FOOD AND DRUG LAW JOURNAL

Analyzing the Laws, Regulations, and Policies Affecting FDA-Regulated Products

Food Allergen Law and the Food Allergen Labeling and Consumer Protection Act of 2004: Falling Short of True Protection for Allergy Sufferers

Jonathan B. Roses

FDLI

VOLUME 66 NUMBER 2 2011

Food Allergen Law and the Food Allergen Labeling and Consumer Protection Act of 2004: Falling Short of True Protection for Food Allergy Sufferers

JONATHAN B. ROSES*

I. INTRODUCTION

Anaphylactic food allergies claim approximately 150 to 200 lives and are responsible for an estimated 30,000 to 50,000 emergency room visits each year in the United States.[1] There is no cure for these allergies, so the approximately 11 million American food allergy sufferers have no choice but to avoid the allergens present in food.[2] The labeling and mislabeling of allergens in food is thus a critical issue for that population. Despite the prevalence of food allergies, until recently the federal government had enacted no legislation to protect these consumers. Congress expressly addressed the issue of allergens in food for the first time in 2004 by amending the Federal Food, Drug and Cosmetic Act (FD&C Act) with the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). This change required packaged foods to indicate the presence of eight major allergens believed to account for more than 90 percent of all food allergies.[3]

Despite this important step forward, FALCPA left unregulated the use of precautionary statements that warn consumers about the possibility of allergen contamination.[4] This failure has left a back door wide open for makers of foods to mark their products with blanket warnings of the potential presence of allergens, regardless of whether they pose an actual risk to consumers. This action may then preclude potential tort liability from consumers who suffer allergic reactions to the items, and disables the Food and Drug Administration (FDA) from declaring the products misbranded or adulterated.[5] Food manufacturers thus have a great incentive to use these warnings rather than to monitor products that do not specifically include one of the eight major allergens as an ingredient. Simultaneously, food allergic consumers may waive any right to litigate allergic reactions if they consume foods bearing precautionary warnings.

FALCPA also falls short because it only regulates packaged food, and fails to regulate allergen labeling in restaurants.[6] Restaurants present an even greater

* Mr. Roses is an Associate in the Intellectual Property Department at Wilmer Cutler Pickering Hale and Dorr LLP.

1 Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, Title II, §202(1)(B), 118 Stat. 905 (codified as amended in scattered sections of 21 U.S.C.); Food Labeling; Current Trends in the Use of Allergen Advisory Labeling: Its Use, Effectiveness, and Consumer Perception, 73 Fed. Reg. 46302-01 (notice of public hearing; request for comments, Aug. 8, 2008); Janet Rausa Fuller, *Food Label Law 'Raises the Bar,' Gives Allergy Sufferers a Break: Ingredients that Can Trigger Attacks Must Be Named*, Chi. Sun-Times, Dec. 27, 2005, at 7.

2 *See* 150 Cong. Rec. H6093-01, H6100 (2004) (also noting a special concern for children with peanut allergies, whose numbers have doubled in the last five years).

3 The eight allergens are milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans. FALCPA §§202(2)(A), 203(a).

4 Examples of precautionary statements include "may contain [allergen]," "may contain traces of [allergen]," "processed in a facility that also processes [allergen]," "processed on shared equipment that also processes [allergen]," etc.

5 *See* 21 U.S.C. §§ 342(a), 343(a), 343(w).

6 FALCPA in its current form does not apply to restaurants. *See Food Allergen Labeling and Consumer Protection Act of 2004 Questions and Answers* (Dec. 12, 2005, updated July 18, 2006), http://www.fda.gov/food/labelingnutrition/foodallergenslabeling/guidancecomplianceregulatoryinformation/ucm106890.htm, Dec. 12, 2005 (last visited Apr. 13, 2011).

danger to food allergy sufferers because they lack uniform methods for informing customers of the contents of food and the possibility of allergen contamination. These consumers are instead left to rely on the assurances of wait staff and indirect communication with kitchen workers and chefs.

Apart from federal legislation, food allergic consumers have had few other avenues for redress. State Consumer Protection statutes have afforded little basis for litigation in food allergen cases. Instead, most consumer action in this area has been under common law products liability causes of action, but even there litigation has been sparse and success for plaintiffs rare due to challenges in proving causation and prevalence of their allergic condition. Potential plaintiffs have also pursued other sources of law, such as the Americans with Disabilities Act of 1990 (ADA)[7] and suits against airlines for failing to provide reasonable accommodations to allergy sufferers, but without any success in the few reported cases.[8] Overall, the likely reason for the sparse record of litigation is that the vast majority of incidents settle before ever reaching a courtroom, but at the same time the rarity of success probably colors settlement terms in a way adverse to the would-be plaintiffs.

Congress should rectify this situation and better protect food allergic consumers by further amending the FD&C Act to give FDA the power to regulate the use of precautionary statements and universally regulate food allergen labeling in restaurants. FDA could then set specific standards for the use of these warnings on food products, requiring more thorough investigation by manufacturers into the possibility of contamination before blanket warnings could be applied. This would ensure that products that bear such warnings would pose an actual risk to food allergy sufferers, and would not serve as a low-cost shield to liability. Allergic consumers would thereby be enabled to easily avoid foods that pose legitimate risks to them, while allowing them to consume safe foods that might otherwise bear precautionary warnings. By enacting additional legislation to mandate allergen labeling in restaurants, Congress could close another loophole and give even greater protection to food allergy sufferers with a universal scheme of food allergen labeling. Consumers would thus be better informed and better protected from products that pose potential dangers to them, both in the grocery store and dining out.

II. HISTORY OF FOOD ALLERGEN LAW

A. *Federal Legislation*

On June 30, 1906, the United States government took the first step in regulating the disclosure of ingredients in food when Congress passed and President Theodore Roosevelt signed into law the Federal Food and Drugs Act of 1906 (also known as the Wiley Act).[9] This Act was the first to give an agency of the federal government the power to deem a food "misbranded" if the ingredients or substances therein were "false or misleading in any particular," or to deem it "adulterated" if it contained any added "deleterious ingredient which may render [it] injurious to health."[10] Though it would be nearly a century before this power would be brought

[7] 42 U.S.C. §12102 et seq. (2008).

[8] Notably, recent amendments to the ADA appear to have improved the chances of success for plaintiffs claiming that food allergies are a disability within the meaning of the Act. *See* Americans with Disabilities Act Amendments Act of 2008 (ADAAA), Pub. L. No. 110-325, § 2, 112 Stat. 3553 (2008).

[9] *See* 21 U.S.C. §1 (1934).

[10] *See id.* §§7, 8, 343(a)(4), 343(i)(2).

to bear on the presence of allergens in food, the basic authority of today's FDA to regulate food allergen labeling is the same as was created by this Act.

The next step came when Congress responded to the Elixir Sulfanilamide disaster[11] by passing the Federal Food, Drug and Cosmetic Act of 1938, which President Franklin D. Roosevelt signed into law on June 25 of that year.[12] In addition to giving FDA the power to regulate cosmetics, medical devices and drug labeling and establishing a pre-market approval process for drugs, the new law created legally enforceable standardized recipes for food products.[13] These "standards of identity" prescribed recipes for foods which manufacturers were required to follow before labeling their foods as "heavy cream," "macaroni," "fruit jelly," "margarine" and certain other regulated products.[14] The policy behind standards of identity was that because consumers often made these food items in their own homes, they would expect specific ingredients to be present in foods so labeled.[15] Allergic consumers were therefore protected from allergens in these products because their contents were considered common knowledge and were enforced by regulation, rendering explicit ingredients listings and allergen warnings superfluous.[16]

The standardized food regime was left in place for over 50 years, until the Nutrition Labeling and Education Act (NLEA) was passed by Congress and signed into law by President George H.W. Bush on November 8 of 1990.[17] Recognizing that by this time many consumers were ignorant as to the contents of these standardized foods, NLEA required manufacturers to list all ingredients of standardized foods by May of 1993.[18] This step forward for food allergic consumers meant that increased information was available for them to guard themselves against consuming products that may contain undisclosed and potentially dangerous allergens.

Recognizing the serious risks faced by food allergic consumers, FDA began to take steps towards informing and protecting that population beginning in the mid-1990s. In 1994, FDA published "Food Allergies: Rare But Risky," a consumer guide aimed at educating those with food allergies as to the dangers of allergen-containing foods and steps they might take to protect themselves from serious reactions.[19] In 1996, FDA followed this action by issuing an Allergy Warning Letter to manufacturers[20] communicating FDA's concerns regarding adverse consumer reactions to

---

[11] Sulfanilamide was a drug used to effectively treat streptococcal infections, which was available in tablet and powder form. However, when S.E. Massengill Co., a Tennessee producer of sulfanilamide, made a liquid (elixir) preparation of the drug by dissolving the powder in diethylene glycol, the new product was not tested for toxicity before being shipped to sellers, as safety studies were not required for new drugs at the time. Because diethylene glycol is a severe toxin, in September and October of 1937, Elixir Sulfanilamide was responsible for over 100 deaths (many of whom were children) in 15 states. *See* Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA Consumer Magazine, June 1981, *available at* http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SulfanilamideDisaster/default.htm (last visited Apr. 13, 2011).

[12] 21 U.S.C. §301 et seq. (1938).

[13] *Id.* at 341.

[14] *See, e.g.*, 21 C.F.R. §§131.150 (setting out the standard of identity for heavy cream); 139.110 ("" macaroni); 150.140 ("" fruit jelly); 166.110 ("" margarine).

[15] *See* Marian Segal, *Ingredient Labeling: What's in a Food?*, FDA Consumer, Vol. 27, April 1993.

[16] *See id.*

[17] Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.).

[18] *See id.* §8. A major exception was dairy and maple syrup products, which are still subject to less stringent standard of identity regulation. *See id.*

[19] FDA Consumer, May 1994, updated Dec. 2004, *available at* http://www.foodconsumer.org/777/8/Food_Allergies_Rare_but_Risky.shtml (Sep. 3, 2006) (last visited Apr. 13, 2011).

[20] Authored by FDA Center for Food Safety and Applied Nutrition Director Fred R. Shank, Ph.D.

undeclared allergens in food.[21] The agency expressed concern that manufacturers were misinterpreting an exemption to FDA labeling requirements which allowed for non-declaration of incidental additives and processing aids in certain cases.[22] Though the 1996 Allergy Warning Letter merely clarifies the exemption,[23] it makes the important declaration that "clearly, an amount of a substance that may cause an adverse reaction is not insignificant [and must be declared]."[24] FDA also encouraged voluntary declaration of allergenic ingredients otherwise exempt as colors, flavorings and spices at the end of ingredients lists.[25] Importantly, the letter concludes by informing manufacturers that precautionary statements are not an alternative to adhering to good manufacturing practices (GMPs) and urging manufacturers "to take all steps necessary to eliminate cross contamination and to ensure the absence" of allergens in foods.[26]

Eight years later, in February of 2004, Congress amended a pending piece of legislation[27] to include the Food Allergen Labeling and Consumer Protection Act, which was subsequently passed by Congress and signed into law by President George W. Bush on August 3 of 2004.[28] In enacting this legislation into law, Congress followed up on FDA's 1996 Allergy Warning Letter, expressly recognizing the grave dangers faced by food allergic Americans due to the insidious presence of eight major allergens in food: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans.[29] The findings section of FALCPA points to the fact that 25 percent of sampled foods in a 1999 Minnesota and Wisconsin study failed to list peanuts or eggs as ingredients on food labels, and that even when ingredients derived from major food allergens were listed, many parents of children with food allergies reading those labels were unable to correctly identify them because they were unfamiliar with the "common" or "usual" names of these ingredients.[30]

FALCPA enacted a new regime of food allergen labeling requirements whereby manufacturers were required to list the presence of the eight major allergens in a clear and conspicuous manner.[31] These requirements were put in place by amending the FD&C Act to provide that a food shall be deemed misbranded unless the label either indicates below or adjacent to the list of ingredients that it contains one of the eight major allergens, or specifically lists the allergen in the list of ingredients

---

[21] Fred R. Shank, *Notice to Manufacturers, Label Declaration of Allergenic Substances in Foods* (June 10, 1996), *available at* http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/ucm106546.htm (last visited Apr. 13, 2011).

[22] *See* 21 C.F.R. §101.100(a)(3) (2001).

[23] To qualify for the exemption, a substance must be *both* present in the food at insignificant levels *and* must not have any technical or functional effect in the finished food. Shank, *supra*.

[24] *See id.*

[25] *Id.* FDA later indicated that it believes the exemption for incidental additives does not apply to allergenic ingredients. FDA Compliance Policy Guides Manual Update, *Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens* (issued Apr. 19, 2001, revised May 2005, updated Nov. 29, 2005), *available at* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074552.htm (last visited Apr. 13, 2011).

[26] Shank, *supra*.

[27] The proposed legislation initially only included the Minor Use and Minor Species Animal Health Act of 2004, aimed at increasing legal availability of medications to veterinarians and animal owners to treat minor animal species (such as guinea pigs, ornamental fish, and uncommon species kept at zoos) and uncommon diseases in major animal species (such as cattle, horses, swine, poultry, dogs and cats). *See* Minor Use and Minor Species Animal Health Act, S. 741, 108th Cong. (2003).

[28] Pub. L. 108-282, Title II.

[29] FALCPA §202(2).

[30] *Id.* §202(3)(A), (4), (5)(B).

[31] *Id.* §203(a).

by a name easily understandable by consumers.[32] The Act was also amended to include labeling requirements for allergens which manufacturers were previously not required to list because they were used solely as flavorings, colorings or incidental additives.[33] In this way, FALCPA dramatically decreased information costs for food allergic consumers, making foods containing the eight major allergens readily identifiable in a way they might not have been before.

Despite the indication in the 1996 Allergy Warning Letter that FDA was concerned with the use of precautionary statements, FALCPA left the use of these statements totally unregulated.[34] However, many manufacturers have responded to the request for voluntary compliance by placing these warnings on all foods made in facilities that also use the major allergens.[35] While this ensures that allergic consumers do not come into contact with trace amounts of allergens that could lead to anaphylaxis, the potential exists for abuse of these statements to preclude liability despite the lack of any real risk to food allergy sufferers.[36] Because of the expense of analysis required to determine if trace amounts of allergens are present in foods, or the risk of contamination in a food production or processing facility, manufacturers have a substantial cost-savings incentive to simply place precautionary warnings on all their products, ensuring protection against potential allergy litigation.

Congress has also pursued other protections for food allergic consumers. Recognizing the special risks faced by children with food allergies, in 2010 Congress passed the Food Allergy and Anaphylaxis Management Act (FAAMA)[37] as part of the Food Safety Modernization Act,[38] which was signed into law by President Barack Obama on January 4, 2011. FAAMA directs the Secretary of Health and Human Services, in consultation with the Secretary of Education, to develop and make publicly available voluntary food allergy guidelines to manage the risk of food allergy and anaphylaxis in schools and early childhood education programs.[39] These guidelines are purposed to reduce the risk of exposure to food allergens, assure prompt response in the event of an anaphylactic reaction, and give incentive grants to local educational agencies to assist in the adoption and implementation of these guidelines in public schools.[40] While this legislation represents an important step in protecting children with food allergies,[41] its voluntary nature affords no avenue for recourse by parents in the event of an anaphylactic reaction resulting from a violation of the guidelines.

---

[32] *Id.* In the Congressional debate, Congresswoman Nita Lowey (D-NY) lamented that "common" or "usual" names for ingredients amounted to "scientific jargon commonly used by only those wearing lab coats, not average citizens." *See* 150 Cong. Rec. at H6100.

[33] *See* 21 U.S.C. §343(w)(4) (2006); FALCPA §203(a).

[34] *See* Pub. L. 108-282, Title II; Shank, *supra*.

[35] *See* Shank, *supra*.

[36] *See id.*

[37] Pub. L. No. 111-353, Title I, § 112, 124 Stat. 3916 (codified as amended at 21 U.S.C. § 2205 (2011)).

[38] Pub. L. No. 111-353, 124 Stat. 3885 (codified as amended in scattered sections of 21 U.S.C.) (2011).

[39] 21 U.S.C. § 2205(b)(1). Proposed guidelines are due by January 4, 2012. *Id.*

[40] 21 U.S.C. § 2205(b)(2), (c). Guidelines are to address, among other things, creation and maintenance of individual plans for food allergy management, communication strategies between schools and providers of emergency medical services, strategies to reduce risks of exposure to allergens in classrooms and cafeterias and authorization and training of school personnel to administer epinephrine when a nurse is not immediately available. 21 U.S.C. § 2205(b)(1).

[41] *See* FALCPA §202(1)(A) (noting that children suffer from food allergies at more than twice the rate of adults).

In August of 2008, FDA announced a Notice of Public Hearing on the use of advisory labeling of allergens in food.[42] Specifically, FDA solicited comments on how food manufacturers currently use advisory labeling, how consumers interpret these statements and what wording might be most effective in warning consumers about the potential presence of allergens.[43] The administrative record for this hearing closed on January 14, 2009, but the only action FDA has taken since that time has been the issuance of a Consumer Information article later that month.[44]

B. *State Legislation*

Federal legislation has not been the exclusive source of law for food allergens, as state consumer protection statutes have afforded some basis for litigation based on alleged mislabeling.[45] Still, with the exception of state statutes that codify common law products liability doctrines, incidences of litigation under these statutes are rare, with few cases reported.

Recently, a number of states have also enacted or are considering legislation requiring establishment of school-based guidelines concerning food allergies and the prevention of life-threatening incidents in schools.[46] However, like FAAMA, these guidelines are generally voluntary in nature, and thus would not form an independent basis for lawsuits.

C. *Common Law*

Despite an increase of food allergen legislation in the federal and state arenas of late, by far the greatest source of litigation for food allergies has been the common law, mostly based on the tort doctrines of failure to warn and product or manufacturing defect. Because these are strict liability causes of action, a plaintiff need not prove that the defendant had knowledge of the presence of the allergen, substantially lowering their burden of proof.[47]

In the context of a food allergen case, the failure to warn theory of liability alleges that based on the presence of a food allergen in the product, the manufacturer or food provider has a duty to warn the consumer of the presence of the allergen.[48] In these cases, the general rule is that a warning is required by the manufacturer

---

[42] Food Labeling; Current Trends in the Use of Allergen Advisory Labeling: Its Use, Effectiveness, and Consumer Perception, 73 Fed. Reg. 46302-01 (notice of public hearing; request for comments, Aug. 8, 2008).

[43] *Id.*

[44] *Id. Food Allergies: Reducing the Risks* (Jan. 23, 2009), http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm089307.htm?FORM=ZZNR4 (last visited Apr. 13, 2011).

[45] *See e.g.*, *In re McDonald's French Fries Litig.*, 503 F.Supp.2d 953, 955 (N.D. Ill. 2007) (dismissing gluten-intolerant plaintiffs' class action complaint alleging violations of various states' consumer protection statutes); *Thompson v. E. Pac. Enters.*, No. 49924-6-I, 2003 WL 352914, at *1 (Wash. App., Feb. 18, 2003) (dismissing peanut-allergic plaintiff's Washington Product Liability Act claim against defendant restaurant).

[46] *See e.g.*, Rhode Island 2007-H 5671 Aaa, PL 2007-304, *available at* http://www.rilin.state.ri.us/BillText07/HouseText07/H5671aaa.pdf (last visited Apr. 13, 2011); Massachusetts Department of Education, *Managing Life Threatening Food Allergies in Schools*, http://www.doe.mass.edu/cnp/allergy.pdf (last visited Apr. 13, 2011).

[47] *See, e.g.*, Restatement (Third) of Torts: Prods. Liab. §1 cmt. a (1998). However, some jurisdictions impose the additional requirement that the plaintiff prove that the manufacturer knew, or in the exercise or reasonable care, should have known about a risk associated with the allergen. *See, e.g.*, *Brown v. McDonalds's Corp.*, 655 N.E.2d 440, 442 (Ohio App. 1995); *Livingston v. Marie Callender's, Inc.*, 85 Cal.Rptr.2d 528, 531 (Cal. App. 1999).

[48] *See* Restatement (Third) of Torts: Prods. Liab. §2.

only when the allergen is one to which a "substantial number" of persons are allergic.[49] While what determines a "substantial number" of allergic persons can vary significantly from jurisdiction to jurisdiction (and even from case to case), courts generally find that as the severity of harm suffered by the plaintiff increases, the threshold for "substantial" decreases, thus easing the burden for plaintiffs who suffer anaphylactic reactions to food allergens.[50] Still, the manufacturer is required to warn the consumer only when the general public is unaware of either the presence of the allergen in the product (unknown ingredient cases, where the consumer is unaware that the ingredient is present in the food item) or the risks presented by the allergen itself (unknown harm cases, where a reasonable consumer is not aware of harm a food item may cause, even if they are aware of the ingredients).[51]

Under a product or manufacturing defect theory of liability for a food allergen case, a plaintiff would allege that the food product became defective or adulterated when a food allergen was unexpectedly introduced into the product (such as by a peanut falling into a salad or a can of corn).[52] Despite the likelihood that such incidents are common, especially at restaurants, a search of all state and federal cases in the United States found only a single food allergy case involving a manufacturing defect theory of liability.[53]

III. DIFFICULTIES IN FOOD ALLERGEN LITIGATION

Despite the prevalence of food allergies, there is little history of food allergen litigation in the United States. A March 2000 law review note enlisted the help of FAAN, but was unable to find any cases of litigation over anaphylactic reactions to

---

[49] *See id.* at §2 cmt. K (1998) (noting that the allergic predisposition cannot be unique to the plaintiff); Restatement (Second) of Torts §402A cmt. j (1965) (noting that a substantial number of the population must share the allergy for it to be compensable).

[50] *See* Restatement (Third) of Torts: Prods. Liab. §2 cmt. k. Note that the —substantial number of persons requirement can be seen as a proxy for knowledge or foreseeability by the manufacturer in a strict liability case. In other words, while there s no requirement to prove that the manufacturer knew the allergen was harmful, if a substantial number of persons share an allergy to that substance, it can be presumed that the manufacturer knew of the danger, or at least that it was reasonably foreseeable.

[51] Restatement (Second) of Torts §402A cmt. j; *see Livingston*, 85 Cal.Rptr.2d at 531. For example, in a hypothetical case where a plaintiff with an anaphylactic allergy to peanuts became ill after eating a can of mixed nuts which contained peanuts, although the "substantial number" test would inevitably be met, the presence and danger of peanuts in a can of mixed nuts would be generally known, and plaintiff would likely be unable to recover. *See Livingston*, 85 Cal.Rptr.2d at 531; Restatement (Second) of Torts §402A cmt. j. *See, e.g.*, *Brown*, 655 N.E.2d at 442 (seaweed unexpectedly found in hamburger); *Mills v. Giant of Maryland*, 508 F.3d 11, 12 (D.C. Cir. 2007) (consumers allegedly unaware of potential ill effects of milk to the lactose intolerant).

[52] *See* Restatement (Third) of Torts: Prods. Liab. §§2 cmt. h, 7 cmt. a.

[53] *Roome v. Shop-Rite Supermarkets, Inc.*, No. CV020281250, 2006 WL 2556572, at *1, *5 (Conn. Super. Aug. 16, 2006) (affirming judgment against defendants who sold and distributed blueberry bread whose ingredient list failed to include nuts which caused plaintiff's anaphylactic reaction). But note the prevalence of this theory of liability in non-food allergy cases. *See, e.g.*, *Lowgren v. Inman, Spinosa & Buchan, Inc.*, No. B164713, 2005 WL 2512821, at *5-7 (Cal. App., Oct. 12, 2005) (manufacturing defect claim by mold-allergic plaintiff against defendants who built plaintiff's condominium); *In re Coordinated Latex Glove Litigation*, 99 Cal.App.4th 594, 598 (Cal. App. 2002) (manufacturing defect claim alleging defendant latex glove manufacturer's gloves contained substances which caused serious latex allergies); *Morson v. Superior Court*, 109 Cal.Rptr.2d 343, 359 (Cal. App. 2001) (manufacturing defect claims alleging defendants' latex gloves contained toxic substances). *See* Jonathan Bridges, *Suing for Peanuts*, 75 Notre Dame L. Rev. 1269, 1275-77 (2000) (citing the example of an allergist-immunologist who suffered an anaphylactic peanut reaction after eating a box of gingersnaps which did not list peanuts as an ingredient, but did not bring suit and instead published on his experience); Stephen F. Kemp et al., *Peanut Anaphylaxis from Food Cross-Contamination*, 275 J. Am. Med. Ass'n 1636 (1996).

nuts prior to 1992, and only six between 1992 and 2000.[54] Notably, there has been no reported food allergy case or act of the FDA for misbranding or adulteration due to the undisclosed presence of food allergens, under either the FD&C Act, NLEA or FALCPA.[55] Instead, litigation has proceeded almost exclusively based on failure to warn and manufacturing or product defect causes of action. In the few cases of litigation on the record, virtually all plaintiffs seeking redress under these tort theories of liability have faced difficulties in proving causation and duty to warn about the risk of allergic reaction (because the allergies are either too rare or too common, or because defendant investigated as far as could reasonably be expected). Plaintiffs have also attempted to proceed under other tort theories of liability (such as implied warranty of fitness of foods and infliction of emotional distress) and state statutory claims (such as Workers' Compensation laws), but with mixed results. Other suits have been brought against airlines based on common law and statutory claims for refusing to accommodate food allergy sufferers on their flights, and against day care and other services providers under the ADA, alleging that food allergies are a disability as defined by the Act. While plaintiffs have had no success in any of those cases, recent amendments to the ADA appear to make it substantially more likely that food allergies will be found to be disabilities, giving plaintiffs a better chance of successful litigation under that Act.[56]

On the whole, the dearth of case law is likely because the vast majority of cases settle prior to going on record.

A. *Proving Causation*

The earliest litigation involving a food allergy in a reported United States case is in *Industrial Commission of Ohio v. Zelmanovitz*, a brief, two page opinion by the Court of Appeals of Ohio in 1936.[57] In that case, the court dismissed a restaurant employee's claim under the Ohio Workmen's Compensation Act because she had failed to establish a causal connection between her facial irritation and peach juice she had earlier wiped on her face.[58] The court noted that despite plaintiff's alleged allergic reaction, she admitted to peeling and eating peaches both before and after the incident, a fact which served to confound the link between the peach juice and claimant's reaction.[59]

Seventy-one years later, in *Moore v. P.F. Chang's China Bistro, Inc.*, a plaintiff had similar difficulties when the California Court of Appeals affirmed summary judgment for the defendant restaurant because the shellfish-allergic plaintiff was unable to offer evidence that her beef and broccoli dish was contaminated with shrimp.[60] Though the plaintiff was taking blood pressure medication which could have conceivably caused her reaction, plaintiff's expert witness testified that the cause of her

---

[54] Bridges, *supra* at 1275.

[55] The author's search included all reported federal and state cases on both Westlaw and LexisNexis as well as extensive searches using internet search engines, such as Google (http://www.google.com/). One prominent case for litigation under the changes introduced by the NLEA was a class action lawsuit brought by New York Newsday columnist Meredith Berkman against Robert's American Gourmet Foods, the makers of the Pirate's Booty snack when she found the snack had originally been mislabeling declaring less than a third of its fat content. Duncan Campbell, *Junk Food Firms Fear Being Eat Alive by Fat Litigants*, Guardian (London), May 24, 2002, Guardian Foreign Pages at 16. In December, 2002, Robert's paid Berkman's attorney $790,000 and issued $3.5 million in coupons to settle the suit. *Weighty Developments*, Dallas Morning News, Nov. 8, 2003, News at 26A.

[56] *See* ADAAA, Pub. L. No. 110-325, 112 Stat. 3553.

[57] 4 N.E.2d 265, 265 (Ohio App. 1936).

[58] *Id.* at 266.

[59] *See id.* at 266-67.

[60] No. B193396, 2007 WL2121240, at *6 (Cal. App., July 25, 2007)

hospitalization resulted from exposure to shellfish at defendant's restaurant, and not as a side effect from her blood pressure medication.[61] The court, however, found no reasoned explanation of the facts underlying the doctor's one-sentence conclusion, and in light of defendant's ample evidence of hygienic and controlled kitchen conditions, found no triable issue of fact.[62]

These two cases illustrate the need for "smoking gun" type evidence of causation to prevail in food allergy cases. Unless the allegedly contaminated food is fortuitously available and preserved for analysis, plaintiffs may have a difficult task in proving that the food was responsible for their allergic reaction.[63] It is worth noting that in *Moore*, a doctor's expert testimony of causation was insufficient to defeat defendants' motion for summary judgment, let alone to persuade a jury to return a verdict for plaintiff, demonstrating a steep uphill battle for plaintiffs attempting to prove causation.[64]

B. *Prevalence and Severity of the Allergy*

Though the requirement that a "substantial number of persons" share the plaintiff's allergy comes from products liability law, similar language appears in other types of cases.[65] For example, the court in *Zelmanovitz*, after rejecting claimant's Workmen's Compensation Claim on causation grounds, further notes that her injury is not compensable because her allergy was "[her] own unusual or exceptional physical condition or peculiarity," and not something experienced by a substantial portion of the population.[66] This finding can be seen as analogous to the "substantial number of persons" requirement for duty to warn cases, and indicates that the court did not see claimant's condition as common enough to require compensation.[67]

Although there are few reported products liability cases involving food allergens prior to enactment of the NLEA,[68] these cases began to appear with more frequency beginning in the 1990s. In *Brown v. McDonald's Corporation*, a plaintiff became ill after eating a McDonald's McLean Deluxe hamburger which contained carrageenan, a seaweed-derived ingredient.[69] At trial for plaintiff's Ohio statutory products liability

---

[61] *See id.* at *5.

[62] *Id.* at *1, *5.

[63] *But see Knight v. Just Born, Inc.*, No. CV-00-606-ST, 2000 WL 924624, at *4, *6 (D. Or., Mar. 28, 2000) (granting defendant candy manufacturer's summary judgment motion in plaintiff's manufacturing defect suit when analysis of the allegedly defective candy in question was inconclusive because it was partly consumed).

[64] *See Moore*, 2007 WL2121240, at *5-6. It is worth noting that allergic plaintiffs in non-food products liability cases face similar difficulties proving causation. *See, e.g.*, *Morris v. Pathmark Corp.*, 592 A.2d 331, 334 (Pa. Super. 1991) (finding no evidence of causation where plaintiff's treating physicians were unable to identify the alleged allergenic ingredient in defendant's hair straightening product).

[65] *See, e.g.*, *Presbrey v. The Gillette Co.*, 435 N.E.2d 513, 520-21 (Ill. App. 1982) (finding plaintiff failed to show defendant's antiperspirant contained an ingredient to which a substantial number of the population is allergic).

[66] *See Zelmanovitz* at 265.

[67] *See, e.g.*, Restatement (Second) of Torts §402A cmt. j. Similarly, other workmen s compensation claims based on a plaintiff s allergies to foods produced in the workplace (such as wheat dust) have typically been treated as not being an occupational disease, rather being attributable to the employee s own individual innate sensitivity or allergy to the offending food. *See e.g.*, *Sanford v. Valier-Spies Mill Co.*, 235 S.W.2d 92, 95(Mo. App. 1951). *See Booker v. Revlon Realistic Prof'l Prods., Inc.*, 433 So.2d 407 (La. App. 1983) (finding that an unusual or rare idiosyncratic sensitivity of plaintiff provided no basis for recovery, or even the requirement of a warning from the manufacturer absent evidence that a significant number of persons suffered allergic reactions to the product).

[68] *See, e.g.*, *MacLehan v. Loft Candy Stores*, 172 So. 367, 369 (La. App. 1937) (ruling out food allergy as the cause of plaintiff's reaction to mincemeat pie); *Swengel v. F. & E. Wholesale Grocery Co.*, 77 P.2d 930, 936 (Kan. 1938) (ruling out allergy as a cause for sickness from drinking sauerkraut juice).

[69] 655 N.E.2d at 440.

action against McDonald's and its franchisee for failure to warn that the hamburger might be harmful to customers, the trial judge granted all defendants' motions for summary judgment.[70] The Court of Appeals of Ohio reversed as to McDonald's and Keystone (a producer of the McLean), but upheld summary judgment in favor of the franchisee, Richard K. Potts.[71] Despite this preliminary success for the plaintiff, the court implied that she would have a much more difficult time at re-trial proving that McDonald's and Keystone knew or should have known of the risk of an adverse reaction to carrageenan because of the rarity of such an allergy.[72]

While a rare food allergy may prevent a plaintiff from recovering, so might an allergy whose incidence is quite common. In *Mills*, the Court of Appeals for the District of Columbia affirmed the District court's dismissal of a class action products liability failure to warn action brought against milk producers by lactose-intolerant plaintiffs who were ignorant of their condition.[73] Though the decision below rested partly on preemption grounds,[74] the Court of Appeals focused its affirmation on its finding that the plaintiffs' claim was not cognizable under D.C. tort law.[75] The court found that a manufacturer's duty of reasonable care does not entail a duty to warn of risks that are generally known by foreseeable product users.[76] In essence, there was no duty to warn because the average customer would be aware of the prevalence and risks of lactose intolerance, and a manufacturer's warning would therefore have no additional effect.[77]

These cases make clear that plaintiffs with both extremely rare and very common allergies may have a difficult time prevailing under the failure to warn theory of liability. Notably, *Mills* further indicates that while a severe allergic reaction may mitigate the need to prove a substantial number of similarly situated consumers in tort cases, a mild reaction may not be compensable at all.[78] Both the District and Appellate Courts in *Mills* found that even were the risk of lactose intolerance not widely known, so that a manufacturer's warning might have an effect on consumers, the fact that the alleged harm was temporary and limited to discomfort might still preclude any duty to warn.[79]

---

[70] *Id.*

[71] *Id.* at 446. Due to the Ohio products liability statute's characterization of Potts, the plaintiff could only maintain suit against him as a negligence cause of action. *Id.* at 442. This required plaintiff to prove that Potts had a duty to his customers to make reasonable inquiry into the ingredients in the McLean and the potential harmful effects associated with them. *Id.* at 445. The court, however, found that Potts had offered ample evidence of his reasonable belief that the McLean was a safe product, that he therefore had no duty to inquire further as to its safety, and that plaintiff had offered no evidence that Potts knew or had reason to know about the possibility of an allergic reaction. *Id.* at 446.

[72] *See id.* at 444. A dissent by Judge Dickinson indicates that plaintiff's sole evidence that the hamburger was defective was based on the expert witness opinion of Dr. Schwartz, which he claims lacked a proper foundation. *Id.* at 448 (Dickinson, J., dissenting). In stating that he would affirm summary judgment for all defendants, the implication was that the plaintiff offered no evidence as to the number of people allergic to carrageenan, how serious those reactions might be, and that plaintiff could not possibly prevail at trial. *See id.* at 448-49. *See, e.g.*, *Blalock v. Westwood Pharms, Inc.*, CIV. A. No. 89-2117, 1990 WL 10557, at *2 (E.D. La. 1990) (finding defendant's sunscreen not defective because injuries resulted from rare or idiosyncratic reactions, and no duty to warn where defendant had sold nearly one million units of sunscreen without a complaint except by plaintiff).

[73] 508 F.3d at 12.

[74] Because milk is a standard of identity under the NLEA (which preempts establishment of any requirement for standard of identity foods different from the federal standard), the court found that the District of Columbia could not impose labeling requirements for milk different from the federal labeling requirements. *See* 21 U.S.C. §343-1(a); *id.* at 13.

[75] *Mills*, 508 F.3d at 13.

[76] *Id.*

[77] *See id.* at 15. Note that the author's search failed to find a case where a plaintiff was aware of their allergy yet still failed to prevail on a failure to warn-type cause of action.

[78] *See* Restatement (Second) of Torts §402A cmt. j.

[79] *See Mills*, 508 F.3d at 15. The District Court implied that if harm to plaintiffs was serious, it might weigh towards requiring a duty to warn, but plaintiffs instead only alleged gastrointestinal discomfort. *Mills v. Giant of Maryland, LLC*, 441 F.Supp.2d 104, 111 (D. D.C. 2006), *aff'd*, 508 F.3d 11 (D.C. Cir. 2007).

C. *Other Causes of Action*

Food allergy issues have appeared occasionally in other reported cases where the cause of action did not arise under the tort theories of manufacturing defect or failure to warn. For example, in *Frankes, Inc. v. Bennett*,[80] a 1941 case before the Arkansas Supreme Court, the plaintiff became ill after eating sea scallops at defendant's restaurant and instituted a suit alleging a breach of the implied warranty of fitness of the food.[81] The court dismissed her claim for failure to prove that anything was wrong with the meal, and instead surmised that plaintiff was unknowingly allergic to scallops, based on her admission that she had never before tried them.[82] In noting that many people are allergic to particular foods which might make them ill even if they were entirely wholesome, the court makes the implication that plaintiffs who are unaware of their food allergies cannot recover even under failure to warn causes of action, likely because in that situation a warning would be ineffective.[83]

In contrast, in *Bruse v. Holiday Inn*, the Appellate Division of the Supreme Court of New York found in favor of a New York Workers' Compensation claimant who suffered repeated anaphylactic allergies to shellfish through work, despite the fact that he was not aware of the allergy.[84] In affirming the Workers' Compensation Board's finding of compensable accidental injury, the court reasoned that claimant's work-related exposures to shellfish significantly precipitated, aggravated and accelerated his preexisting condition, regardless of plaintiff's ignorance of his allergy.[85] Unlike in the tort context, however, the claimant here was only required to prove that his work-related exposures to shellfish worsened his condition, and not to offer proof of the severity, peculiarity or even his own knowledge of his allergy.[86]

In *Abbhi v. AMI*, the estate of a peanut-allergic child who died after ingesting a Danish whose packaging failed to list peanuts as an ingredient brought a variety of claims against the distributor and seller of the Danish, including one under the Connecticut Product Liability Act.[87] Because of an exclusivity provision in the Product Liability Act, the court dismissed plaintiff's claims for bystander liability, negligent infliction of emotional distress and a claim under the Connecticut Unfair Trade Practices Act, leaving only the product liability and medical malpractice claims standing.[88] The situation may be similar in other states, where bystander liability, infliction of emotional distress and unfair trade practices claims would be considered duplicative to a products liability claim, and would be dismissed by courts.[89] These exclusivity provisions thus limit plaintiffs in their choice of cause of action against food manufacturers and restaurants, leaving them unable to rely on parallel theories of liability based on the same set of facts.

Additionally, despite the fact that the presence of food allergens on airplanes (especially peanuts) has been a hotly debated issue, there have been no successful

---

[80] 146 S.W.2d 163, 163-64 (Ark. 1941).

[81] *Id.*

[82] *See id.* at 164.

[83] *See id.*

[84] 790 N.Y.S.2d 765, 766-67 (N.Y. App. Div. 2005).

[85] *See id.* at 767.

[86] *Id.*

[87] No. CV 960382195S, 1997 WL 325850, at *1 (Conn. Super. June 3, 1997).

[88] Conn. Gen. Stat. §§52-572m to r (1991 & Supp. 1999).; *Id.* at *18.

[89] *See* Restatement (Third) of Torts: Prods. Liab. §2 cmt. n (noting that plaintiff may pursue any theory of liability he or she chooses, but the trier of fact may not consider duplicative claims on the same facts).

claims sustained against airlines, and only two reported cases.[90] In *Khan ex rel. Haque v. American Airlines*, the plaintiffs filed suit against the defendant airline after the crew served peanuts on their flight, despite alleged assurances that no nuts of any kind would be served, and flight attendants were allegedly abusive towards plaintiffs.[91] The court, in granting the defendant's motion to dismiss, found that all of the plaintiff's common law and civil rights claims were preempted by the Airline Deregulation Act of 1978 as relating to the service of an air carrier.[92] The result was the same in *Panitch v. Continental Airlines*, where the plaintiff alleged New Jersey statutory handicap discrimination as well as common law infliction of emotional distress claims when the defendant airline refused to ensure a nut-free flight to accommodate plaintiff's severe peanut and tree-nut allergy.[93] The court summarily dismissed the claims as preempted under the same provision of the Airline Deregulation Act.[94] Because of the broad preemption in the airline context, it appears plaintiffs are unlikely to have any success in these suits.[95]

Plaintiffs have also attempted to bring claims for food allergies under disability theories of liabilities, albeit with very little success. In the handful of cases addressing food allergies as a disability under the ADA, courts have found that even very serious food allergies don't rise to the level of a disability within the meaning of the Act.[96] Specifically, the ADA defines a disability as "a physical or mental impairment that substantially limits one or more major life activities of such an individual,"

---

[90] In August of 1998, the U.S. Department of Transportation sent a letter to ten major airlines explaining their policy that the Air Carrier Access Act regulations required air carriers to accommodate passengers with documented severe peanut allergies by providing peanut-free buffer zones. Letter from Norman A. Strickland, Chief of the Aviation Consumer Protection Division, U.S. Dep't of Transp., to the 10 Largest U.S. Certificated Airlines (Aug. 12, 1998); Bridges, *supra* at 1287. However, Congress refused to give the Department of Transportation's the funds to enforce these policies, absent a peer-reviewed scientific study finding severe reactions by passengers to very small airborne peanut particles. *See* Department of Transportation and Related Agencies Appropriations Act of 2000, Pub. L. No. 106-99, Title III, §346, 113 Stat. 1023 (Oct. 9, 1999) (codified as amended as a note to 49 U.S.C. §41705 (2003)). This refusal has resulted in a confusing mix of unchanged airline policies and voluntary compliance. *See* Kathleen Doheny, *Healthy Traveler; Airline Policy on Peanuts is Mixed Bag After DOT Raised Allergy Concerns*, Los Angeles Times, Dec. 13, 1998, at L12. One author surmises Congress' refusal to fund the policy stemmed from powerful influence of a senator from a peanut-producing state. *See* Bridges, *supra* at 1287 n.124. Though the spending bill was only effective through September of 2000, no further information was available if Congress has since funded the policy.

[91] No. 08 CV 5246(NRB), 2008 WL 5110852, at *1-2 (S.D. N.Y., Nov. 26, 2008).

[92] *See* 49 U.S.C. §41714(b)(1) (2000); *id.* at *5.

[93] No. 06-3611 (JAG), 2008 WL 906240, at *5, *6 (D. N.J., Mar. 31, 2008).

[94] *Id.*

[95] Note that although the Department of Transportation announced in June 2010 that it was seeking comments on a proposal to ban the service of peanuts on commercial airlines to provide greater access to air travel for individuals with peanut allergies, in its final rule it declined to take action on this subject, referring to the Appropriations Act of 2000, which required a peer-reviewed scientific study on the effect of airborne peanut particles on airline passengers before regulations of peanuts could be implemented. Enhancing Airline Passenger Protections, 76 Fed. Reg. 79, 23156 (final rule Apr. 25, 2011); *see* 49 U.S.C. §41705 notes; Enhancing Airline Passenger Protections, 75 Fed. Reg. 109, 32318 (proposed June 8, 2010).

[96] 42 U.S.C. §12102(1)(A); *see* 42 U.S.C. §12102(2)(A). *See, e.g.*, *Fraser v. Goodale*, 342 F.3d 1032, 1040 (9th Cir. 2003) (finding eating to be a major life activity, and noting that being allergic to peanuts may interfere with that ability, but ultimately leaving the decision for other circuits to decide); *Land v. Baptist Med. Ctr.*, 164 F.3d 423, 425 (8th Cir. 1999) (holding plaintiff's severe peanut allergy does not substantially limit the major life activity of breathing because her ability to breathe is otherwise "generally unrestricted," and plaintiff is not actually disabled where her physical ability to eat is not in any way restricted); *Miles-Hickman v. David Powers Homes, Inc.*, 589 F.Supp.2d 849, 862 (S.D. Tex. 2008) (finding plaintiff's occasional allergic reactions to smells do not establish a genuine issue of fact that she generally is unable to perform the major life activity of breathing); *Bohacek v. City of Stockton*, No. CIV S-04-0939 GGH, 2005 WL 2810536, at *4 (E.D. Cal. Oct. 26, 2005) (finding peanut allergy only potentially affects the life activity of breathing); *see also* Marie Plicka, *Mr. Peanut Goes to Court: Accommodating an Individual's Peanut Allergy in Schools and Day Care Centers Under the Americans with Disabilities Act*, J. L. Health, Mar. 22, 1999, at Vol. 14 No.1, pg. 87.

and courts have held that even severe anaphylactic food allergies only potentially or temporarily limit the major life activity of breathing.[97]

However, in 2008, Congress passed and President George W. Bush signed into law the Americans with Disabilities Act Amendments Act of 2008 (ADAAA), which was intended to clarify that the ADA should be applied with a broad scope of protection.[98] The Act expressly rejected Supreme Court precedent that had limited the ADA's protection by requiring strict construction of the terms "substantially" and "major" to create a demanding standard for qualifying as disabled, and required courts to take into account mitigating measures in making that determination.[99] Importantly, the ADAAA mandated that intermittent or sporadic impairments will be considered substantially limiting if they would substantially limit a major life activity when active.[100] These changes are likely to expand the protections of the ADA to more clearly encompass food allergies as disabilities. However, no cases to date have applied the ADA as amended by the ADAAA in the context of food allergies.

D. *Settled Cases*

There are several possible reasons for the general lack of food allergen litigation, including lack of deep pockets (especially in allergic reactions in non-chain and non-franchise restaurants) and the general difficulties of proving a food allergen products liability case, but the most likely cause is that these cases often settle before being filed or proceeding to verdict.[101] Details of settlements of this sort are generally kept confidential, so it is difficult to track the frequency or outcomes of these incidents. One of the few prominent settlements occurred in 1994 when Janet Walker, a 33-year old Massachusetts resident, ordered a chicken pesto sandwich at a Bertucci's restaurant in Salem, New Hampshire.[102] Despite receiving a definitive negative answer to her specific and repeated questions as to whether the sandwich contained nuts, she was served a pesto sandwich made with pignoli (which is the Italian name for pine nuts).[103] Walker quickly went into anaphylactic shock, fell into a coma and died seven days later.[104] The decedent's estate subsequently filed a wrongful death suit in Middlesex Superior Court in Massachusetts seeking $10.4 million in damages, but the case never went to trial.[105] Though no terms were disclosed, the case is presumed to have settled.

Settlement is also a likely explanation for the many cases that appear in the record as an intermediate decision, but whose final outcomes are not reported. For example, in *Livingston*, the plaintiff brought suit over an allergic reaction to MSG in the defendant restaurant's soup, which had been promised by wait staff to be

---

[97] 42 U.S.C. § 12102(1); *see Land* at 425; *Bohacek* at *4.

[98] *See* 112 Stat. at 3553.

[99] *See id.*; *Toyota Motor Mfg., Ky., Inc. v. Williams*, 534 U.S. 184, 196-97 (2002), *superseded by statute on other grounds*, Americans with Disabilities Amendments Act of 2008, 112 Stat. 3553 (holding that the terms "substantially" and "major in the ADA's definition of disability must be interpreted strictly to create a demanding standard for qualifying as disabled); *Sutton v. United Air Lines, Inc.*, 527 U.S. 471, 482 (1999), *superseded by statute*, ADAAA, 112 Stat. 3553 (finding that measures taken to mitigate a physical or mental impairment must be taken into account when deciding if the person qualifies as disabled under the ADA).

[100] 112 Stat. at 3553, 3556.

[101] Dick Dahl, *Restaurant Industry May Face a Spate of Food Allergy Suits*, St. Louis Daily Record/ St. Louis Countian, July 4, 2006.

[102] Robin Lee Allen, *Bertucci's Inc. Served with $10.4 M Wrongful-Death Suit*, Nation's Restaurant News, Aug. 21, 1995, at Vol. V29 No. 33 p3(1).

[103] *Id.*

[104] *Id.*

[105] *See id.*; Bridges, *supra* at 1272 n.19.

MSG-free.[106] The California Court of Appeals rectified the District Court's failure to apply the law[107] by remanding to a trial on plaintiff's failure to warn theory, but the case does not appear further in any records and is likely to have settled.[108] Settlement was the most likely the outcome in *Abbhi* as well, as there is also no further procedural history in that case.[109]

IV. PRECAUTIONARY STATEMENTS AND FOOD ALLERGEN LABELING IN RESTAURANTS

In addition to the litigation challenges faced by plaintiffs who suffer reactions to food allergens, two other important hurdles exist which may prevent plaintiffs from even reaching the courthouse steps. FALCPA, by omission, highlights these problems: the lack of regulation of both precautionary statements and food allergen labeling in restaurants.

A. *Precautionary Statements*

Despite FDA's 1996 Food Allergy Warning Letter cautioning manufacturers that precautionary statements are not a replacement for GMPs, neither FDA nor Congress has taken action to regulate the use of these statements. Under the current scheme, manufacturers are able to use blanket generic warnings on all of their products, regardless of what actual risk they may pose to consumers.[110] In many situations, these warnings may serve as either a complete bar to litigation or at least a substantial hurdle for food allergic plaintiffs to overcome. Further, FDA would likely be unable to declare products so marked as misbranded or adulterated because the warnings are conditional and factually accurate.[111]

Apart from litigation and regulatory concerns, precautionary statements (or the lack thereof) also present a myriad of practical difficulties for consumers which may result in exposure to food allergens. The near-ubiquity of these statements on food labels, which are sometimes vague or over-inclusive, may have caused consumers to mistakenly believe that they represent a complete and accurate list of the allergens contained in the food. Additionally, because their use is optional, consumers may rely on the lack of a precautionary statement as an implicit assurance that no food allergens are present in that food. The lack of regulation in this area often results in a confusing mix of similarly worded but subtly different warnings which frequently differ by manufacturer, or even among a given manufacturer's products. Consumers also risk exposure to allergens because manufacturers are under no obligation to add, change or update precautionary statements on the label of a product following a change in its ingredients. Examples of these difficulties follow.

---

[106] 85 Cal.Rptr.2d at 528-89.

[107] The trial court dismissed plaintiff's claims on the grounds that "there was nothing wrong with the soup or the MSG in the soup." 85 Cal.Rptr.2d at 529.

[108] *See id.* at 529, 534.

[109] *See* 1997 WL 325850, at *18.

[110] This trend is illustrated by a comment submitted by FAAN in response to an FDA Notice of Public Hearing on Current Trends in the Use of Allergen Advisory Labeling, which notes that a bag of peanuts (whose sole listed ingredient was "peanuts") bore the precautionary statement "may contain peanuts." *See Food Allergy & Anaphylaxis Network (FAAN) - Precautionary Allergen Labeling: Trends and Concerns* - Testimony, posted Oct. 10, 2008, *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2008-N-0429-0021 (last visited Apr. 13, 2011).

[111] *See* 21 U.S.C. §§ 342(a), 343(a), 343(w).

Under current law, a manufacturer may draft a FALCPA-compliant ingredients listing which includes the allergen by a name easily understandable to consumers (*e.g.*, "eggs") within the list itself, but omits a precautionary statement altogether. Consumers, not seeing the now-typical bold allergy warning in all capital letters (*e.g.*, "**CONTAINS EGGS**") may assume that the food does not contain any allergens. Similarly, a manufacturer may include a precautionary statement which mentions less than all of the allergens present in the food (*e.g.*, "contains wheat," where the food also contains milk). Such a label would comply with current regulations, provided all allergens are listed by a name easily understandable to consumers in the ingredients listing. In that case, consumers might interpret the precautionary statement mentioning one allergen (*e.g.*, wheat) to be an exclusive list, and not read the ingredients listing which discloses that other allergens are also present (*e.g.*, milk).

In addition, the lack of regulation means that when manufacturers do choose to use precautionary statements, they need not use any particular prescribed wording, or even be consistent in the wording used. The result is numerous different warnings which may leave consumers puzzled as to the significance of different phrasings, and unsure of the actual threat these products pose.[112] Inconsistency in the use of precautionary statements, both across manufacturers and even among products made by the same manufacturer may lead to further problems for food allergy sufferers. For example, a consumer may become a repeat purchaser of manufacturer A's potato chips after noting the lack of a precautionary statement and further confirming the absence of allergens in the ingredients list. The consumer might then rely on the lack of a precautionary statement on manufacturer B's potato chips without reading the ingredients list, assuming they also do not include the allergen. Both labels would currently comply with FALCPA even if manufacturer B's potato chips do in fact contain allergens, provided they are listed by names easily understandable by consumers in the ingredients listing. In another example, a manufacturer may include a precautionary statement on product X which discloses all major allergens present, but elect not to include such a statement on its product Y, despite the presence of a major allergen. Thus, a consumer allergic to soybeans who purchases product X (which discloses "contains milk and wheat ingredients") might rely on the lack of a precautionary statement on product Y, believing them to also be soybean-free, and thus exposing themselves to the allergen.

Consumers may also be at risk following a change to the ingredients of a product they routinely consume. Again, due to the lack of a requirement for consistency in the use of precautionary statements, a consumer who was initially diligent in confirming the lack of an ingredient in a product may be at risk following the addition of an allergen to the product. For example, a consumer allergic to peanuts who routinely purchases manufacturer A's chocolate bars may have come to rely on the precautionary statement's failure to list peanuts (or lack of a precautionary statement altogether) after an initial careful reading of the ingredients listing confirmed their absence. If the manufacturer later changes the ingredients to include peanuts, there is no requirement to change, update or add a precautionary state-

[112] For example, testimony submitted by FAAN in its response to FDA's request for public comments on allergen advisory labeling asks how customers should interpret the following precautionary statements which were seen on food labels: "may contain the occasional nut," "may contain peanuts, nuts, and other allergens not listed on the label," "may contain peanuts or trace amounts of allergens not listed in the ingredients," "good manufacturing practices used to segregate ingredients in a facility that also processes wheat, milk, and soy ingredients," "carefully baked in a nutty environment," "made in a facility that uses [allergen]," and "while no nuts products are used to prepare this product, we cannot guarantee that nut products were not used in the animal feed." *See Food Allergy & Anaphylaxis Network (FAAN) - Precautionary Allergen Labeling: Trends and Concerns* - Testimony, posted Oct. 10, 2008, *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2008-N-0429-0021 (last visited Apr. 13, 2011).

ment as long as peanuts are listed in the ingredients list. Thus, the consumer may continue to purchase and consume the product, relying on past experience and the lack of change in (or presence of) a precautionary statement, rather than reading the complete ingredients list before each purchase.

B. *Food Allergen Labeling in Restaurants*

FALCPA also leaves consumers at risk for its failure to regulate allergen labeling in restaurants.[113] Absent comprehensive federal regulation, consumers must rely on waiters to communicate with kitchen staff regarding their allergy and confirm the absence of particular allergens in foods they order and consume. While food allergen labeling in restaurants presents a potentially more complex set of challenges than regulation of packaged foods (*e.g.*, changing menus, lack of baseline regulation requiring restaurants to display or make available ingredients listings), one state has taken an important first step in protecting consumers with food allergies in restaurants as well as in grocery stores. This law serves as an important example of how allergen labeling in restaurants can be practically and manageably implemented.

In January 2009, Massachusetts became the first state[114] to universally mandate a food allergen awareness scheme in restaurants when Governor Deval Patrick signed the Massachusetts Food Allergy Awareness Act into law.[115] The act is purposed to enhance industry and consumer awareness of major food allergens[116] and minimize risk of illness and death due to accidental exposures to food allergens in restaurants.[117] Beginning October 1, 2010, Massachusetts restaurants[118] are required to display the following notice on or near menu boards or at points of services:

---

[113] *See Food Allergen Labeling and Consumer Protection Act of 2004 Questions and Answers* (Dec. 12, 2005, updated July 18, 2006), http://www.fda.gov/food/labelingnutrition/foodallergenslabeling/guidancecomplianceregulatoryinformation/ucm106890.htm, Dec. 12, 2005 (last visited Apr. 13, 2011).

[114] An extensive search of different states' regulations (*e.g.*, public health codes) was not undertaken, but a search of state statutes revealed only a handful of other laws concerning food allergen awareness, and none as extensive as Massachusetts. *See, e.g.*, Cal. Health & Safety Code § 110673 (2011) (defining food as misbranded under California law if it does not conform with FALCPA food allergen labeling requirements); N.Y. Pub. Health Laws (McKinney) § 1352(4) (2011) (requiring that New York food service establishments have an individual trained and certified in food safety who attends a course which addresses, *inter alia*, food allergies); S.C. Code Ann. § 39-25-180(M) (2010) (explicitly adopting FALCPA food allergen and labeling regulations for South Carolina); S.D. Codified Laws § 34-18-37 (2011) (requiring a disclaimer on baked and canned goods in South Dakota that the product was "home-processed in a kitchen that may also process common food allergens such as tree nuts, peanuts, eggs, soy, wheat, milk, fish, and crustacean shellfish"). New York City and St. Paul, MN have enacted laws requiring food service establishments to display posters with information on food allergies. *See* N.Y. City Law 2009/017, Int. No. 818, enacted Mar. 18, 2009, *available at* http://legistar.council.nyc.gov/View.ashx?M=F&ID=677978&GUID=B6A9C447-6EBF-4951-9015-5CDB3156D06C (last visited Apr. 13, 2011); City of St. Paul, Minn., Code of Ordinances Ch. 331A § 331A.12, C.F. No. 09-1289, enacted Dec. 9, 2009, *available at* http://www.stpaul.gov/DocumentView.aspx?DID=14376 (last visited Apr. 13, 2011); *see also FAAN – Restaurant State Legislation*, http://www.foodallergy.org/page/restaurants (last visited Apr. 13, 2011).

[115] *See* M.G.L. Ch. 140 § 6B (2011).

[116] The implementing public health regulations define a "Major Food Allergen" as "milk, eggs, fish (such as bass, flounder, or cod), crustaceans (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans," and any food ingredient containing protein derived from one of these foods. *See* 105 C.M.R. 590.002 (2010). However, highly refined oils derived from these foods and ingredients exempt under FALCPA are excluded from this definition. *See id.*

[117] *See Massachusetts Department of Public Health Bureau of Environmental Health/Food Protection Program: Q&As for MDPH Allergen Awareness Regulation*, *available at* http://www.mass.gov/Eeohhs2/docs/dph/environmental/foodsafety/food_allergen_3_reg_faqs.pdf, Aug. 19, 2010 (last visited Apr. 13, 2011). Relevant provisions of the law were developed in consultation with the Massachusetts Restaurant Association (MRA) and FAAN. *See* M.G.L. Ch. 140 § 6B(b).

[118] While the Massachusetts Food Allergy Awareness Act applies to "[a] person licensed as an innholder or common victualler, when serving food," the implementing public health regulations apply to "all food establishments that cook, prepare, or serve food intended for immediate consumption either on or off the premises." *See* M.G.L. Ch. 140§ 6B(b); 105 C.M.R. 590.002; 105 C.M.R. 590.009(H) (2010).

> Before placing your order, please inform your server if a person in your party has a food allergy.[119]

Massachusetts restaurants must also display posters in employee work areas which include information on the major food allergens, health risks of food allergies, procedures to follow when a customer states they have a food allergy and emergency procedures to follow should a customer have an allergic reaction to food.[120] In addition, by February 1, 2011, restaurants are required to have on staff a "certified food protection manager" who is issued a Massachusetts certificate of allergen awareness training issued by the Massachusetts Department of Public Health (MDPH).[121] The certified food protection manager must demonstrate knowledge of major food allergens and ensure that employees are properly trained in food allergy awareness as it relates to their assigned duties.[122] The Massachusetts Food Allergy Awareness Act also mandates the establishment of a voluntary program where restaurants may be designated as "Food Allergy Friendly," for, *inter alia*, maintaining publicly available master lists of all ingredients used in the preparation of each food item available for consumption.[123]

While the Massachusetts Food Allergy Awareness Act does not implement more rigorous protections (such as mandating ingredients listings and precautionary statements), the law extends at least some FALCPA-type protection for consumers with food allergies to restaurants. Importantly, the law provides a model for other states and the federal government to begin the process of regulating food allergen labeling in restaurants in a way acceptable to both consumers with food allergies and the restaurant industry.

V. CONCLUSION

In light of the growing prevalence of Americans with food allergies, the dearth of food allergen litigation and even rarer instances of success for plaintiffs is a clear indication that this population needs protection beyond what the law currently provides. While FALCPA marks an important step forward for the federal

---

[119] 105 C.M.R. 590.009(H)(2).

[120] 105 C.M.R. 590.009(H)(1); *Food Allergies: What You Need To Know*, 2009, *available at* http://www.mass.gov/Eeohhs2/docs/dph/environmental/foodsafety/food_allergen_2009_poster.pdf (last visited Apr. 13, 2011). The poster was developed by FAAN. *See FAAN – Restaurant State Legislation*, http://www.foodallergy.org/page/restaurants (last visited Apr. 13, 2011).

[121] 105 C.M.R. 590.009(H)(3). Allergen awareness certificates can be obtained online from one of three vendors approved by the MDPH by paying $10 and viewing an allergen awareness video produced by MRA and FAAN and featuring celebrity chef Ming Tsai, a spokesman for FAAN who helped draft and lobby for the law. *See* Letter from Michael Moore to Local Boards of Health and Health Departments, Jan. 3, 2011, *available at* http://www.mass.gov/Eeohhs2/docs/dph/environmental/foodsafety/allergen_awareness_vendors.pdf (last visited Apr. 13, 2011); Ming Tsai, *Safe for All Eaters: A Breakthrough*, The Atlantic, Feb. 16, 2010, *available at* http://www.theatlantic.com/life/archive/2010/02/safe-for-all-eaters-a-breakthrough/36030/ (last visited Apr. 13, 2011); *see also* Food Allergy Training Video at Massachusetts Environmental Health Association, *available at* http://www.mehaonline.net/member-services/food-allergy-training-video.html (last visited Apr. 13, 2011).

[122] 105 C.M.R. 590.009(H)(3).

[123] M.G.L. Ch. 140 § 6B(g). This aspect of the Food Allergy Awareness Act does not yet appear to have been implemented, as internet searches failed to find a list of "Food Allergy Friendly" restaurants in Massachusetts. The master ingredients list requirement is based on a three-ring binder used by Tsai in his restaurant Blue Ginger, colloquially referred to by his staff as "the bible." *See* Ming Tsai, *Safe for All Eaters: A Breakthrough*, The Atlantic, Feb. 16, 2010, *available at* http://www.theatlantic.com/life/archive/2010/02/safe-for-all-eaters-a-breakthrough/36030/; *Food Allergy Reference Book*, http://www.ming.com/foodallergies/food-allergy-reference-book.htm (last visited Apr. 13, 2011).

government's efforts to protect food allergic consumers, Congress needs to close the loophole of precautionary statements to better promote the compelling interests of preservation and improvement of public health and safety. FAAN and other public interest groups are pushing hard for this reform,[124] and even absent legislative action, FDA's Food Allergen Labeling Notice of Public Hearing shows the agency's acute interest in further regulating these warnings. Industry has taken notice, and voluntary compliance with more comprehensive allergen labeling is becoming more and more prevalent both in the supermarket and in restaurants. There are also examples of voluntary recalls by manufacturers who have discovered allergen contamination in foods already shipped to distributors, sellers and consumers.[125] The uncertain situation of food allergen labeling regulation in flux has also given rise to specialty sellers of allergen-free foods.[126]

Further, Congress needs to follow the example set by the Massachusetts Food Allergy Awareness Act to begin the process of enacting legislation to allow universal regulation of food allergen labeling in restaurants. The packaged foods industry has been heavily legislated for food allergen labeling in comparison to the restaurant industry, where food allergic consumers face the same risks. What little food allergen litigation there is generally finds its cause in restaurants, and the low incidence of consumer success suggests that this is an area where consumers most need federal legislation to protect them. By enacting a scheme of clear and conspicuous labeling for food allergen ingredients in restaurants, Congress could universalize food allergen labeling and offer a level of protection to consumers that state legislation and common law has been unable to provide. Food allergy sufferers would then be informed and protected both in the grocery store and restaurants, and what is currently a grave threat to public health and safety could be substantially mitigated.

---

[124] Christopher Weiss, Director of Legislative and Regulatory Research at FAAN indicated that his organization had not considered filing a Citizen's Petition with FDA. However, his opinion is that the issue of precautionary statements are on the minds of FDA and food manufacturers, and that they were moving towards a solution to this problem, though the time frame is uncertain. His opinion is that FDA and industry are trying to establish threshold levels for each of the eight major allergens, in other words the minimum amount of each allergen required to cause an anaphylactic reaction. Under such a system, food manufacturers would analyze their products, and label any product meeting or exceeding that level as "Contains…" and anything below that level as not requiring any labeling. This would entirely eliminate precautionary statements, yielding a simple "Yes or No" system.

[125] *Texas Firm Recalls Chili Because of Misbranding* (Dec. 19, 2003), *available at* http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OA/recalls/prelease/pr066-2003.htm (last visited Sep. 21, 2010) (Texas firm voluntarily recalls over 15,000 pounds of chili because the label fails to list wheat and corn flour); *Ohio Firm Recalls Salisbury Steak Products Because of Misbranding, Including Undeclared Allergens* (Oct. 4, 2002), *available at* http://www.fsis.usda.gov/OA/recalls/prelease/pr087-2002.htm (last visited Sep. 21, 2010) (Ohio establishment voluntarily recalls over 16,000 pounds of frozen Salisbury steak products because the label fails to list eggs).

[126] For example, Vermont Nut Free (http://www.vermontnutfree.com/, seller of peanut and tree-nut free chocolates, energy bars and candies) and Cherrystone Kitchen (http://www.cherrybrookkitchen.com/, seller of nut free cake, cookie and brownie mixes).