluten-free" declaration on products without gluten could have gone significantly further to assist people living with this disease.

c. *Are Ninety Percent of Food-Sensitive Americans Helped by the FALCPA?*

The FALCPA touts a statistic that the Big Eight allergens are responsible for ninety percent of "food allergies."[454] Congress, FDA, and the media all seized on this figure that implies that the FALCPA alleviates problems faced by ninety percent of food-sensitive individuals. Does the FACLPA actually help ninety percent of people with food sensitivities? This question is worth exploring insofar as it sheds light on why the FALCPA requires the declaration of only eight foods. Also, the meaning and accuracy of

[448] *Id.*; *see also* Melin-Rogovin, *supra* note 217, at 11:

> The reality of enacting food labeling legislation for celiacs is that a label stating 'gluten-free' will not be acceptable to lawmakers and the industry (think of the last time you called a company and they said 'we cannot guarantee that this product is gluten-free'). Eliminating the fear of lawsuits is the key to developing—and passing—food labeling laws.

[449] Telephone Interview with Andrea Levario, ACTF, *supra* note 217; *see also* Levario, *Food Allergen Labeling*, *supra* note 439, at 2-4.

[450] *See, e.g.*, Press Release, UMD Medical Center, *supra* note 426.

[451] Telephone Interview with Andrea Levario, ACTF, *supra* note 217; *see also* Levario, *Food Allergen Labeling*, *supra* note 439, at 1; Kupper Presentation, *supra* note 361 (saying that the FALCPA takes care of ninety percent of the problem by requiring the disclosure of wheat on food labels).

[452] Telephone Interview with Andrea Levario, ACTF, *supra* note 217; *see also* Ratner, *supra* note 295, at 13.

[453] Earlier versions of the FALCPA had adopted later deadlines. *See, e.g.*, S. 3001 and H.R. 5747, 107th Cong. § 6(c) (2d Sess. 2002) (requiring the Secretary of HHS to issue a proposed rule defining "gluten-free" within four years of the passage of the act and a final rule within six years).

[454] FALCPA § 202(2)(a), 21 U.S.C.A. § 343(note).

this statistic is important because it may generate a sense of complacency by FDA, the food industry, and Congress with regard to expanding the list of allergens warranting attention; the belief that problems have been remedied for ninety percent of food-sensitive individuals lessens the impetus to work to provide more widespread allergen labeling coverage.

First, it is inaccurate to view the statistic as asserting that ninety percent of Americans with food sensitivities are helped by the FALCPA. As the term "food allergies" may make plain to the initiated, this ninety percent figure refers only to people with IgE-mediated, immediate hypersensitivity reactions to food, not to people with delayed hypersensitivity reactions such as those with celiac disease. The ninety percent claim, thus, is an assertion limited to people with food allergies proper.

Second, the history behind this statistic reveals that it is not the case that an estimated ninety percent of food-allergic people are allergic to Big Eight allergens, as the FALCPA's preamble itself suggests;[455] rather, Big Eight allergens are responsible for about ninety percent of *adverse reactions*.[456] Although ninety percent of allergic reactions may be caused by the Big Eight, that does not mean that ninety percent of allergy-sufferers are helped. People could experience multiple reactions and be counted multiple times, meaning the percent of food-allergic individuals with a Big Eight allergy actually is less than ninety.

Third, within the subset of food-sensitive individuals who have food allergies, many people allergic to a Big Eight food also are allergic to non-Big Eight foods. For some people who theoretically should be helped by the act, the FALCPA in fact may have little, if any, benefit. As one Allergen Labeling Survey respondent explained, "A lot of my allergens aren't covered [by the FALCPA, so] I will still have to avoid any products that contain natural flavorings or spices."[457] Another respondent noted that she is allergic to some Big Eight foods and some non-Big Eight foods, and she has found her reactions from the non-Big Eight foods to be "more dangerous" than those from the Big Eight.[458] Studies confirm these anecdotes about the prevalence of multiple allergies. A 2001 study demonstrated that among children with food allergies, over thirty percent were allergic to two or more foods.[459] A study published in 1990 found that among children allergic to more than one

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[455] See the imprecise language employed in the FALCPA. Section 202(2)(a) states that the Big Eight allergens "account for 90 percent of food *allergies*" (emphasis added); *see also, e.g.*, FDA, Advice to Consumers, *supra* note 5 ("[T]he eight major food allergens identified by FALCPA account for over 90 percent of all documented food allergies in the U.S. and represent the foods most likely to result in severe or life-threatening reactions.").

[456] *See, e.g.*, H.R. 4704, 107th Cong. § 2 (2d Sess. 2002) ("Eight major foods—milk, egg, fish, Crustacea, tree nuts, wheat, peanuts, and soybeans—cause 90 percent of *allergic reactions*.") (emphasis added); FAO CONSULTATION, *supra* note 290; Hefle et al., *supra* note 4. Even though the impression left by the media and congressional debate frequently was that 90% of *people with food allergies* would be helped by the FALCPA, FDA tended to employ more accurate terminology that indicated that the Big Eight represent the allergens most frequently responsible for *serious* adverse *reactions*. *See, e.g.*, 66 Fed. Reg. 38,591, 38,592 (July 25, 2001) ("FDA's allergen awareness efforts are currently focused on the eight foods that are most frequently implicated in *serious allergic responses* ... .") (emphasis added).

[457] E-mail from MT to Author, Response to Allergen Labeling Survey (Jan. 8, 2005). The respondent continues:

> For those whose allergens are not in the 'top eight,' this really doesn't help, because those allergens will still not be listed. It will basically be the same as before, only with longer food labels that are even harder for me to sort through in order to find the term 'natural flavorings' or 'spices.' I do give it a 1 [rating of helpfulness on a scale of 1 to 5], however, because it will help me if the one food I currently consume with 'natural flavorings' suddenly lists an allergen. I'll get off that food immediately.

Id.

[458] E-mail from MB to Author, Response to Allergen Labeling Survey (Jan. 10, 2005).

[459] *See* Sicherer et al., *Impact of Childhood Food Allergy on Quality of Life*, *supra* note 72, at 461-62.

food, about 7.5% were sensitive to at least one Big Eight and one non-Big Eight food.[460] An internal survey conducted at FAAN's annual member conference in 2004 found that, of the approximately 500 members responding to the survey, roughly one third of respondents who indicated that they were affected by a Big Eight food allergy stated they also were allergic to at least one non-Big Eight food.[461]

Thus, use of the ninety percent figure as it has been touted in the media can leave the false impression that the FALCPA solves the problems of ninety percent of Americans with food sensitivities. Because people with multiple food allergies and those with celiac disease are not fully helped by the FALCPA, the actual percentage of *people with food sensitivities* who are empowered by the FALCPA to know if a food is safe for their consumption is far less than ninety percent. If FDA, Congress, the food industry, or the public believes almost all Americans with food sensitivities already have received adequate assistance, the impetus to work to add more allergens to the labeling requirement or to implement new food allergy-related reforms may be hindered.

d. *Sources of the Big Eight and the Ninety Percent Statistic*

It is not self-evident that the eight allergens covered by the FALCPA are the only ones that warrant labeling. Other countries have adopted more expansive lists of allergens requiring mandatory declaration. In addition to the Big Eight, the European Union requires the labeling of gluten-containing cereals, celery, mustard, sesame seeds, sulfur dioxide, and sulfites.[462] As the European Public Health Alliance notes, "The new U.S. rules do not go as far as the new EU Directive ... on the indication of ingredients in food."[463] Most of the contemporary discussion about food allergens in America has centered on the Big Eight allergens and the Big Eight consequently have gained a carved-in-stone quality.[464] But as one Allergen Labeling Survey respondent asked, "Who decided how many are the 'top' number of allergens to include?"[465] This question warrants attention because the provision requiring declaration of only the Big Eight "major allergens" is perhaps the most crucial—and controversial—element of the FALCPA.

The proposition that the Big Eight allergens identified in the FALCPA are responsible for ninety percent of allergic reactions is somewhat more muddled than the rhetoric tossed around in the debate surrounding the FALCPA suggests. The authoritative aura surrounding the major eight allergens typically is traced back to an expert panel (the

[460] *See, e.g.*, Bock & Atkins, *supra* note 49, at 564. Another study discovered that among children allergic to milk, 35% also were allergic to oranges, 18% were allergic to bananas, 14.5% were allergic to beef, 12% were allergic to tomatoes, and 11% were allergic to strawberries. *See* Bishop et al., *supra* note 56, at 864, 866 (noting, however, that "[b]ecause most of the patients with adverse reactions to non-cow-milk foods were not challenged in the allergy unit, and because we relied on parental observation and assessment of those reports by the chief investigator in an outpatient setting, these results should be interpreted cautiously").

[461] Telephone Interview with Chris Weiss, FAAN, *supra* note 216. Members listed over a hundred non-Big Eight foods to which they or their child is allergic. None of these other foods alone, however, in terms of prevalence, exceeded the least-prevalent Big Eight food (fish). The most prevalent non-Big Eight foods were seeds (such as sesame, sunflower, and mustard).

[462] *See* EU Labeling Directive, *supra* note 346, at Annex IIIa.

[463] European Public Health Alliance, *supra* note 33.

[464] *See, e.g.*, Falci et al., *Food Allergen Awareness*, *supra* note 27:

> Agency allergen awareness efforts currently focus on the eight foods that are most frequently implicated in serious allergic responses: milk, eggs, fish, wheat, tree nuts, legumes (particularly, peanuts and soybeans), crustaceans and mollusks. Allergic proteins in these eight foods are estimated to cause 90% of the allergic reactions in the U.S.

[465] E-mail from DE to Author, Response to Allergen Labeling Survey (Jan. 14, 2005).

Consultation) at a 1995 conference convened by the FAO.[466] In addition to the Big Eight allergens, FAO's Report list included gluten-containing cereals and sulfites. A similar list of allergens that also included mollusks and a broader category of legumes than just peanuts and soybeans appeared three years earlier in the *Federal Register*.[467]

The Consultation based its recommendations of what allergens should be declared on food labels on three factors: severity of reaction provoked by the allergen, estimated prevalence internationally, and amount of the allergenic protein in the food.[468] The Consultation thus composed the list not just on the basis of what types of food allergies are most common but also on the *severity* of the reaction and the prevalence of adverse reactions *globally*.

The FAO Report did not purport to speak definitively, however, on the prevalence of known allergens:

> [T]hese studies are not fully conclusive as the prevalence of food allergy is also influenced by genetic and geographic factors as well as regional diets. ... It was recognized that there is significant information available concerning food allergies, but that there are also significant gaps in that information particularly in regard to prevalence, and that much research remains to be done on a number of additional issues.[469]

The Consultation understood that its list was not inviolable. It "recognized that the proposed listing would also require modification in the future as new allergenic problems are identified."[470] The Consultation noted that rice, celery, and certain seeds (e.g., cottonseed, poppy, sesame, and sunflower), in particular, are prevalent in certain geographic regions and should be studied further for possible inclusion in the list.[471] Elsewhere the FAO Report states that "among the major sensitizing foods are fruits, legumes ... , vegetables

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[466] *See generally* FAO CONSULTATION, *supra* note 290. The Codex Committee on Food Labelling convened an FAO Technical Consultation on Food Allergies in Rome in 1995, bringing together thirteen experts on food allergies representing nine countries to provide guidance on the development of science-based criteria to determine which foods are known to cause hypersensitivity and, because of their allergenic properties, should always be declared in the ingredients list on the food label. This list was intended to serve as guidance for countries to standardize labeling for international trade purposes.

An FDA Compliance Policy Guide cites the 1995 FAO Technical Consultation report and a 1996 *Critical Reviews in Food Science and Nutrition* article written by Susan Hefle et al., discussed in the text of this article *infra*, in support of the agency's belief that "there is scientific consensus" that peanuts, soybeans, milk, eggs, fish, crustacea, tree nuts, and wheat "can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies." FDA, CPG on Cross-contact, *supra* note 56; *see also* Hefle & Taylor, *supra* note 19, at 71 ("In 1995, an expert consultation of the Food and Agriculture Organization of the United Nations determined that these eight foods or food groups were the most common causes of food allergy on a worldwide basis.").

[467] *See* 57 Fed. Reg. 22,984, 22,987 (May 29, 1992) ("Examples of foods that commonly cause an allergenic response are milk, eggs, fish, crustacea, mollusks, tree nuts, wheat, and legumes (particularly peanuts and soybeans).").

[468] FAO CONSULTATION, *supra* note 290, at 6-7:

> It was recognized that listing all foods which have caused severe systemic reactions or death in at least one case would result in an extensive list which would be only confusing. It was therefore considered necessary to concentrate on the major foods which cause the majority of food-induced hypersensitivity reactions. ... The Consultation agreed that the practical approach should be to list those foods which are generally recognized by experts to be frequent causes of severe systemic reactions.

[469] *Id.* at 4-5.

[470] *Id.* at 7.

[471] *See id.*

(celery and other foods of the Obelliferae family), wheat and other cereals, sesame seed and other seeds."[472]

In addition to the 1995 FAO Technical Consultation, the origins of the ninety percent figure also are rooted in a 1996 article by food allergy experts Susan Hefle and Steve Taylor who surveyed and summarized the scientific literature studying food allergies.[473] They developed a list of the most common allergenic foods and food groups based on "a thorough search of the medical literature." The list of allergens and the number of documented reactions due to those allergens thus is influenced by the methodologies of the studies upon which the list was generated, and such factors as whether researchers tested for allergic reactions only to specific foods. As the authors note, "the absence of a particular food on this list may not mean that it is nonallergenic, but may indicate that its allergenicity has not been documented."[474]

The article identifies over 170 allergenic foods, some of which also have been documented to cause severe, life-threatening allergic reactions. In fact, "a rather large percentage of the 160 or more other allergenic foods has been reported to elicit severe allergic reactions in isolated cases."[475] The prevalence of allergic sensitivities varies depending on the frequency with which the food is eaten in a given country and the typical age at which the food is introduced into the diet. Mollusks (clams, oysters, etc.), seeds (sesame, poppy, sunflower, and cotton), and certain legumes (dry beans, peas, lentils, and garbanzo beans) also are significant allergens in America.[476] These allergens can produce severe reactions, although they impact fewer people than the Big Eight. Susan Hefle and Steve Taylor also note that allergies to certain fresh fruits and vegetable are common, but "the allergens tend to be liable to processing and cooking and the symptoms are mild and confined primarily to the oropharyngeal area."[477]

Over the past decade, the lists of major allergens have been largely harmonized within the international scientific community, with the exception of a few outliers. The prudence of Congress' and FDA's decision to focus its attention solely on the Big Eight allergens, however, is not obvious. The Big Eight allergens did not receive this designation because they necessarily are the most prevalent in terms of people affected. The list was constructed using not just prevalence, but also typical severity of adverse reactions. What constitutes a major allergen differs according to age group and geographic region. Several other "second-tier" allergens have been documented to be widespread and provoke serious reactions. Even foods that rarely provoke allergic responses can cause serious adverse reactions in some sensitive individuals. Moreover, the *original* Big Eight list as determined in the 1995 FAO Food Consultation, unlike the list adopted by the FALCPA, included gluten-containing grains in addition to wheat. There appears to be scientific agreement that information on the prevalence of various food allergies and the severity of adverse reactions still is incomplete, and that as research progresses other allergens may deserve attention. The confinement of the FALCPA's scope to the Big Eight allergens to the exclusion of other allergens should not be viewed, therefore,

[472] Bousquet et al., *supra* note 4, Annex 3, at 9. Major studies of allergen prevalence prior to the 1995 FAO Technical Consultation reveal disagreement but a growing scientific consensus about the most common and severe allergens. *See, e.g.*, Bock & Atkins, *supra* note 49, at 565 ("Ninety-five percent of the food reactions objectively confirmed in this study were to egg, peanut, milk, tree nuts, soy, fish, and wheat."); *MSG, Chocolate, Spices Not on Steve Taylor's "Top Ten" Allergy List*, FOOD CHEM. NEWS, May 9, 1994, at 47-49.

[473] *See generally* Hefle et al., *supra* note 4.

[474] *Id.* at S69.

[475] Hefle & Taylor, *supra* note 19, at 71.

[476] *Id.*

[477] Hefle et al., *supra* note 4, at S69.

as a forgone conclusion. Whether the FALCPA should have included more allergens—and more importantly, whether FDA should authorize the inclusion of more allergens in the future—thus warrants critical consideration.

2. *Beyond Intentionally-Added Ingredients: The FALCPA's Weaknesses Related to Cross-contamination*

The FALCPA takes important steps toward addressing the problem of the inadvertent contamination of nonallergenic foods with major allergens. The FALCPA directs the Secretary of HHS to provide to Congress by February 2006 a detailed report on the issue of cross-contact because cross-contact "deserves further study by both FDA and the food industry."[478] The report will analyze a host of areas:

- the ways in which foods are contaminated unintentionally during manufacturing and processing (both for foods produced on shared production lines and on dedicated lines);
- how commonly cross-contact occurs in the food industry;
- the nature of labeling violations due to undeclared allergens;
- whether compliance with GMPs can reduce or eliminate cross-contact;
- what types of and to what extent advisory labeling currently is used by manufacturers;
- the preferences of food-sensitive consumers regarding how information about the risk of cross-contact should be communicated; and
- "the extent to which the Secretary and the food industry have effectively addressed cross-contact issues."[479]

With the data it gathers for its report to Congress, as well as from its efforts to determine threshold levels for allergens and gluten, FDA will have the background information upon which the agency could develop an informed approach to curtailing cross-contamination.[480]

In fact, as part of its efforts in 2004 to update GMPs generally,[481] FDA already had begun to collect data about cross-contamination before the FALCPA was enacted.[482] FDA made the development of "a comprehensive food allergen strategy to address considerations such as cross-contamination problems" a 2005 CFSAN program priority, an initiative that it expects may span several years.[483] In November 2005, FDA released a report analyzing ways that food GMPs could be modernized.[484] The report contains several recommendations that address cross-contact, including required training for food production employees regarding the prevention of cross-contamination, the development of allergen control plans that address segregation of food allergens during food storage and handling, validated cleaning procedures for food contact equipment,

[478] S. REP. NO. 108-226, at 4.

[479] FALCPA § 204, 21 U.S.C.A. § 321(note).

[480] *See* CFSAN, FDA, THRESHOLD WORKING GROUP, DRAFT REPORT, *supra* note 78 ("Understanding food allergen thresholds and developing a sound analytical framework for such thresholds is also likely to be useful in addressing food allergen cross-contact and the use of advisory labeling.").

[481] "In the almost 20 years since the food CGMPs were revised, the food industry has undergone considerable change, and the agency believes that it is now time to revisit these regulations and determine appropriate revisions to better ensure a safe and sanitary food supply." 69 Fed. Reg. 29,220, 29,221 (May 21, 2004).

[482] 69 Fed. Reg. 29,220, 29,221 (May 21, 2004).

[483] FDA, CFSAN 2005 Program Priorities, *supra* note 425.

[484] *See generally* CFSAN, FDA, FOOD CGMP MODERNIZATION REPORT, *supra* note 135.

and the prevention of cross-contact during food processing. FDA is expected to use these recommendations to develop a proposed rule updating food GMPs.

Also, the FALCPA instructs FDA to conduct inspections of food producers to ensure that facilities comply with practices to reduce or eliminate cross-contamination with major allergens and to ensure that major food allergens are labeled properly on foods.[485] Inspections that include cross-contact will increase awareness among food producers about the seriousness of this problem and may lead to voluntary efforts to reduce it.

Despite this progress, the FALCPA leaves several conspicuous gaps with regard to managing the problem of cross-contamination. Even before the bill was passed, critics of the FALCPA objected to the legislation's failure to regulate the problem of cross-contamination directly.[486] Dr. Alessio Fasano, head of the Celiac Research Center, has cited the problem of cross-contact and advisory labeling as a major ongoing concern,[487] as have representatives of FAAN.[488] Allergen Labeling Survey respondents identified the problem of cross-contamination as one of the top three areas in need of further reform after passage of the FALCPA.[489]

The FALCPA's detrimental shortfalls with respect to cross-contamination are several. The FALCPA's labeling scheme does not apply to allergens that inadvertently become a part of a food product through cross-contact,[490] therefore, even after the FALCPA, food labels do not consistently and uniformly reveal whether foods contain major allergens.[491]

The FALCPA provides no guidance as to the continued use of precautionary "may contain" language, neither standardizing the meaning nor the format of such warnings.[492] The act, in fact, has exacerbated the problem of advisory labeling; the use of "may contain" language on food labels has skyrocketed since passage of the FALCPA as more allergen-aware manufacturers seek to insulate themselves from liability.

The FALCPA fails to direct FDA to act on the report on cross-contamination findings by issuing any guidance or amending its regulations regarding the management of

[485] *See* FALCPA § 205, 21 U.S.C.A. § 321(note).

[486] *See* Mark Kissel, *Labeling Rules Likely for Food Allergies by Next Week*, WALL ST. J., July 7, 2004, at D7:

> The current legislation isn't perfect, critics say. For instance it doesn't regulate the problem of "cross contact" of food during manufacturing. ... Critics say this is a problem for people who are hypersensitive, since they can unknowingly consume a food that triggers a reaction. "You get sick if you eat a crumb of bread," explains Dr. Alessio Fasano, Director of the Center for Celiac Research at the University of Maryland.

[487] Fasano Remarks, *supra* note 51.

[488] Telephone Interview with Chris Weiss, FAAN, *supra* note 216.

[489] Several respondents expressed their desire to have more information—and more accurate information—about trace amounts of food allergens in food items processed using shared equipment. Others noted that, if advisory labeling must be used, they wished it would be employed in a uniform, meaningful manner.

[490] *See* FDA, Food Allergen Guidance for Industry, *supra* note 294 ("FALCPA's labeling requirements do not apply to major food allergens that are unintentionally added to a food as the result of cross-contact.").

[491] Although cross-contact is not regulated directly by the FALCPA, FDA may exercise its enforcement discretion against firms that produce products contaminated with allergens through cross-contact. *See infra* note 497.

[492] FDA iterates in a recent guidance document to industry that even though the FALCPA does not address the use of advisory labeling, "advisory labeling such as 'may contain [allergen]' should not be used as a substitute for adherence to [GMPs]. In addition, any advisory statement such as 'may contain [allergen]' must be truthful and not misleading." FDA, Food Allergen Guidance for Industry, *supra* note 294.

precautionary labeling or practices to reduce cross-contact.[493] The FALCPA further falls short of codifying FDA's policy that advisory labeling cannot be used in lieu of following food GMPs.[494]

The FALCPA's inspection provision is intended to allow FDA to check whether facilities are "engaging in efforts to reduce the possibility of" and are "taking appropriate steps to reduce or eliminate" cross-contamination.[495] It is not clear, however, what steps are sufficient to "comply with practices to reduce" cross-contact or whether visual inspections or scientific testing will be employed to determine the existence of cross-contact.[496] The FALCPA does not specify what repercussions, if any, a manufacturer may face if inspectors are not satisfied.[497] Moreover, it is questionable how effective FDA inspections can be policing cross-contact without providing the agency with more funding to increase the number of FDA inspections.[498]

Thus, it appears the advances made in allergen labeling under the FALCPA's labeling scheme are incomplete;[499] consumers still may encounter undeclared allergens due to

[493] The FALCPA simply calls for further study of the cross-contact problem. *See, e.g.*, S. REP. NO. 108-226, at 3-4:

> In some instances it may not be possible to eliminate the possibility of cross-contact following good manufacturing practice. In such instances, it may be appropriate for food manufacturers to use advisory labeling (such as 'may contain') to indicate the possible presence of food allergens in a food product. Many food manufacturers currently use such advisory language. However, 'cross-contact' deserves further study by both FDA and the food industry.

[494] FDA, Notice Letter, *supra* note 224:

> The agency is aware that some manufacturers are voluntarily labeling their products with statements such as "may contain (*insert name of allergenic ingredient*)." FDA advises that, because adhering to good manufacturing practices (GMPs) is essential for effective reduction of adverse reactions, such precautionary labeling should not be used in lieu of adherence to GMPs. The agency urges manufacturers to take all steps necessary to eliminate cross contamination and to ensure the absence of the identified food. The agency is open to suggestions on how best to address this issue.

[495] H.R. REP. NO. 108-608, at 8.

[496] FDA's current guide for allergen inspections lists what inspectors should examine during their inspections but does not identify how many or which steps a firm must take to "appropriately" reduce cross-contact. *See generally* FDA, Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients, *supra* note 252. It also is unclear whether FDA will update its 2001 inspection guide for allergens in light of what the agency learns from the report on cross-contact and its efforts to establish threshold levels for major allergens and gluten.

[497] It appears that FDA will enforce its pre-FALCPA policy, articulated in the 2001 Compliance Policy Guide, that undisclosed cross-contamination "may" render the food injurious to health and cause the food to be considered adulterated where specified criteria are met. *See* FDA, CPG on Cross-contact, *supra* note 56 (stating that one criteria for recommending legal action is if a food "is not labeled as containing an allergen, but inspection of the firm shows that it was manufactured under conditions whereby the food may have become contaminated with an allergen").

[498] *See, e.g.*, FDA, 2001 Public Meeting Transcript, *supra* note 44, at 104 (statement of Michael Jacobson, CSPI):

> Currently, FDA inspectors rarely visit factories that make cookies, pastries and other foods that may contain dangerous and unlabeled allergens. FDA simply lacks the funds and so companies don't even have to worry about inspections. We urge FDA to use some of its budget increases to hire additional inspectors. In addition, we urge FDA to seek new funding on the order of roughly $10 million a year for more inspectors, more tests, educational efforts and research to develop quick reliable testing methods.

[499] In contrast, earlier regulatory and legislative proposals more fully addressed the problem of cross-contact. The Nine State Attorneys General Citizens Petition asked FDA to amend 21 C.F.R. part 110, which sets forth GMPs, to require manufacturers to adopt several specific practices aimed at preventing cross-contamination, such as:

continued

cross-contact or overly-broad precautionary labeling that will deter consumers unnecessarily from purchasing a product. Although the report on cross-contact and the explicit mandate for FDA to inspect for cross-contact represent a significant start and have the potential to produce great strides in the reduction of cross-contact, their impact is as yet uncertain. It is evident, however, that the FALCPA does not go nearly as far to address cross-contamination issues as many had advocated.

3. *Beyond Packaged Food: The Continuing Challenge of Restaurants*

Plain English labeling assuredly will improve the experiences of food-sensitive individuals dining out. Now when people allergic to a major allergen communicate their allergy to food establishment staff, food service personnel will be able to read labels for a single, clearly-identifiable word, rather than needing to search labels for a litany of unfamiliar, hard-to-remember terms. The FALCPA's labeling requirements for prepackaged foods also apply to bulk items typically used in restaurants[500] and to foods packaged and labeled by retail and food-service establishments.[501] Appropriate revision of the Food Code to help food establishments prepare allergen-free foods could contribute to a greater appreciation of the seriousness of food sensitivities among food preparers and could reduce the many opportunities for cross-contact that occur during food preparation.

More reform is needed, however, for people with food sensitivities to safely eat out. The desirability of further improvement with regard to restaurants ranked high among the concerns of Allergen Labeling Survey respondents, second only to the expansion of the list of allergens covered by the FALCPA's labeling scheme.

As food allergy expert Steve Taylor of the University of Nebraska's Food Allergen Research and Resource Program observes, commercial food preparation is made dangerous by a "lack of restaurant labeling," shared utensils and frying oils, uninformed wait staff or cooks, and "creative" recipe formulations.[502] Without clear controls in place

- the dedication of certain facilities, personnel, equipment, and utensils to foods that do not contain allergenic substances;
- the physical separation of facilities, personnel, equipment, and utensils used to produce food containing allergenic substances from those that are not;
- adequate sanitation of facilities, equipment, and utensils before producing foods that do not contain allergenic substances;
- the exclusion of allergenic substances from reworked food products; and
- lastly, "in instances where despite reasonable measures and precautions, migration of allergenic substances has occurred or is likely to have occurred, foods shall, in addition to the foregoing, be labeled to notify the consumer that an allergen may be present."

Nine State Attorneys General Citizens Petition, *supra* note 104, at 10. An earlier proposed allergen labeling bill also addressed cross-contamination more directly. H.R. 4704 and S. 2499 (before it was amended) proclaimed that a food would be deemed misbranded if a label bore precautionary allergen labeling that was not in compliance with regulations issued by the Secretary of HHS to provide for advisory labeling of known food allergens. *See* H.R. 4707, 107th Cong. § 4 (2d Sess. 2002); S. 2499, 107th Cong. § 4 (2d Sess. 2002) (original version). The legislation required FDA to issue regulations outlining GMPs to "minimize, to the extent practicable, the unintentional presence of allergens in food" and authorized the use of advisory labeling only when compliance with GMPs would not eliminate the unintentional presence of the known allergen and its presence in the food posed a risk to human health. *See* H.R. 4707, 107th Cong. § 5 (2d Sess. 2002). Succumbing to opposition from the food industry and political pressures, these provisions were eliminated in the compromise amendment to S. 2499 and, therefore, are not in the FALCPA.

[500] Levario, *Food Allergen Labeling*, *supra* note 439, at 1.

[501] FDA, Advice to Consumers, *supra* note 5 (stating also that the FALCPA's labeling requirements do not apply to foods placed in a wrapper or container in response to a customer's order).

[502] *Allergen Awareness Said Presenting Firms With New Labeling Choices*, FOOD LABELING & NUTRITION NEWS, Nov. 6, 1997, at 7.

regarding cross-contact and with no requirements for restaurants to disclose food ingredients, food-sensitive customers still are at risk. Customers' explanations about their food sensitivities can become lost in the translation from the wait staff to the kitchen and among food preparers once inside the kitchen. It only takes one missed food label or one disruption in communication along the chain of food preparers for a mistake to occur,[503] and clearer terms on food labels offer little relief for people with non-Big Eight allergies.

Many food-sensitive individuals argue that, to better meet the FALCPA's objective of empowering people with food sensitivities to know what is in the food on their table, restaurants should be obligated to make ingredient lists available to customers. The following words of an Allergen Labeling Survey respondent capture this desire:

> What is really needed is legislation that gets the food service industry up to speed. Dining out feels like Russian roulette. The wait staff are clueless, try to help from kindness, but cannot because they are not educated. It would be great if all selections on the menu revealed ingredients. Not necessarily on the menu but available if asked. ... The menus are set, the food they have in kitchen is ordered, inventoried and known. Why can they not have a system to accurately reveal ingredients for any food selection? This information coupled with the request that the allergic person's safe selection not be contaminated in any way with other food would go a long way in making life good, and will save lives long term.[504]

For years, many "fast food" restaurants have provided basic nutrition information to consumers,[505] yet disclosures regarding hazardous allergens have by and large been conspicuously—and detrimentally—lacking. Ingredients could be printed on the menus or appear as supplemental information upon request. Even short of full ingredient disclosure, eating out would be a safer experience if food establishments provided lists of foods that are, or can be, prepared free of various allergens.[506] One Allergen Labeling Survey respondent suggested that if mandating restaurants to disclose ingredient information is too burdensome for restaurants, legislative or regulatory incentives to encourage voluntary disclosure, nevertheless, may help.[507]

Ingredient or allergen disclosure understandably may be more feasible—and beneficial (due to their prevalence and national scope)—for chain restaurants with standardized

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[503] *See, e.g.*, Duecy, *supra* note 396, at 143:

> Thomas J. Fischer, an allergist and professor of clinical pediatrics at Cincinnati Children's Hospital Medical Center] said he teaches his food-allergic patients to be proactive in asking to talk with a manager or a chef when they are dining out. "But there's a lot of frustration among people with food allergies," he noted. "For every 10 times a restaurant gets it right, that one time they slip up sours you on the restaurant experience."

[504] E-mail from CM to Author, Response to Allergen Labeling Survey (Jan. 11, 2005). Another typical expression of the desire for improved restaurant information is the following Allergen Labeling Survey response: "More also needs to be done to help at restaurants. ... Most sit down restaurants are unable/unwilling to list ingredients for their foods." E-mail from MP to Author, Response to Allergen Labeling Survey (Jan. 10, 2005).

[505] *See, e.g.*, 55 Fed. Reg. 29,487 (July 19, 1990) ("On November 19, 1976, FDA published a policy statement (21 C.F.R. 3.207 (recodified as § 101.10 in the *Federal Register* of March 15, 1977 (42 F.R. 14302))) on the nutrition labeling of restaurant foods.").

[506] As one Allergen Labeling Survey respondent explains, "[I]n a really ideal world, restaurants should also be required to offer a separate menu that lists allergens in each menu item." E-mail from D to Author, Response to Allergen Labeling Survey (Jan. 10, 2005).

[507] E-mail from N to Author, Response to Allergen Labeling Survey (Jan. 26, 2005).

ingredients and menus than for independent restaurants.[508] Under growing scrutiny in recent years due to nutritional and (increasingly) allergen concerns, many major fast food chains have undergone significant changes with regard to ingredient disclosure. In 2001, McDonald's was one of the first national fast food chains to provide some allergen information to consumers.[509] Within the past few years, many major fast food chains, including the fast food behemoths Burger King, Wendy's, Subway, and Kentucky Fried Chicken, have begun providing allergen information for each menu item on their websites and sometimes on materials in their restaurants.[510]

For sit-down chain restaurants, allergen labeling still is rare. A handful of sit-down restaurant chains do provide separate gluten-free menus, however, that identify which dishes are safe for customers with celiac disease, but similar menus for people with Big Eight food allergies are exceptionally rare.[511] In the month after the FALCPA was passed,

[508] Conversely, some independent restaurants may find it easier than chain restaurants to disclose ingredients, such as where chefs design the menu and select ingredients themselves, wait staff and food preparers are more accustomed to handling consumer requests for deviations from the standard menu, and/or the kitchen prepares dishes made-to-order.

[509] *See* Steve Lash, *Food Allergy Group Praises McDonald's Labeling Decision*, FOOD CHEM. NEWS, Aug. 27, 2001, at 25, *available at* 2001 WL 12773884:

> A group representing food allergic consumers this week hailed as 'a great first step' McDonald's decision to tell customers whether dairy, meat or vegetable ingredients are contained in the natural flavorings of its menu items. The Food Allergy & Anaphylaxis Network said the hamburger giant should now take the additional step of informing consumers whether specific allergens, such as milk or soy, are in the natural flavorings. ... Muñoz-Furlong said she hopes Burger King follows the lead of its hamburger rival McDonald's.

[510] As of January 2006, the allergen chart on the McDonald's website provides information on the gluten, MSG, and sulfites in addition to the Big Eight allergens. Subway's website now offers information on foods containing gluten, lactose, nitrites/nitrates, sesame, autolyzed yeast and hydrolyzed protein, and sulfites, as well as the Big Eight allergens. While Burger King focuses solely on the Big Eight allergens, its website includes information on the use of common fryers and cross-contamination during food processing. The Wendy's website provides details on shared fryers and, rather than stating which menu items contain a major allergen, lists the ingredients in every food so consumers can decide for themselves whether to consume an item. Kentucky Fried Chicken's and Taco Bell's websites provide information regarding the Big Eight allergens, gluten, MSG, and fryer cross-contact. *See also, e.g.*, Duecy, *supra* note 396, at 1, 143 ("While fine-dining restaurants long have catered to customers with food allergies, chains increasingly are creating and publicizing menu options for food-allergic customers."). For an example of complications that such allergen charts may cause for restaurants and consumers, however, see FoodNavigator-USA.com, McDonald's Faces Lawsuit After Nutritional Info Slip, (Feb. 22, 2006), http://www.foodnavigator-usa.com/news-by-product/news.asp?id=65995&idCat=0&k=mcdonald-s-faces ("[C]onfusion resulted after McDonald's last week acknowledged that its fries contain wheat and milk ingredients. It immediately came under attack by consumers who suffer from celiac disease ... who filed three lawsuits against the burger chain. However, McDonald's has since modified the information, announcing on Monday that new tests reveal its fries are actually 'gluten and allergen free.' ... According to UK solicitor Jessica Burt, 'technical advances with the ability to show up more and more minute levels of contamination, illegal or unlisted ingredients' are set to be 'a major liability risk' for manufacturers and caterers. And fears of a legal backlash are likely to place a limit on the type of nutritional claims companies will chose to make when not legally required to do so. Indeed, the Celiac Spruce Association (CSA) ... has announced that it does not support the lawsuits brought against McDonald's. 'What incentive will there be for restaurants to offer or continue to offer gluten-free menus or even provide voluntary information for customers?' it said in a statement. ... According to CSA executive director Mary Schluckebier, the current confusion has resulted from the 'complexities of communication' brought upon as companies and suppliers try to comply with new allergen labeling regulations, which require all products labeled for sale in the US to indicate the presence of any of the eight major food allergens.").

[511] A handful of major restaurant chains, such as Outback Steakhouse and P.F. Chang's China Bistro, have offered gluten-free menus for years. Outback Steakhouse has even expanded its menu to expressly provide other dishes free of major allergens. Other national chains and local restaurants have begun more recently to create specialized menus for customers with celiac disease. *See* Duecy, *supra* note 396, at 1, 143; *see also* Sutel, *supra* note 68:

continued

a national restaurant trade publication hailed food allergies as a "front-burner issue for restaurant chains."[512] Several chains have improved training, management, and disclosure of food allergens in response to the increased media coverage of the problems of food sensitivities in the wake of the FALCPA, concerns over liability,[513] and worries that "restaurants are next in line for mandatory ingredient disclosures on menus."[514]

As an alternative to, or in conjunction with, improving ingredient disclosure or utilizing allergen-free-themed menu designs, food-sensitive individuals would be aided if food establishments designated a trained staff person to the task of allergen management. This person would communicate allergy information between the customer and the kitchen, and would facilitate the ordering and preparation of food for sensitive individuals. Several restaurants already have adopted this helpful practice.[515] Despite the recommendation of the National Restaurant Association in 1992 that restaurants designate a specific manager or chef during each shift to answer customer inquiries about ingredients,[516] such allergen management practices remain aberrations.

Numerous past efforts have attempted—and failed—to improve the transparency of food establishment menus. While most of the debate about restaurant labeling has

> Last month, Mitchell's Fish Market, a 13-restaurant chain based in Columbus, Ohio, introduced gluten-free menus, and six months ago Boston-based Legal Sea Foods did the same in its 31 restaurants. Richard Vellante, the executive chef for Legal Sea Foods, said his company adopted a gluten-free menu after hearing requests from customers and also noticing that competing restaurants were doing it. ... "They're a very loyal following," Ben Novello, president of Outback Steakhouse, said of celiac patients. "The return goes beyond the sales that we generate from the loyal customers we get. It goes to goodwill."

Cf. FDA, Public Meeting on Gluten-Free Food, *supra* note 326 (statement of Frank Hamilton, M.D., M.P.H., Chief, Digestive Diseases Program, Division of Digestive Diseases and Nutrition, National Institute of Diabetes and Digestive and Kidney Diseases, NIH) ("I was in Canada five years ago or six years ago and I was very struck that most of the Canadian restaurants always label their meals with what is gluten and what is gluten-free.").

[512] Sutel, *supra* note 68.

[513] *See, e.g.*, Norman Martin, *Survey Says: Restaurant Managers Should Focus on Food Allergies* (Dec. 27, 2004), http://spectre.nmsu.edu/media/news2.lasso?i=657 ("Food allergy training is an emerging priority among New Mexico's restaurant industry, Mandabach said. Allergic reactions and subsequent deaths of restaurant patrons in Wisconsin and Rhode Island have led to costly, high-profile legal settlements, which have put many restaurant owners across the nation on their toes, he said.").

[514] Duecy, *supra* note 396, at 143 ("While there currently is no pending legislation regarding mandatory menu labeling at restaurants, the National Restaurant Association is working to avoid the possibility of future legislative action by developing its own allergy training programs and guidelines, said Sheila Cohn, the NRA's senior manager of nutrition policy.").

[515] One example of a restaurant that has made a stellar effort to respond to food sensitivity concerns is highlighted in a 2004 restaurant trade publication:

> At Levy Restaurants' upscale Bistro 110 in Chicago, executive chef-partner Dominique Tougne created a multipoint food-allergy response system that offers personalized service to customers. The restaurant, which serves about 700 people daily, typically has at least one customer per day with a food allergy. Tougne developed the system after his 4-year-old son developed a life-threatening peanut allergy. Under the restaurant's procedure, when a diner mentions having a food allergy, the staff member alerts the floor manager. The manager then talks with the customer, finds out about the severity of the allergy and asks if the guest has emergency medication. The manager then communicates that information to the chef. One cook at Bistro 110 is designated to make all food for allergic customers on surfaces that are free from cross-contamination. The cook then personally delivers the dish to the table to ensure that it has not been contaminated or switched inadvertently in coming from the kitchen. Bistro 110 also prepares custom meals for its food-allergic customers with alternative ingredients, such as gluten-free pasta and gluten-free cookies, Tougne said.

Id.

[516] *Food Allergies*, FOOD CHEM. NEWS, Oct. 12, 1992, at 2, *available at* 1992 WL 2212049.

centered on nutrition content rather than allergen and ingredient information, FDA, as early as the late 1970s, recognized the deleterious effects of unlabeled restaurant ingredients that provoke hypersensitivity reactions.[517] FDA has adopted a hands-off approach, however, to restaurant labeling. In 1997, CFSAN's Director, stated his belief that imposing allergen labeling rules for restaurants goes beyond FDA's permissible regulatory scope.[518] Discussion of restaurant labeling was off-limits at the 2001 Public Meeting on allergen labeling because it was beyond the intended scope of the meeting.[519]

Efforts by the restaurant industry to improve allergen management and ingredient disclosure voluntarily in the wake of the FALCPA's passage are a promising sign to people with food sensitivities that industry will respond better to the concerns of food-sensitive individuals in the future. Depending on the level of zeal and commitment the restaurant industry brings to the problem of addressing food allergy concerns in upcoming years, the creation of standardized, consistent restaurant labeling and allergen management practices still may be important areas for further reform.

4. *Beyond Label Ingredients: The Continued Lack of Adequate Customer Service Information*

Because of the FALCPA's failure to standardize or require cross-contamination advisory labeling and the fact that its labeling scheme encompasses only the major eight allergens (leaving other allergens still hidden in a product), some food-sensitive consumers will continue to find it necessary to contact manufacturers to obtain information about a product that is not available on the label. While the FDCA does mandate that manufacturers include their name and place of business on the product package,[520] writing letters to manufacturers to obtain product information is cumbersome, slow, and an impractical solution for inadequate ingredient information. The FALCPA neglects to require manufacturers to train customer services representatives regarding allergen information or to print a customer service telephone number on food packaging. Many of those food producers that do provide a telephone number on their products do not make sufficient allergen information available through that medium.

Imposing obligations on manufacturers to identify customer service telephone numbers on labels and to appropriately staff and train customer service personnel enjoys tremendous popular support among consumer groups. FAAN's Muñoz-Furlong, one of the strongest driving forces behind consumer efforts for improved labeling, has urged manufacturers to include toll-free numbers on packaging.[521] CSPI supported imposing a

[517] *See* 44 Fed. Reg. 75,990, 76,000 (Dec. 21, 1979) (discussing consumer desires for restaurant food ingredient information); 52 Fed. Reg. 46,968, 46,974 (Dec. 10, 1987) ("[C]onsumers in retail food establishments are presented with potato products that may contain sulfite residues. However, they are not presented with any ready means to determine whether sulfite residues are present on these potato products.").

[518] *FDA Asks Food Processors for Help*, *supra* note 233. CSFAN Director Fred Shank may be referring to the fact that jurisdiction over meat and poultry products is reserved to USDA. For an argument that FDA has jurisdiction to regulate at least some restaurant food labeling under 21 U.S.C. § 331, as well as for a thorough overview of the history of efforts to label restaurant foods, see Miriam P. Hechler, Nutrition Labeling and Restaurants: Issues, Options, and the FDA, 1970-1995 (1995) (unpublished paper), http://leda.law.harvard.edu/leda/search/toc.php3?handle=HLS.Library.Leda/hechlermp-nutrition_labeling_restaurants.

[519] *See* FDA, 2001 Public Meeting Transcript, *supra* note 44, at 9 (statement of Christine Lewis, FDA).

[520] *See* 21 U.S.C.A. § 343(e)(1).

[521] *See Allergen Labeling May Become FDA Priority, Agency Official Tells AFDO Meeting*, FOOD LABELING & NUTRITION NEWS, June 30, 1999, at 12 ("Consumers need plain language statements about ingredients in foods, declaration of flavors and spices, and an 800 number to contact the manufacturer for more information, Ann (sic) Muñoz-Furlong, president of the Food Allergy Network, told the meeting."); FDA, 2001 Public Meeting Transcript, *supra* note 44, at 35 (statement of Anne Muñoz-Furlong, FAAN).

telephone number requirement on manufacturers.[522] Two Allergen Labeling Survey respondents cited the lack of mandatory publication of customer service contact information on the label as a serious limitation of the FALCPA. In contrast with the FALCPA, a proposed bill[523] and at least two proposals submitted to FDA by state representatives calling for regulatory reform[524] with regard to food allergen labeling called for manufacturers to provide on labels a toll-free telephone number consumers could use obtain answers to their allergen-related inquiries.

It also would be beneficial to consumers if manufacturers maintained up-to-date ingredient lists for their food products online. One Allergen Labeling Survey respondent recommended that grocery stores provide Internet kiosks to allow easy consumer access to such web-based information.[525]

The identification of telephone numbers or website addresses where consumers can obtain fast, accurate, and detailed allergen information may provide an overall benefit to manufacturers—even small firms for whom such a requirement presumably would be the most burdensome. A telephone number on every package would facilitate consumers' ability to purchase products because consumers could call on cell phones to ask questions when determining whether to purchase a product, rather than waiting to receive a reply from a letter or calling multiple numbers (and, frequently, giving up on a product before an answer is found). A telephone number helps obviate the need for potentially cumbersome complete ingredient disclosure on the food label. It may result in more sales for manufacturers because, if consumers feel confident in their ability to determine a product's safety, they will be more likely to experiment with new products. Moreover, as an earlier proposed allergen labeling bill provided, customer service-related requirements could be tailored based on the size of a business to ease the financial burden on small companies.[526]

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[522] *See* FDA, 2001 Public Meeting Transcript, *supra* note 44, at 105 (statement of Michael Jacobson, CSPI):

> [T]he FDA should require labels to bear a toll-free telephone number that people could call to get up-to-date information about ingredients and possible contaminants. Companies periodically modify product composition and manufacturing practices. Many people with severe allergies like to contact companies just to make sure that labels are still correct and that accidental or incidental additives have not crept into a food that had been safe to eat.

[523] *See* H.R. 4704, 107th Cong. § 6(a) (2d Sess. 2002) (amending the FDCA to include, *inter alia*, the following provision: "[I]n the case of a manufacturer, packer, or distributor whose annual gross sales made or business done in sales to consumers equals or exceeds $500,000, a toll-free telephone number (staffed during reasonable business hours) for the manufacturer, packer, or distributor (including one to accommodate telecommunications devices for deaf persons, commonly known as TDDs); or in the case of a manufacturer, packer, or distributor whose annual gross sales made or business done in sales are less than $500,000, the mailing address or the address of the Internet site for the manufacturer, packer, or distributor."). H.R. 4704's sister allergen labeling bill in the Senate had eliminated the toll-free number requirement by the time it was reported to the Senate.

[524] *See* Nine State Attorneys General Citizens Petition, *supra* note 104, at 7 (calling for FDA to enact regulations that, in addition to plain English labeling of the Big Eight allergens and measures to help reduce cross-contamination, require manufacturers to provide on labels a toll-free number consumers may call "to talk to trained and knowledgeable customer service representatives concerning the ingredients contained in the food. ... Manufacturers can meet this requirement by using its own personnel or participating in a centralized information source established by a trade group or other third party."); *see also* House Joint Resolution 2 (Delegate Stern), *supra* note 122, at 1 (requesting that FDA "create a toll-free hot line where consumers can obtain food ingredient information").

[525] E-mail from MB to Author, Response to Allergen Labeling Survey (Jan. 10, 2005). Additionally, although not at this point a viable legislative or regulatory option, one Allergen Labeling Survey respondent suggested a creative alternative to labeling altogether: "[L]abeling itself may not really be the answer. An electronic database with easy access mechanisms [such as through bar code scanning] really would be so much more powerful—it could be frequently updated as products change, could be tailored to provide information specific to an individual's needs, etc." E-mail from MD to Author, Response to Allergen Labeling Survey (Jan. 25, 2005).

[526] *See* H.R. 4704, 107th Cong. § 6(a) (2d Sess. 2002).

5. *Beyond Food Regulated by FDA: Food, Drug, and Cosmetic Products Outside the Scope of the FALCPA*

Congress had the opportunity to address issues beyond the scope of the FDCA and outside the purview of FDA when fashioning a law to improve allergen labeling. Instead, Congress limited the FALCPA's scope to food products regulated by FDA, thereby exempting alcoholic beverages and meat and poultry products from its labeling requirements. Congress also failed to extend the FALCPA's labeling scheme to over-the-counter (OTC) or prescription drugs and cosmetic products within FDA's jurisdiction, even though Big Eight allergens in these products also can trigger allergic reactions.

a. *Alcoholic Beverages*

The European Union requires its manufacturers to provide allergen information on alcoholic drinks in addition to packaged foods.[527] Conversely, the food items regulated by the FALCPA do not encompass alcoholic beverages.[528] This is problematic for food-sensitive individuals who want to determine if a beverage, restaurant meal, or food product flavored with alcohol is safe to consume.

Many types of alcoholic beverages can be derived from a variety of grains, including wheat and barley.[529] Alcohol also is vexing for people with allergies to corn, apples, grapes, and potatoes. Ingredients in a particular drink may vary depending on the specific type or name brand.[530] Although allergenicity decreases through the distilling process, as yet there is no scientific consensus regarding at what point distillation sufficiently reduces allergenicity, and it is impossible for a consumer to discern from mere taste or appearance to what extent a product has been distilled.

A debate has long surrounded the labeling of ingredients on alcoholic beverages.[531] Congressional initiatives to require alcoholic drink labels to include a list of ingredients have been unsuccessful.[532] Currently, alcohol labels are subject to few labeling requirements.[533] Alcoholic beverages are within the jurisdiction of the Alcohol and Tobacco

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[527] *See* EU Labeling Directive, *supra* note 346, Art. 6, at 7 (requiring the identification of allergens on the labels of beverages containing more than 1.2% by volume of alcohol).

[528] *See, e.g.*, 150 CONG. REC. H6101 (July 20, 2004) (statement by Rep. Radanovich):

> Mr. Speaker, upon reading S. 741, there appears to be some confusion over the application of the allergen labeling requirements. It is my understanding that the requirements contained in this bill only apply to food subject to regulation by the Food and Drug Administration (FDA). I would like to clarify that wine and other alcoholic beverages are regulated by the Alcohol and Tobacco Tax and Trade Bureau. Subject to a Memorandum of Understanding with the FDA, the Tax and Trade Bureau has primary jurisdiction over the production and labeling of most wine and other alcoholic beverages.

[529] As one Allergen Labeling Survey respondent notes, alcoholic beverages can be "particularly toxic" to people with celiac disease when they are made from wheat, rye, or barley. E-mail from D to Author, Response to Allergen Labeling Survey (Jan. 10, 2005).

[530] For a list describing the varied source ingredients in alcoholic beverages, see http://www.celiac.com/st_prod.html?p_prodid=271&sid=3m22sY0WXMMaCHg-05102604299.58 (last visited Feb. 21, 2006).

[531] For a detailed overview of this history, see generally Jenna Myers, Fomentation About Fermentation: A Study on Ingredient Labeling on Alcoholic Beverages (Apr. 2002) (unpublished manuscript), http://leda.law.harvard.edu/leda/data/513/Myers.html.

[532] *See generally* The Alcohol Ingredient Labeling Act of 1993, H.R. 1420, 103d Cong. (1st Sess. 1993); The Alcohol Ingredient Labeling Act of 1996, H.R. 3115, 104th Cong. (2d Sess. 1996).

[533] The Alcoholic Beverage Labeling Act of 1988 was the first successful initiative to impose warning requirements on alcoholic drinks. *See* Alcoholic Beverage Labeling Act, Pub. L. No. 100-690, tit. VIII, § 8001(a)(3), 102 Stat. 4518 (1988) (codified at 27 U.S.C.A. §§ 213-219).

Tax and Trade Bureau (ATTTB), not FDA.[534] As early as 1974, the federal government had evidence that alcohol could endanger the safety of individuals with food sensitivities and the then-Bureau of Alcohol, Tobacco and Firearms (BATF) proposed regulations requiring ingredient disclosure on alcoholic beverages. In November 1975, BATF withdrew the proposed rule, citing, among other reasons, the cost of ingredient labeling to the industry and minimal benefits to consumers.[535]

Subsequently, in 1979, BATF again proposed regulations. After receiving input from 1,873 comments, the agency issued a final rule for the labeling of wine, distilled spirits, and malt liquors.[536] In its notice of the final rule, BATF stated that a study found "strong evidence" in the medical research literature that "ingredients used in alcoholic beverages can cause adverse health effects in humans," including "allergic reactions."[537] BATF rescinded this rule in 1981, citing a reappraisal of the cost-benefit analysis of imposing such regulations on the alcoholic beverages industry.[538] When BATF later revisited alcohol ingredient labeling, it promulgated a rule requiring only the labeling of FD&C Yellow No. 5, concluding that there was insufficient evidence of a substantial consumer interest in having disclosure of allergen information.[539] BATF later expanded disclosure requirements to include sulfites based on FDA's determination that "undeclared sulfites pose a risk to public health."[540]

Thus, in the 1980s, both FDA and BATF implemented mandatory labeling of sulfites and FD&C Yellow No. 5 (for foods and alcoholic beverages, respectively), but fell short of requiring labeling for natural food allergens. Both agencies did not require the disclosure of natural food allergens despite the fact that the number of people sensitive to the Big Eight allergens dwarfs the (albeit still substantial) number of people afflicted with allergies to sulfites and FD&C Yellow No. 5.[541]

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[534] *See generally* Federal Alcohol Administration Act, 27 U.S.C. § 201 et seq. (passed in 1935); FDA and BATF, Memorandum of Understanding, 52 Fed. Reg. 45,502 (Nov. 30, 1987) (stating that BATF is responsible for promulgating and enforcing regulations concerning the labeling of ingredients in alcoholic beverages pursuant to the FAA Act, and that if FDA determines that an ingredient must be identified on the label of a food product for health or safety reasons, BATF will initiate rulemaking proceedings to promulgate labeling regulations for alcoholic beverages); Brown-Forman Distillers v. Mathews, 435 F. Supp. 5 (W.D. Ky. 1976) (holding that BATF has exclusive labeling jurisdiction over alcoholic beverages, based on the language and legislative history of the Federal Alcohol Administration Act of 1935 [27 U.S.C. § 201] and the FDCA).

[535] *See* Center for Science in the Public Interest (CSPI) v. Dep't of the Treasury, 573 F. Supp. 1168, 1170 (1983); *Brown-Forman Distillers*, 435 F. Supp. at 7.

[536] *See* T.D. ATF-66 (issued June 13, 1980); *see also CSPI*, 573 F. Supp. at 1169.

[537] *CSPI*, 573 F. Supp. at 1171; *see also id.* at 1169 ("These regulations ... were designed to inform consumers, especially those with allergies, of the contents of alcoholic beverages."); 45 Fed. Reg. 40,540 (1980) ("[C]onsumers who are allergic to certain ingredients generally should be able to find out, whether from the label or some other source, if those ingredients are used in alcoholic beverages so that they can avoid the possibility of adverse reactions if they so choose.").

[538] *See* 46 Fed. Reg. 55,094 (Nov. 6, 1981):

> [I]ngredient labeling regulations would result in increased costs to consumers and burdens on industry which are not commensurate with the benefits which might flow from the additional label information ... [and] ingredient labeling would not result in an appreciable benefit to consumers when compared to the existing label information requirements and standards of identity.

[539] *See* 48 Fed. Reg. 45,549 (Oct. 6, 1983) (stating that evidence did not support the more comprehensive labeling of alcoholic beverages for allergy purposes).

[540] *See* 51 Fed. Reg. 34,706 (Sept. 30, 1986).

[541] *See, e.g.*, 51 Fed. Reg. 24,519, 24,522 (July 7, 1986) ("FDA estimated that 47,000 to 94,000 persons were sensitive to FD&C yellow No. 5."); Ruth Papazian, *Sulfites: Safe for Most, Dangerous for Some*, FDA CONSUMER MAG., Dec. 1996, *available at* http://www.healingwell.com/library/allergies/papazian1.asp ("The Food and Drug Administration estimates that one out of a hundred people is sulfite-sensitive, and that 5 percent of those who have asthma ... are also at risk of suffering an adverse reaction to the substance."); *see also supra* note 201.

Even though the FALCPA does not mandate the labeling of alcoholic beverages, some sparse legislative history indicates that Congress anticipates the ATTTB will issue separate rules addressing allergen labeling for alcohol-containing products.[542] The House Committee Report cites a 1987 Memorandum of Understanding between FDA and ATTTB,[543] which provides that if FDA determines that an ingredient must be identified on the label of a food product for health or safety reasons, BATF will initiate rulemaking proceedings to promulgate labeling regulations for alcoholic beverages.

Under the terms of the 1987 Memorandum, the ATTTB retains discretion, however, to decide whether a rule is needed and, if so, what requirements such a rule would entail. The 1987 Memorandum merely requires the ATTTB to "*initiate* rulemaking proceedings" consistent with ATTTB's health policy with respect to alcoholic beverages when *FDA* has determined an ingredient poses a public health problem and requires disclosure on the food label.[544] Congress declined to seize the opportunity provided by the FALCPA to codify any expectations with respect to this process, including what allergens such a rule should encompass, guidelines for a labeling format, or timing specifications. The ultimate influence of this legislative history and the result of a possible consideration of allergen labeling by the ATTTB, therefore, is highly speculative.

b. *Meat and Poultry Products*

The FALCPA's labeling requirements are restricted to foods under the jurisdiction of the FDCA; therefore, they fall short of covering meat and poultry products, which are regulated by the U.S. Department of Agriculture (USDA). USDA interprets the statutes governing meat and poultry products as requiring disclosure in the ingredients statement of all ingredients used to formulate a meat or poultry product, otherwise the product will be deemed misbranded.[545] USDA regulations exclude from specific identification, however, the constituents in colors, spices, and flavors.[546] Although USDA encourages producers to *voluntarily* alert consumers to the presence of major allergens by using the plain English terms for the allergen in parentheses following the offending ingredient or employing a phrase such as "Contains: soy and milk" at the end of the ingredients list, disclosure and the use of plain English names are not *required*.[547]

These are potentially serious limitations given the fact that use of ingredients derived from Big Eight allergens are "becoming more common as meat and poultry product manufacturers search for ways to lower product fat levels and provide consumers with an array of differently priced proteins."[548] Today, meat and poultry products commonly incorporate a multitude of ingredients to enhance flavor or improve a product's nutri-

[542] H.R. REP. No. 108-608, at 3:

> The Committee expects, consistent with the November 30, 1987, Memorandum of Understanding, that the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the Department of Treasury will pursuant to the Federal Alcohol Administration Act determine how, as appropriate, to apply allergen labeling of beverage alcohol products and the labeling requirements for those products. The Committee expects that the TTB and the FDA will work together in promulgation of allergen regulations, with respect to those products.

[543] FDA and BATF, Memorandum of Understanding, 52 Fed. Reg. 45,502 (Nov. 30, 1987).

[544] *Id.* at 45,502-03, 45,504 (emphasis added).

[545] *See* Office of Policy and Program Development, Food Safety and Inspection Service (FSIS), USDA, Labeling and Consumer Protection: Allergens—Voluntary Labeling Statements, http://www.fsis.usda.gov/OPPDE/larc/Ingredients/Allergens.htm (last visited Feb. 21, 2006).

[546] *See* 44 Fed. Reg. 75,990, 75,997 (Dec. 21, 1979) ("Under USDA regulations, the ingredients in meat, poultry, and egg products must be listed on the label in order of predominance. Colors, spices, and flavors may be generally identified, but all other ingredients must be specifically identified.").

[547] *See* FSIS, USDA, Labeling and Consumer Protection, *supra* note 545.

[548] Bodendorfer et al., *supra* note 46.

tional value. Undeclared food allergens were responsible for nearly one-fourth of the total recalls of meat and poultry products in 2003, an increase from less than one-tenth of recalls in 1999.[549] Allergen labeling for meat and poultry products is particularly important given the fact that the presence of a Big Eight food allergen such as milk or soy generally is more unexpected in these types of "natural" foods than with other packaged, processed foods.

The Director of Labeling and Consumer Protection Staff at USDA's Food Safety and Inspection Service (FSIS), Robert Post, has stated that FSIS will "likely endeavor" to "be as consistent as possible with the requirement that FDA establishes in response to the Food Allergen Labeling and Consumer Protection Act."[550] The consequences of the FALCPA's failure to address meat and poultry products thus will depend on whether and how USDA proceeds to fashion and enforce an allergen labeling scheme.

c. *Drugs and Dietary Supplements*

Another shortfall of the FALCPA's labeling scheme is that it does not extend to pharmaceuticals, and the FALCPA's application to dietary supplements is not totally clear. The labeling of medicines and dietary supplements is an area of particular concern for food-sensitive individuals because these products are ingested, sometimes on a regular basis, and often contain Big Eight and other food allergens—frequently under imprecise terms for additives such as "starch."[551]

Prescription and OTC drugs must declare on their label the presence of FD&C Yellow No. 5, FD&C Yellow No. 6, and phenylalanine, and prescription drugs must provide a warning when sulfites are present.[552] The FALCPA does nothing to remedy the fact that no equivalent warning requirements exist for the major allergens, and major allergens need not be declared using plain English terms in patient package inserts.

Specific, comprehensible labeling of OTC drugs is vital if food-sensitive consumers are to be able to make informed product selection decisions. Plain English labeling of allergens in ingredients of prescription pharmaceuticals is critical not only so the patient can feel confident in a product's safety, but also for the ease of prescribing physicians who may be unfamiliar with the myriad terms for major allergens. Clear labeling of drugs is especially important because a particular drug is often administered on a physician's orders without the patient's input and, if patients are hospitalized or ill, they may not be in a position to be as vigilant about scrutinizing labels as they would ordinarily. When a food-sensitive person is ill and decisions regarding drugs must be made at the drug store, the hospital, or the doctor's office, it is all the more essential that the individual, physician, or pharmacist be able to obtain allergen information promptly and easily.

Four Allergen Labeling Survey respondents criticized the FALCPA's failure to address the labeling of drugs. As one Survey respondent opines, "We also need labeling for medications. I have severe reactions to soy-derived hormones, but finding out which are soy-derived and which are not is extremely challenging."[553] According to a former CSA president:

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[549] *See id.*

[550] *Id.*

[551] An Allergen Labeling Survey respondent with a corn allergy states anecdotally that she has found corn "in most ... medications" she once used. E-mail from MB to Author, Response to Allergen Labeling Survey (Jan. 10, 2005).

[552] *See* 21 C.F.R. §§ 201.22, 201.21, 201.20.

[553] E-mail from MP to Author, Response to Allergen Labeling Survey (Jan. 10, 2005); *see also, e.g.*, Posting of Nutternomore et seq., PeanutAllergy.com Thread: Living With a Food Allergy, Topic: Allergic Reaction to Prescription or OTC Drugs?, http://www.peanutallergy.com/bbpage.htm (begun Dec. 9, 2004) (requesting that people send to PeanutAllergy.com their personal examples of experiencing allergic reactions to big eight allergens in medications).

> For a celiac patient who requires medicines on a daily long-term basis, information about all ingredients in each medicine is of vital concern in order to avoid any [gluten]. Obtaining the necessary information about generic drugs is a difficult situation and becomes more challenging for older individuals, particularly those with multiple drug needs.[554]

Some consumers already have considered mobilizing to garner congressional support for allergen labeling of medicines to address this significant shortfall in the FALCPA.[555]

As for dietary supplements, these products are considered "a food" for purposes of the FDCA,[556] so it appears that the amendments to the FDCA rendered by the FALCPA apply to dietary supplements. Although the FALCPA's legislative history does not mention the treatment of dietary supplements, so Congress' views on the issue are unclear, nothing suggests that dietary supplements would be exempt. That the FALCPA covers vitamins and dietary supplements "is the operating assumption of the people implementing the law," CFSAN Policy Advisor Catherine Copp explained in March 2005, "but we have not received a legal opinion on that."[557] She speculated that, as often is the case with how FDA's positions are articulated, FDA may issue guidance about whether the FALCPA embraces dietary supplements once it receives a question about the issue, such as via a letter from a dietary supplement trade association. Given the immense effort FDA must expend to implement the FALCPA with regard to prepackaged food products, dietary supplements are "not high on FDA's list" of priorities.[558]

d. *Cosmetics*

Lastly, the FALCPA also fails to address the labeling of cosmetic products. Cosmetics pose hazards to some food-sensitive individuals through ingestion (e.g., lipstick) or mere skin contact.[559] Cosmetics, in fact, are the most frequent non-food-related subject

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[554] Paley Remarks, *supra* note 129. Paley continues:

> Information about generic drugs in general is, at best, questionable. For example, little, if any, information about excipients is available to either patients or pharmacists. The formula can and does change without notice. This presents a very significant, real and implied risk to celiac patients. CSA strongly urges that all source ingredients for all medicines be made available in package inserts and other patient/pharmacist informational resources. As many as two million diagnosed and undiagnosed celiacs in the United States need information at the point of purchase to realistically live their required lifestyle "cure".

Id.

[555] *See, e.g.*, Nutternomore, PeanutAllergy.com Thread: Food Allergen and Consumer Protection Legislation, http://www.peanutallergy.com/bbpage.htm (Dec. 2, 2004):

> We at FoodAllergyAction.org hope to find congressional sponsorship for FALCPA-type legislation to cover drugs during the 109th Congress, which convenes beginning in January ... . Rest assured that if we (or someone else) are able to get the ball rolling, we'll be looking for another push from the food allergic community to stand up and voice concerns directly to members of Congress to do something about this. I hope many of you will be joining us on this journey ... stay tuned ... .

[556] *See* 21 U.S.C.A. § 321(ff).

[557] Telephone Interview with Catherine Copp, FDA, *supra* note 388. Some people involved in lobbying for the FALCPA also believe the act's labeling scheme applies to dietary supplements. *See* Levario, *Food Allergen Labeling*, *supra* note 439, at 1 ("In addition to food ingredient labels, labels on dietary supplements or vitamins will also need to conform to the new FALCPA law.").

[558] Telephone Interview with Catherine Copp, FDA, *supra* note 388.

[559] *See, e.g.*, FDA, Public Meeting on Gluten-Free Food, *supra* note 326 (statement by Frank Hamilton, NIH) ("As most of you know, and there are going to be other discussions, these are the sources that all of us sort of ingest: bread, bagels, cakes, you name it, but the other thing that was not mentioned is that periodically cosmetics, lipstick or things in mouth washes as well, have gluten in them as well and some patients are not aware of this.").

of telephone calls made by concerned consumers to FAAN.[560] Several threads on discussion boards at PeanutAllergy.com also deal with consumers' concerns about which cosmetic products are safe for peanut-allergic individuals to use.[561]

Allergenic proteins may be hidden in myriad ingredient names on cosmetic products. Cosmetics may contain, for instance, "vegetable oil" (that may include peanut, corn, soy, sesame, or other allergenic proteins). Thus, the accurate, easy-to-read labeling of cosmetic products also is important to many individuals with food sensitivities.

VI. CONCLUSION

"Now, after so much hard work and incredible efforts to secure passage of the legislation, the food allergy and celiac communities can finally let out a collective sigh of relief. Starting January 1, 2006, they will be able to conduct shopping trips at the local supermarket with far less stress and anxiety because food ingredient statements will be straightforward, accurate, and easy to read."
Representative Nita M. Lowey (D-NY)[562]

The primary justification for passage of the FDCA in 1938 was the desire to safeguard consumers economically and to protect consumer health by allowing them to make informed decisions about the products they purchase and consume. Aiding people with food allergies was a stated aim and claimed benefit of the FDCA and, certainly, it is difficult to overstate the benefit that the FDCA's labeling requirements had on the lives of people with food sensitivities. Nevertheless, the FDCA contained exceptions and gaps that left ingredient disclosure considerably—and dangerously—inadequate. These inadequacies became increasingly apparent as knowledge about food sensitivities improved.

The congressional effort to improve food labeling to benefit food-sensitive consumers began with a one-page resolution introduced in the House of Representatives in 1999 and culminated in August 2004 when President Bush signed the FALCPA into law. This groundbreaking legislation overcame years of a dearth of information about food sensitivities, a lack of consumer organization and mobilization, an absence of prioritization of food-sensitivity issues within FDA, resistance from the food industry, and general deficiency in public awareness and concern about food sensitivities. The FALCPA was the product of significant labors of FDA, the political leadership of a few congressional champions, impassioned and mobilized consumers, growing scientific knowledge and consensus, and the initiative of the food industry. The FALCPA embodied a watershed event—diverse interests created a window of opportunity to finally address on a national scale food sensitivity issues that deeply affect millions of Americans.

For people with food sensitivities, the FALCPA is a remarkable achievement, but it is not ideal. Several key drawbacks of the act's provisions and scope, and questions concerning the FALCPA's implementation, restrict the act's assistance to food-sensitive individuals and render the ultimate benefits of the legislation uncertain.

Unquestionably, however, the FALCPA is a promising start to improving the lives of people with food sensitivities. An examination of the FALCPA's limitations illuminates several legal and policy areas related to food sensitivity that offer the potential for future reform.

[560] Telephone Interview with Chris Weiss, FAAN, *supra* note 216.

[561] At least five discussion board threads at PeanutAllergy.com concern cosmetics. *See, e.g.*, Posting of Kim Canada et seq., PeanutAllergy.com Thread: Adults Living With Peanut Allergy; Topic: Safe Makeup in the US?, and Topic: Makeup for TNA/PA, http://www.peanutallergy.com/bbpage.htm (begun Jan. 10, 2003) ("I have stopped wearing makeup after having 2 anaphylactic reactions in 2001. It has been nearly impossible to find 'safe' makeup and am wondering which brands you [tree nut allergic/peanut allergic] women wear.").

[562] Lowey Statement, *supra* note 275.

Author's Note

At the time of publication, additional information about the death of a teenager described in the *Associated Press* article referenced in footnote 5 entitled, "Teen with Peanut Allergy Dies After Kiss" was reported suggesting that the teen's peanut allergy may not have caused her death. (*See generally* Coroner: Peanut-butter Kiss Didn't Kill Teen (Mar. 5, 2006), http://www.cnn.com/2006/WORLD/americas/03/05/peanut.kiss.ap/index.html.) Although the details surrounding the event are unclear at press time, it remains that the story as originally reported garnered much attention by food allergy groups and the media because it described a scenario that many people with food allergies and their caregivers constantly fear could come true.