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Student Note

An Analysis of "Natural" Food Litigation to Build a Sesame Allergy Consumer Class Action

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ABSTRACT

In a world where food allergy is still an incurable disease, law and regulation stand as necessary mechanisms to provide food-allergic consumers with the information they need to protect their health. The Food Allergen Labeling and Consumer Protection Act of 2004 provided specific labeling requirements for the "Top Eight" allergens in the U.S.: milk, soy, gluten, egg, tree nut, peanut, fish, and Crustacean shellfish. Since then, sesame has become more prevalent as an allergen and remains just as dangerous, inducing anaphylactic shock in some sesame-allergic individuals. Yet sesame remains unregulated, despite advocates and congressional members arguing for its inclusion.

This note entertains one solution to this problem by exploring the most strategic way to bring a sesame allergy class action against a private food company under California's consumer protection statutes. Because this kind of class action does not have much, if any, precedent, this note analyzes the basic, preliminary issues that any litigant would have to navigate around to certify a class, including preemption, standing, and the claim itself, by focusing on how courts have examined these issues in the recent "natural" class action litigation. It also analyzes the legal, moral, and practical aspects of choosing a type of relief, as well as whom to include in the class. Finally, this note briefly considers how FDA itself can ensure sesame is regulated on the labels of food products, given that some of the legal issues may well be insurmountable for this particular class action. This note explores the potential solutions to difficult legal hurdles in constructing a sesame allergy class action, arguing that litigating a sesame allergy class action—even if it is not ultimately successful—could start a productive conversation that might lead Congress or FDA to provide greater public health and consumer protection for those with sesame allergy.

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INTRODUCTION

> *"When the woman saw that the fruit of the tree was good for food and pleasing to the eye, and also desirable for gaining wisdom, she took some and ate it." (Genesis 3:6).*

There is perhaps no greater mystery of our modern world than why one person's food is another person's poison. A study conducted by the Center for Disease Control found that "food allergies among children increased approximately 50% between 1997 and 2011."[1] This rise in food allergy for children, as well as its prevalence among adults, particularly in more developed countries, has incurred dangerous consequences.[2] For example, anaphylactic shock, one of the many food-allergic responses, produces symptoms such as "[s]kin reactions, including hives along with itching, and flushed or pale skin," "[c]onstriction of the airways and a swollen tongue or throat, which can cause wheezing and trouble breathing," or "[n]ausea, vomiting or diarrhea."[3] Once a life-threatening reaction has begun, the best thing someone can do to stop a person from dying is to inject epinephrine to counteract the reaction. Yet even that remedy is not always successful, despite dutifully following medical protocol.[4] Such stark, new realities have led to not only a cultural awareness and recognition of a new form of "disease" primarily within more developed countries, but also to legislative reform.

In 2004, to address the statistics that "approximately 2 percent of adults and about 5 percent of infants and young children in the United States suffer from food allergies," and that "each year, roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food," Congress passed and President Bush signed into law the Food Allergen Labeling and Consumer Protection Act (FALCPA).[5] The law named eight foods as "major allergens": "[m]ilk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans."[6] The consequence for having a major food allergen in a company's food product is significant, as the company is then subject to FDA's very specific food allergen

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[1] Food Allergy Research & Education, FARE, *Food Allergy Facts and Statistics for the U.S.*, FOOD ALLERGY RES. & EDUC., http://www.foodallergy.org/file/facts-stats.pdf (last visited Oct. 20, 2016) [hereinafter *Food Allergy Facts*].

[2] *See id.* (explaining that 4% of adults in the United States have food allergies).

[3] *Diseases and Conditions: Anaphylaxis*, MAYO CLINIC (Jan. 16, 2013), http://www.mayoclinic.org/diseases-conditions/anaphylaxis/basics/symptoms/con-20014324.

[4] In 2013, a 13-year-old girl with a peanut allergy and her father, a doctor, made national news when the girl experienced an anaphylactic reaction to a peanut at a Sacramento, California summer camp. The girl subsequently died in her father's arms, despite the father dutifully following medical protocol to stop the reaction. *See 13-Year-Old Dies at Sacramento Camp from Peanut Allergy Despite Receiving Medicine*, CBS NEWS (July 31, 2013, 11:00 AM), http://www.cbsnews.com/news/13-year-old-dies-at-sacramento-camp-from-peanut-allergy-despite-receiving-medicine/.

[5] Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, 118 Stat. 905 (codified as amended in scattered sections of title 21).

[6] 21 U.S.C. § 321(qq)(1) (2012); *see also* Jonathan B. Roses, *Food Allergen Law and the Food Allergen Labeling and Consumer Protection Act of 2004: Falling Short of True Protection for Allergy Sufferers*, 66 FOOD & DRUG L.J. 225 (2011).

labeling requirements.[7] Crucial to Congress's action was its recognition that "at present, there is no cure for food allergies" and "a food allergic consumer must avoid the food to which the consumer is allergic."[8] Today, while tests for food allergy exist, they are not conclusive.[9] Therefore, the statute's purpose remains relevant for the now estimated eight percent of Americans who live with food allergy.[10]

Since the creation of the original list of "Top Eight" allergens, sesame has become the sixth or seventh most prevalent allergen in the U.S.[11] Sesame allergy also induces anaphylactic shock, making it all the more concerning in terms of protecting an individual's physical health and safety.[12] Despite this data, as well as public interest groups and some senators calling for inclusion of sesame as a major allergen, sesame remains outside of food regulation as a "major" or "non-major" food allergen.[13] In the past, when legislative and agency change seemed less likely, litigation has been used as an alternative strategy for achieving an ultimate social or policy agenda.[14] Though reasonable minds will differ as to how the following protects or does not protect the public health, the discussion of "natural" class action litigation provides an example of litigation in the food law world that has successfully been used as one tool to

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[7] *See* 21 U.S.C. § 343(w) (2012). The company may declare the major food allergen on the product label in one of the following ways. First, the major allergen may be declared in the ingredient list by the recognized name of the food source (e.g., "milk") or by the common or usual name of a food when that name already identifies an allergen's food source (e.g., "buttermilk" because "milk" appears in that word). Second, if the product contains but does not declare a major food allergen on the label, the major food allergen may be properly declared if the food source follows the major allergen in parentheses (e.g., "whey (milk)"). Third, the major food allergen may appear on the product's brand label using the word "contains" followed by the "name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients," subject to type-size requirements. *Id.; see also Food Allergies: What You Need to Know*, U.S. FOOD & DRUG ADMIN., 1, 1 (June 2010), http://www.fda.gov/downloads/Food/ResourcesForYou/Consumers/UCM220117.pdf. This being said, scholars have suggested that these requirements can be easily avoided by members of the food industry should they wish, as FDA does not regulate when a company can and cannot place labels on its products. For further discussion, see Roses, *supra* note 6.

[8] Food Allergen Labeling and Consumer Protection Act of 2004, *supra* note 5.

[9] *See* Jill, *Why Conventional Allergy Testing is Not Accurate and Not Enough*, REAL FOOD FORAGER (Nov. 14, 2013), http://realfoodforager.com/why-conventional-allergy-testing-is-not-accurate-and-not-enough/; Patricia M. Herman & Lisa M. Drost, *Evaluating the Clinical Relevance of Food Sensitivity Tests: A Single-Subject Experiment*, 9 ALTERNATIVE MED. REV. 198, 207 (2004) http://www.altmedrev.com/publications/9/2/198.pdf (finding that no one test will identify all foods to which someone is allergic, but multiple tests in combination may have more success).

[10] *See* Ruchi S. Gupta et al., *The Prevalence, Severity, and Distribution of Childhood Food Allergy in the United States*, 128 PEDIATRICS e9, e10 (2011).

[11] *Open Sesame: Why Sesame Must be Disclosed as an Allergen on Food Labels*, CTR. FOR SCI. IN THE PUB. INT. (Sept. 17, 2015), at 1, https://cspinet.org/new/pdf/open-sesame.pdf [hereinafter *Open Sesame*] (citing C. Laino, *Sesame Allergies on the Rise in U.S.*, WEBMD ALLERGIES HEALTH CTR., (Mar. 16, 2009) http://www.webmd.com/allergies/news/20090316/sesame-allergies-on-the-rise-in-us; *see also* V. Gangur, C. Kelly, and L. Navuluri, *Sesame Allergy: A Growing Food Allergy of Global Proportions?* 95 ANNALS OF ALLERGY, ASTHMA & IMMUNOLOGY 1, 4–11 (2005)).

[12] James Roland, *Understanding Sesame Allergies: Symptoms, Treatment, and More*, HEALTHLINE (June 10, 2015), http://www.healthline.com/health/allergies/understanding-sesame-allergies.

[13] *Open Sesame*, *supra* note 11, at 1.

[14] *See* Beth Van Schaack, *With All Deliberate Speed: Civil Human Rights Litigation as a Tool for Social Change*, 57 VAND. L. REV. 2305, 2308–09 (2004).

leverage agency action.[15] While the class action as a litigation tool presents an opportunity to at least raise awareness about the importance of including sesame as a top allergen, constructing a claim for injunctive relief—even assuming one narrows the class to include only those who have already been injured as a result of purchasing and consuming a product containing sesame—becomes difficult even at the early stages of litigation. How one approaches creating a successful sesame allergy class action based on what we know of sesame allergy and past food litigation is the focus of this note.

With an eye toward key preliminary legal issues such as preemption, standing, and choosing a viable claim, this note explores the most strategic way to bring a sesame allergy class action against a private food company under California's consumer protection statutes, specifically its Unfair Competition Law (UCL), its False Advertising Law (FAL), and its Consumer Legal Remedies Act (CLRA).[16] To develop such a strategy requires a knowledge of the history behind and rise of sesame allergy, as well as previous food litigation that can offer guideposts on what courts might consider important in future food cases. Therefore, this note consists of four major parts. Part I introduces the history of food allergy by detailing its rise in the last two decades, illustrating Congress and FDA's regulatory response to the problem and explaining the recent prevalence of sesame allergy in the U.S. Part II examines the class action as a tool to create broader social change through public impact litigation and considers how one might influence Congress or FDA to include sesame as a "major" or "non-major" allergen by examining the recent rise in "natural" class action cases that ultimately helped to shape FDA's regulatory policy. It also analyzes the legal, moral, and practical aspects of choosing a type of relief, as well as whom to include in the class. Part III uses important conceptual and legal issues in the "natural" litigation sphere as guideposts for identifying and analyzing important conceptual and legal issues one must consider before bringing a sesame allergy class action against a private industry party. It also provides a window into what courts have held in the past on motions to dismiss and ascertainability issues at the class certification stage. Part IV examines the authority FDA has in ensuring sesame is regulated on the labels of food products, given that some of the legal issues examined above might be insurmountable for this particular class action. This note explores potential solutions to difficult legal hurdles in constructing a sesame allergy class action, arguing that litigating a sesame allergy class action—even if it is not ultimately successful—could start a productive conversation that might lead Congress or FDA to provide greater public health and consumer protection for those with sesame allergy.

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[15] *Use of the Term "Natural" in the Labeling of Human Food Products*, 80 Fed. Reg. 69,905, 69,905 (Nov. 12, 2015). FDA's comment period ended in May 2016. *See FDA Requests Comments on Use of the Term "Natural" on Food Labeling*, FDA, http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm471919.htm (last updated Dec. 24, 2015).

[16] *See* CAL. BUS. & PROF. CODE §§ 17200, 17500 (West 2016); CAL. CIV. CODE § 1750 (West 2016).

I. THE CASE FOR SESAME ALLERGY PROTECTION

A. A Brief History of Anaphylactic Responses in the First World

In the last two decades, food allergy has transformed in popular imaginings from medical mythology to a very real part of American life. In the past, medical science was skeptical of food allergy, and studies questioned whether the number of people who claimed to suffer from food allergy was not inflated.[17] However, as food allergy began to rise in children in the United States, Canada, Australia, the United Kingdom, and other countries,[18] that questioning ceased and was replaced instead with inquiries as to what could have caused the modern malady in the first place.[19]

Part of the rise of public awareness and social acceptance of the new medical condition stems from the seriousness of some allergic reactions. Anaphylactic shock, an allergic response documented in mostly children from peanuts, tree nuts, fish, and shellfish, can cause "[d]ifficulty breathing," "[r]educed blood pressure (e.g., pale, weak pulse, confusion, loss of consciousness)" that can lead to "weakness or fainting," "skin symptoms or swollen lips," and/or "gastrointestinal symptoms (e.g., vomiting, diarrhea, or cramping)."[20] Once a reaction has begun, the first step toward preventing a fatality is to inject epinephrine into the bloodstream as soon as possible,[21] typically through a person's leg.[22] But there is no guarantee that this action will cause the reaction to abate,[23] and death can result if the reaction is not stopped.[24] For instance, in 2013 a young girl experienced an anaphylactic response to food that she thought was peanut-free while attending a summer camp with her parents in Sacramento, California.[25] Her father, a doctor, administered three rounds of epinephrine while they waited for the ambulance to arrive.[26] By the time the paramedics came, the girl had

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[17] *See* Daryl R. Altman & Lawrence T. Chiaramonte, *Public Perception of Food Allergy*, 97 J. ALLERGY & CLINICAL IMMUNOLOGY 1247, 1247 (1996); Rebecca C. Knibb & David A. Booth, *Situation-Specific Cognitive Behavioral Self-Therapy for Erroneously Suspected Allergy or Intolerance to a Food. A Short Self-Assessment Tool*, 57 APPETITE 439, 439 (2011).

[18] *See* Caroline Hadley, *Food Allergies on the Rise?* 7 EMBO REP. 1080, 1082–31 (2006); Noah Davis, *The Rise of Food Allergies and First World Problems*, PAC. STANDARD (Oct. 1, 2013) http://www.psmag.com/health-and-behavior/rise-food-allergies-first-world-problems-67067; *Food Allergy Facts*, *supra* note 1; Nina Ragusa, *7 Countries with the Highest Food Allergies*, INSIDER MONKEY (Aug. 17, 2015), http://www.insidermonkey.com/blog/7-countries-with-highest-food-allergies-364829/ (noting China, Thailand, and Japan as other countries where food allergy is on the rise).

[19] *See generally* Mark Jackson, ALLERGY: THE HISTORY OF A MODERN MALADY (2007).

[20] *About Anaphylaxis*, FOOD ALLERGY RES. & EDUC., https://www.foodallergy.org/anaphylaxis (last visited Oct. 20, 2016).

[21] *Id.*

[22] *How to Use Epinephrine Injection, USP Auto-Injector*, EPINEPHRINE AUTO-INJECT, http://www.epinephrineautoinject.com/how_to_use_epinephrine_injection_USP_auto_injector.php (last visited Oct. 20, 2016).

[23] Sam Stanton et al., *Teen's Death Spurs Allergy Alert – Girl Dies after Eating Treat at Sierra Camp*, SACRAMENTO BEE, July 30, 2013, at A1.

[24] *See id.*; *About Anaphylaxis*, *supra* note 20.

[25] Stanton et al., *supra* note 23.

[26] *Id.*

stopped breathing.[27] Modern medicine still has no cure for food allergy,[28] and its diagnosis has yet to be pinned down to a medical science.[29] With such a large public health concern on the line, it is no surprise that in the early 2000s, Congress took action.

B. Congress Passes the Food Allergen Labeling and Consumer Protection Act

Given that "at present, there is no cure for food allergies" and that "a food allergic consumer must avoid the food to which the consumer is allergic,"[30] Congress in 2004 passed the Food Allergen Labeling and Consumer Protection Act (FALCPA).[31] Congress specified that it was taking action to address the fact that "approximately 2 percent of adults and about 5 percent of infants and young children in the United States suffer from food allergies."[32] Moreover, Congress stated that "each year, roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food."[33] FALCPA named eight "major [food] allergens" that were the most common at the time of its passage: "[m]ilk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans."[34] As explained above, the general purpose of the statute—to help the estimated eight percent of Americans publicly avoid substances that would cause allergic reactions[35]—remains relevant.

The statute provides that, should a company use a major food allergen or an ingredient derived from a major allergen in its product, the allergen must be declared on the label.[36] The statute provides a few options for compliance. First, the major allergen may be declared in the ingredient list by the recognized name of the food source ("milk") or by the common or usual name of a food when that name already identifies an allergen's food source (e.g., "buttermilk" because "milk" appears in that

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[27] *Id.*

[28] *Treatment & Managing Reactions*, FOOD ALLERGY RES. & EDUC., https://www.foodallergy.org/treating-an-allergic-reaction (last visited Oct. 20, 2016). However, it seems that medical scientists at Stanford University have been researching methods to cure patients. *See* Cat Wise, *Millions in the US Impacted by Food Allergies, but a Cure May Be on the Rise*, PBS NEWSHOUR (May 11, 2015, 4:29 PM), http://www.pbs.org/newshour/updates/diet-food-allergies/; Melanie Thernstrom, *I Can Eat It: Taking a Bite Out of Food Allergies*, STANFORD MEDICINE, http://stanmed.stanford.edu/2014fall/i-can-eat-it.html (last visited Oct. 20, 2016).

[29] *Diagnosis & Testing*, FOOD ALLERGY RES. & EDUC., http://www.foodallergy.org/diagnosis-and-testing (last visited Oct. 20, 2016).

[30] Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108–282, 118 Stat. 905 (codified as amended in scattered sections of title 21 of the U.S. Code).

[31] *Id.*; *see also* Mary Kissel, *Labeling Rules Likely for Food Allergies; Congress Is Set to Pass Law That Would Require Clear Listings of Problematic Ingredients*, WALL ST. J., July 7, 2004, at D1.

[32] Food Allergen Labeling and Consumer Protection Act of 2004, 118 Stat.

[33] *Id.*

[34] 21 U.S.C. § 321(qq)(1) (2012).

[35] *See* Gupta et al., *supra* note 10.

[36] 21 U.S.C. § 343(w) (2012). However, scholars have suggested that these requirements can be easily avoided by members of the food industry should they wish, as FDA does not regulate when a company can and cannot place labels on its products. *See generally* Roses, *supra* note 6.

word).[37] Second, if the product contains, but does not declare, a major food allergen on the label, the major food allergen may be properly declared if the food source follows the major allergen in parentheses ("whey (milk)").[38] Third, the major food allergen may appear on the product's brand label using the word "contains" followed by the "name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients," subject to type-size requirements.[39] These requirements ensure that consumers are made aware of the dangers of a product before purchase.

According to the Center for Science in the Public Interest (CSPI), as an act of Congress, FALCPA likely preempts "states and municipalities . . . from requiring food manufacturers to add sesame to the list of major allergens, as a provision in the law requires a uniform national approach to the allergy labeling of foods."[40] However, CSPI also claims there are other ways to regulate sesame. One is by "disclos[ing] the presence of sesame in 'flavorings' or 'spices,' either by listing sesame as a sub-ingredient or by using a statement that the food 'may contain' or 'does contain' sesame in a parenthetical."[41] Since the creation of the original list of "Top Eight" allergens, Congress has not added any additional foods to the major allergen list, despite public interest groups and some senators calling for action on sesame in particular.[42] FDA has, however, included cochineal extract and carmine under its authority to promulgate regulations on non-major allergens.[43] The following presents an argument in favor of why sesame should be regulated as a food allergen.

C. Why Sesame, Why Now: The Prevalence of Sesame Allergy

Sesame allergy is not something of which people are commonly aware in the United States, in part because it is not declared by Congress as a "major" allergen.[44] However, "[a]n estimated 300,000 to 500,000 people in the United States suffer from sesame allergy."[45] According to the Director of Pediatric Allergy and Immunology at Johns

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[37] 21 U.S.C. § 343(w); *see also Food Allergies: What You Need to Know*, U.S. FOOD & DRUG ADMIN., 1, 1 (June 2010), http://www.fda.gov/downloads/Food/ResourcesForYou/Consumers/UCM220117.pdf.

[38] *Id.*

[39] *Id.*

[40] *Open Sesame*, *supra* note 11, at 7.

[41] *Id.* Additionally, FALCPA "did not address requirements with regard to restaurant foods or disclosure of major allergens on restaurant menus." *Id.* at 8. For example, California Pizza Kitchen, when asked, "indicated . . . that its pizza dough may contain sesame." *Id.* It is arguable that "[e]ven very cautious allergic consumers would not expect sesame in pizza dough." *Id.* While the scope of this note will only consider consumer class action claims that encompass private company products, readers should note the restaurant industry is also likely rife with potential sesame and other food allergy claims.

[42] *Id.* at 1.

[43] *See* 21 U.S.C. § 343(x) (2012); *see also* Listing of Color Additives Exempt from Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine Declaration, 74 Fed. Reg. 207, 208 (Jan. 5, 2009).

[44] 21 U.S.C. § 321(qq) (2012).

[45] *Open Sesame*, *supra* note 11, at 1 (citing S. H. Sicherer, *Epidemiology of Food Allergy*, 127 J. ALLERGY & CLINICAL IMMUNOLOGY 3, 596–97 (2011); M. Ben-Shoshan, et al., *A Population-Based Study on Peanut, Tree Nut, Fish, Shellfish, and Sesame Allergy Prevalence in Canada*, 125 J. ALLERGY & CLINICAL IMMUNOLOGY 6, 1327–35 (2010); *Food Allergy & Anaphylaxis Connection Team's Basics on*

Hopkins University School of Medicine, Dr. Robert Wood, not only has sesame allergy increased in prevalence "'more than any other type of food allergy over the past 10 to 20 years,'" but "'[sesame allergies are] now clearly one of the six or seven most common allergens in the U.S.'"[46] Studies confirm certain individuals react to even as low as 30 mg of sesame in their food.[47] Those with a sesame allergy can react to sesame seeds or byproducts of sesame, including sesame paste or oil.[48] Because FDA does not currently require manufacturers to label sesame products, sesame can appear in labels as "spices" and "natural" flavorings."[49] Additionally, sesame can be listed on labels with a name that a consumer might not know without thorough knowledge or background of the product itself.[50] These names include tahini, gingelly oil, or til oil.[51] Unfortunately, for those who are anaphylactic to all sesame products, one can find sesame in products like adhesive bandages, "cosmetics, hair-care products, perfumes, soaps, and sunscreens."[52] Those who are affected are predominantly children.[53]

Moreover, other countries around the world have labeled sesame as an allergen, including Canada, the European Union, Australia, and New Zealand.[54] In addition, in December 2014, Europe began requiring restaurants to disclose the use of allergens to customers, including sesame.[55]

Finally, according to CSPI, companies fail to provide information as to what food allergens may be in their products, even upon consumer request.[56] They do so primarily for three reasons: (1) to avoid legal liability; (2) to avoid losing important trade secret information; and (3) because they do not know what food is actually in the "natural" flavorings that they purchase.[57]

Sesame Allergy, Food Allergy & Anaphylaxis Connection Team, http://www.foodallergyawareness.org/foodallergy/food_allergens-11/sesame-33/ (last visited January 1, 2017)).

[46] *Open Sesame, supra* note 11, at 1 (citing Laino, *supra* note 11); *see also* Gangur, *supra* note 11, at 4–11.

[47] M. Morisset et al., *Thresholds of Clinical Reactivity to Milk, Egg, Peanut and Sesame in Immunoglobulin E-Dependent Allergies: Evaluation by Double-Blind or Single-Blind Placebo-Controlled Oral Challenges*, 33 CLINICAL & EXPERIMENTAL ALLERGY 1046, 1048 (2003).

[48] *Open Sesame*, *supra* note 11, at 1.

[49] *Id.*

[50] This is the same with other ingredients that cause allergic reactions but are not recognized by Congress as "Top Eight" allergens. One such example is corn, which can be found in ingredients like high fructose corn syrup, dextrose, maltodextrin, and other ingredients. Consumers without a specialized understanding of which byproducts contain the allergen in question are therefore at a much higher risk for allergic reaction.

[51] *Open Sesame*, *supra* note 11, at 4.

[52] *Id.* at 5.

[53] Davis, *supra* note 18.

[54] *Open Sesame*, *supra* note 11, at 3.

[55] *Id.* Note here that like FALCPA, the Food Code, which governs restaurants, only applies to the eight identified major allergens. Thus, sesame is not included.

[56] *Id.* at 5.

[57] *Id.* at 5–6. A food company might respond that it does not disclose information because industry supply chains are incredibly complex, and as such, it cannot be sure that cross contamination has not occurred somewhere in the supply process. In not disclosing that information, then, a company's primary

To avoid legal liability, companies tend to make blanket warnings to consumers, saying things like: "If you have any allergen concerns outside of the Major Food Allergens, we recommend you do not consume [our products]" and "we suggest that you do not use this product if you are allergic to an ingredient other than those specifically declared on the label."[58] This is something food companies are entitled to do, given FDA permits companies to label products with allergens that they know or do not know to be present in their food products.[59]

This process becomes more complicated when food companies are often unable or unwilling to disclose their ingredients due to trade secret laws.[60] According to CSPI, Heinz wrote that "'because recipes are not patentable, we are unable to share specific ingredient information . . . such as sesame.'"[61] Land O'Lakes also refused to disclose allergen information to CSPI, responding that "'because the flavors that we use are proprietary information, we are unable to disclose more specific information than what can be found on our labels.'"[62]

Finally, because companies purchase flavorings from outside sources, they are sometimes unaware of the product that goes into their food.[63] CSPI reports that Unilever, the producer of Shedd's Country Crock spread, said that "'[m]any of our unique flavors are created for us by flavor suppliers, and we purchase the flavors as a single component. Since the formula of the flavor is proprietary to the flavor supplier, we do not have a list of the flavoring ingredients.'"[64] CSPI also reports that several other companies it surveyed refused to disclose information about sesame when asked.[65]

D. Using Public Impact Litigation to Provide Protection for Sesame-Allergy Sufferers

Despite this evidence, as well as the public interest community's advocacy and three senators' efforts,[66] sesame remains outside of the definition of a "major allergen" or "non-major allergen."[67] However, given that FDA cited litigation between private

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concern is that it does not want consumers to rely on a statement that sesame is absent. However, an omission of anything regarding sesame's presence or absence is problematic for even the most highly conscious sesame-allergic consumer, as the consumer cannot know what he or she does not know (or should not be reasonably expected to know) about a product.

[58] *Id.* at 5 (describing the warnings from ConAgra and Heinz).

[59] Roses, *supra* note 6, at 229.

[60] *Open Sesame*, *supra* note 11, at 5.

[61] *Id.*

[62] *Id.*

[63] *Id.* at 6.

[64] *Id.*

[65] *Id.* Another issue to be aware of is that sesame is sometimes included on the product equipment used in handling the food. *Id.* at 8. While merely labeling the product as "may contain" when it may or may not contain the ingredient (i.e., without an investigation) will not be useful for consumers, manufacturers should also be attentive to this issue. *Id.* at 1. FDA has been attentive to this problem, enacting sanitation controls to minimize the cross-contamination of food allergens, even in legislation that was never designed to protect against cross-contamination. *See* 21 C.F.R. § 117.35 (2016).

[66] *Open Sesame*, *supra* note 11, at 1.

[67] *See* 21 U.S.C. § 321(qq) (2012); 21 U.S.C. § 343(w) (2012).

parties as a reason for its decision to request comments on "natural" as defined by its policy statement,[68] it stands to reason that using public impact litigation to get FDA's attention to protect those with sesame allergy is at least a possibility worth considering.

II. LITIGATION FOR SOCIAL AND REGULATORY CHANGE IN ACTION AND CHOOSING A STRATEGY FOR RELIEF FOR A SESAME ALLERGY CLASS ACTION

A. Litigation for Social Change

The concept of using litigation for social change is nothing new. Many law students enter the legal academy with the hope that they can better society by fighting crime, poverty, racial discrimination, or any number of other social justice causes. Because litigation is one way our justice system can combat these problems with fair process, much scholarship exists on the topic. One way to make sense of the different strategies behind litigation for social change is to divide cases into two major categories: "direct client advocacy" and "public impact litigation."[69] Direct client advocacy occurs when a lawyer focuses exclusively on the client's needs when rendering legal services.[70] Public impact litigation, on the other hand, "seeks to use legal tools and the legal process to achieve more systemic change and advance broader goals than the resolution of a discrete dispute between parties."[71]

Because of its ability to include many individuals under one claim to address broad social needs, the class action has become one of the ultimate tools for social justice in public impact litigation. In one scholar's opinion, the popularity of the class action is

> a reflection of our growing awareness that a host of important public and private interactions—perhaps the most important in defining the conditions and opportunities of life for most people—are conducted on a routine or bureaucratized basis and can no longer be visualized as bilateral transactions between private individuals. From another angle, the class action responds to the proliferation of more or less well-organized groups in our society and the tendency to perceive interests as group interests, at least in very important aspects.[72]

Nowhere else can it quite be said that "important public and private interactions . . . are conducted on a routine or bureaucratized basis" than with the federal agencies. With so many aspects of our daily "private" lives regulated by federal agency input—the food and medications we consume by FDA, the USDA, and the

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[68] *Use of the Term "Natural" in the Labeling of Human Food Products*, 80 Fed. Reg. 69,905, 69,905 (Nov. 12, 2015); CRS Reports and Analysis, *FDA Naturally Requests Public Comments on the Use of "Natural" on Food Labels* (Dec. 11, 2015), https://www.fas.org/sgp/crs/misc/natural.pdf.

[69] Beth Van Schaack, *With All Deliberate Speed: Civil Human Rights Litigation as a Tool for Social Change*, 57 VAND. L. REV. 2305, 2307 (2004).

[70] *Id.*

[71] *Id.*

[72] Abram Chayes, *The Role of the Judge in Public Law Litigation*, 89 HARV. L. REV. 1281, 1291 (1976).

EPA, the advertisements we listen and do not listen to by the FTC and the FCC, the business transactions we can and cannot enter into by the SEC—it is at least understandable that a consumer class action brought against private parties might ultimately be looking for action by the agencies to take its social justice agenda to the next level. And while a number of cases have appeared in recent years to define the limits of plaintiffs' ability to bring a class action,[73] the class action has proved to be a powerful tool in the context of food litigation.

One of the main examples of the food class action's success in forcing agency action is the most recent litigation surrounding the term "natural,"[74] given that the litigation contributed to FDA's recent request for comments on its existing policy statement to consider whether the agency should define the term.[75] Because of its strategy of using litigation to effect regulatory reform, the "natural" class action litigation is a strong test case not only for its results, but also to see what legal issues—particularly preemption, standing, and the claim itself—courts have found sticky in analyzing these consumer protection lawsuits. In addition to these key legal issues, this note will also briefly examine "natural" litigation at the motion to dismiss stage, as well as ascertainbility issues that arise during class certification.[76]

B. What Do You Mean?: The Story of "Natural" Class Action Litigation and FDA's Response

Prior to the mid-1970s, FDA "took the positon that the only food products that could lawfully be characterized as 'natural' were raw agricultural commodities sold in their natural state, without any processing."[77] Then, in the mid-1970s, "FDA concluded that it would prohibit the use of the term 'natural' only on products containing artificial color, artificial flavor, or synthetic ingredients such as chemical additives."[78] In 1991, FDA adopted an "'informal policy'" stating that "natural" means "nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to,

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[73] *See generally* Robert H. Klonoff, *The Decline of Class Actions*, 90 WASH. U. L. REV. (2013). Though the agency adopted this policy statement in the 1990s, it had been hesitant to define the term for years before. *See* Nicole E. Negowetti, *A National "Natural" Standard for Food Labeling*, 65 ME. L. REV. 581, 581 (2013).

[74] Food class actions brought on behalf of consumers have also made claims about organic food products, the false advertising of juice, and other related items. *See Brown v. Hain Celestial Group, Inc.*, 913 F. Supp. 2d 881 (N.D. Cal. 2012); *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2230–31 (2014); *Saeidian v. Coca Cola Co.*, No. 2:09-cv-6309 (C.D. Cal. July 6, 2015) (ECF No. 173) (order denying defendant's motion for summary judgment); CRS Reports and Analysis, *supra* note 68.

[75] *Use of the Term "Natural" in the Labeling of Human Food Products*, 80 Fed. Reg. 69,905, 69,905 (Nov. 12, 2015).

[76] From my research, most cases that are certified immediately settle—and sometimes cases settle even before this point. Thus, I will focus on these preliminary issues and issues of class certification in this note. *See generally* Nicole E. Negowetti, *Food Labeling Litigation: Exposing Gaps in FDA's Resources and Regulatory Authority*, GOVERNANCE STUD. BROOKINGS (June 2014), https://www.brookings.edu/wp-content/uploads/2016/06/Negowetti_Food-Labeling-Litigation.pdf; ASHLEY HARRISON, ET AL., RECENT DEVELOPMENTS AND CASE UPDATES IN FOOD LABELING CLASS ACTIONS AND ADVERTISING LITIGATION (2015),http://www.americanbar.org/content/dam/aba/administrative/litigation/materials/2015-joint-cle/written_materials/01_food_labeling_case_updates.authcheckdam.pdf.

[77] PETER BARTON HUTT, RICHARD A. MERRIL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 451 (4th ed. 2014).

[78] *Id.*

the product that would not normally be expected to be there."[79] Later in the 1990s, FDA was asked to define the term "natural," but declined to do so due to "resource limitations and other agency priorities."[80] Both non-profit and industry stakeholders in the 2000s asked FDA to define the term, which it still refused to do.[81] Beginning in 2010, however, class action litigators began filing cases regarding the word "natural,"[82] and by 2013, judges had joined the conversation. In *Cox v. Gruma Corp.*, "the court referred the issue of GMOs and labeling of 'natural' foods to FDA for the first time."[83] After determining that the Federal Food, Drug, and Cosmetic Act (FDCA) gave FDA complete authority over determining what the term "natural" meant, the court asked FDA "the question of whether and under what circumstances food products containing ingredients produced using bioengineered seed may or may not be labeled 'natural' or 'All natural' or '100% natural.'"[84] However, in 2014 FDA sent a letter in response to the suit, claiming that the reasons it did not define the term "natural" were as follows: (1) defining the term "natural" would mean amending the informal policy statement, rather than accepting an "*ad hoc* decision made 'in the context of litigation between private parties'"[85]; (2) reconsidering the term would require "coordination and cooperation with the USDA and other agencies"[86]; and (3) lacking resources and prioritizing of other issues, such as the Food Safety Modernization Act, were relevant concerns.[87]

Despite the agency's lack of action on this front, FDA did begin sending warning letters to companies that violated the "natural" informal policy in the wake of the class action litigation.[88] As one example, in 2012 FDA alerted the public against an Israeli "berry juice," saying the company's use of the term "natural" was inaccurate because the product contained sulfur dioxide, a listed preservative.[89] But in November of 2015, FDA finally announced it would take comments to consider the following questions: (1) "whether it was appropriate to define the term 'natural'"; (2) "if so, how the agency should define the term 'natural'"; and (3) "how the agency should determine

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[79] Negowetti, *supra* note 76 (citing Food Labeling: Nutrient Content Claims, General Principles Petitions, Definition of Terms, 56 Fed. Reg. 60,466 (November 27, 1991)).

[80] *See* Letter from Andrew Kimball, Exec. Dir. & William Freese, Science Policy Analyst, Ctr. for Food Safety, to Margaret A. Hamburg, Comm'r, U.S. Food and Drug Admin. (Nov. 4, 2013), http://www.centerforfoodsafety.org/files/2013-11-1-letter-to-fda-re-natural-final_85868.pdf.

[81] *Id.*

[82] At least 100 have been filed through 2013. *See* Mike Esterl, *The Natural Evolution of Food Labels*, WALL ST. J., Nov. 6, 2013, at B1; Negowetti, *supra* note 76; Harrison et al., *supra* note 76.

[83] Negowetti, *supra* note 76, at 12.

[84] *Id.* (citing Cox v. Gruma Corp., Case No.: 12–CV–6502 YGR, 2013 WL 3828800, at *2 (N.D. Cal. 2013)).

[85] *Id.* at *13 (citing Letter from Leslie Kux, Assistant Comm'r for Policy, U.S. Food & Drug Admin., to Judge Yvonne Gonzalez Rogers, Jeffrey S. White, & Kevin McNulty 3 (Jan. 6, 2014), www.hpm.com/pdf/blog/FDA%20:r%201-2014%20re%20Natural.pdf ("[W]e respectfully decline to make a determination at this time regarding whether and under what circumstances food products . . . may not be labeled 'natural.'")).

[86] Negowetti, *supra* note 76, at 13.

[87] *Id.*

[88] *Id.*

[89] *Id.*

appropriate use of the term on food labels."[90] In its announcement in the Federal Register, FDA said it was taking this action because:

> [W]e received three citizen petitions asking that we define the term "natural" for use in food labeling and one citizen petition asking that we prohibit the term "natural" on food labels. We also note that some Federal courts, as a result of litigation between private parties, have requested administrative determinations from FDA regarding whether food products containing ingredients produced by genetic engineering or foods containing high fructose corn syrup may be labeled as "natural."[91]

There is no denying that interest in defining the term comes from parties on both sides. On the industry side, one of these citizen's petitions was from the Grocery Manufacturer's Association.[92] On the non-profit/public interest advocacy side, the Center for Food Safety filed at least a letter to FDA asking the agency to go through an informal notice and comment rulemaking process to define the term.[93] However, because FDA notes that "litigation between private parties" in federal courts swayed their decision to make an agency change, there seems to be room for using class action litigation as a strategy to get the agency to act in a sesame allergy context.

C. Who, What, When, Where, and Why?: Strategic and Moral Considerations in Building a Sesame Allergy Class Action

Before one can consider how a new sesame allergy claim might be litigated by examining and comparing the key legal issues present in "natural" litigation, one must consider what kind of relief one is looking for—monetary or injunctive. "Natural" class actions have had difficulty obtaining injunctive relief, as monetary damages are reasoned the more appropriate remedy for one who knows of the danger of a product and therefore would not (or would not allege that he or she would) purchase the product again.[94] But from a public impact litigation perspective, injunctive relief is the goal, as the hope is to stop food manufacturers from omitting sesame from labeling—or, put another way, to get them to label sesame. Therefore, while giving someone who has experienced a life-threatening, anaphylactic response to a food product money for their experience might somewhat compensate them individually, it does not fix the larger problem.

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[90] *Use of the Term "Natural" in the Labeling of Human Food Products*, 80 Fed. Reg. 69,905, 69,905 (Nov. 12, 2015); CSR Reports and Analysis, *supra* note 68.

[91] *Id.*

[92] CSR Reports and Analysis, *supra* note 68.

[93] Letter from Andrew Kimball, *supra* note 80.

[94] *See, e.g.*, Werdebaugh v. Blue Diamond Growers, No.: 12–CV–2724–LHK, 2014 WL 2191901, at *9 (N.D. Cal. May 23, 2014); *In re* ConAgra Foods, Inc., 302 F.R.D. 537, 575–76 (C.D. Cal. 2014). While this objection might also be raised for products that have sesame in them, food allergy reactions arguably raise unique questions. Did the person have a reaction because of sesame that routinely occurs in that product? Did it occur because of a one-time mistake or cross-contamination? It is possible a person who became ill from a product might purchase it again in the scenario where they never were sick from that product before, but became so once. The law requires here that the person allege he or she will purchase the product again. If a court does not find this logic convincing, another way to ask for relief would be to ask a particular company that manufactured a product with sesame to label sesame on all of its products, thus circumventing the initial problem.

Moreover, this framing of the problem assumes that the best way to create the class of people is to look to those who have *already* experienced personal injury. This section draws the conclusion that this assumption is correct, and it is this definition of class and relief—a group of those who have already experienced personal injury based on a non-labeled food product seeking injunctive relief—that informs the legal analysis in part three of the note.[95] But the exercise of walking through how one makes this determination from legal, moral, and strategic perspectives is still worth considering. The following is a brief overview of what considerations may arise in determining how to define a class and selecting the appropriate legal remedy.

D. The Practical Considerations in Choosing a Class

In constructing a legal claim for sesame allergy sufferers, there are basic questions one must consider. Some of these basic questions are relatively clear. For example, California's plaintiff-friendly consumer protection laws and the litigation that has passed through the "Food Court"[96] makes it an ideal forum in which to bring these kinds of claims at the state and/or federal level.[97] But some basic questions are not sufficiently clear, one of which presents a main theoretical and legal problem for this note. That question is: What kind of relief will the class seek?

As explained above, from a public impact lawyer's perspective, the best form of relief is the one that would cause FDA to ultimately include sesame as a major allergen. While gaining national attention from bringing class action lawsuits may cause FDA to act regardless of the kind of relief sought, injunctive relief would (theoretically) force companies to start disclosing sesame on their products, while monetary relief would not cause any labeling changes.[98] Injunctive relief would also be more likely to produce a response in FDA if major food companies that had to disclose sesame on their products complained to FDA to create a uniform rule so that their competitors were held to the same standards that they were. This assumes the class actions would be successfully litigated in favor of the plaintiffs and that there

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[95] *See* Harrison, *supra* note 76 (citing, *e.g.*, Werdebaugh v. Blue Diamond Growers, No.: 12–CV–2724–LHK, 2014 WL 2191901 (N.D. Cal. May 23, 2014); *In re* ConAgra Foods, Inc., 302 F.R.D. at 537). While it may be true that an individual litigant might be able to receive the same benefits for all through this litigation process, this note focuses specifically on testing the class action as a tool for this purpose, given the previous successes of the "natural" litigation. The problems inherent in this model will be explored in this note, and it is important to observe that a claim with an individualized plaintiff would, at least, avoid some of the conflict issues between forms of relief (monetary versus injunctive) that might arise between a class action attorney and her already-personally-injured clients.

[96] This is the common name of the Northern District for the District of California. *See* Paul M. Barrett, *California's Food Court: Where Lawyers Never Go Hungry*, BLOOMBERG (Aug. 23, 2013, 6:21 AM), http://www.bloomberg.com/bw/articles/2013-08-22/californias-food-court-where-lawyers-never-go-hungry.

[97] Nineteen food class actions were filed in 2008. By 2012 there were 102 cases, the majority of which were filed in the Northern District of California. *See* Negowetti, *supra* note 76, at 1.

[98] While there is an argument for having a class based on monetary damages to get industry upset enough to indirectly affect FDA, personal injury classes do not tend to be certifiable, so this is not a realistic option if the plaintiffs are, as this class assumes, all personally injured. DECHERT LLP, *Another Personal Injury Class Action Goes Down in Flames*, LEXOLOGY (July 2, 2012), http://www.lexology.com/library/detail.aspx?g=8ac4f530-f770-495d-822f-5cbbcb7e1cc2.

would be enough incentive that food product companies would act.[99] It also assumes one can find a successful theory that permits injunction.

But from a class member's perspective—at least from one who has purchased a product with sesame without knowing what was in it, consumed the product, and suffered injury—monetary damages might be a preferred remedy. Beyond it being preferred, to deny such individuals monetary damages would be categorically unfair, because it would leave their particular injuries and the expenses they may have incurred from those injuries unaddressed. Finally, should these plaintiffs who are included in the class choose to ask for injunctive relief rather than monetary damages, they would be barred from pursuing monetary damages in a separate class after the judgment with respect to this claim under the res judicata doctrine.[100]

Moreover, depending on the scope of the class, not all class members may have experienced personal injury. Some with sesame allergy may merely have experienced the economic injury of buying the product that they would not have purchased if they had known sesame was in it. However, these individuals are still at risk for personal injury. With all of these diverging class members' interests (some in terms of relief, some in terms of temporal proximity to experiencing at least personal injury) arising from the same transaction (the purchase of a mainstream, large company's food product that contained hidden sesame), it becomes difficult to know what claim one can bring to satisfy the joint interests of all potential class members.

Thus, while one can have a legal theory that seeks injunctive relief and includes both plaintiffs who have already been and have yet to be injured, one cannot have a legal theory common to the class that seeks damages because the future claimants have yet to experience a personal injury.[101] Given the diverging injuries and the concern about ultimately making FDA adopt a labeling requirement for sesame, the best option for a strategic plaintiff-side lawyer is to seek injunctive relief for a class.

E. The Moral Considerations of Choosing a Class

While class action litigators often focus on the strategic construction of a class and the specific outcomes it can achieve, they often ignore a central objective of any litigation: to protect the interests of the client. In cases such as these that hope to construct a class in the name of the public interest, or at least with a competing ideological and strategic goal over that of the individual class members' needs, there are always moral and ethical questions regarding if, how, and under what circumstances lawyers should put classes together. For example, in labor law claims, a class comprised of employees suing on the basis of gender discrimination might hope to receive some form of injunctive relief, i.e., better career prospects, policies that limit

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[99] It may not be enough of an incentive to have food industry members contact FDA about labeling their products, as FDA permits food companies to put a label on a product without any verification that the product contains that ingredient. *See* Roses, *supra* note 6, at 225. However, because it seems that FDA acted when public and private forces came together in the "natural" litigation, it is at least a strategy worth trying.

[100] Res judicata defined: "An affirmative defense barring the same parties from litigating a second lawsuit on the same claim, or any other claim arising from the same transaction or series of transactions and that could have been—but was not—raised in the first suit." *Res judicata*, BLACK'S LAW DICTIONARY (9th ed. 2011).

[101] They may have experienced economic injury, but typically this kind of relief is only recoverable in contract. *See* Ralph C. Anzvino, *The Economic Loss Doctrine: Distinguishing Economic Loss from Non-Economic Loss*, 91 MARQUETTE L. REV. 1081 (2008).

sexual harassment and promote gender inclusion, and other structural changes.[102] While this kind of injunctive relief would be advantageous to current employees, former employees, who also were subject to the same treatment, and thus sharing at least a common question of fact,[103] would not benefit from injunctive relief, and therefore might want monetary damages.[104] In such cases, courts have generally held that such classes are not certifiable.[105]

While it is possible to limit the class of plaintiffs to just those seeking monetary relief or just those seeking injunctive relief, there is arguably a concern that selecting classes like this denies the rights of those individuals who experienced the same harm as those seeking redress. This initial conflict does not take into account the possibility that one member of the class might win less money under a class action suit than he or she would by individually suing for damages.[106] Moreover, there is scholarship addressing the difference in handling claimants with future injuries as opposed to those who have already experienced injury.[107] For instance, in *Ortiz v. Fibreboard Corp.*, the Supreme Court found that "present and future claimants required separate representation because of their very different interests."[108] In *Amchem Prods. v. Windsor*, the Supreme Court denied certifying a settlement for asbestos-related claims because, "[a]lthough comprehensive, [the settlement] did not provide compensation to all alleged victims of asbestos exposure and did not provide compensation, for example, for loss of consortium, emotional distress, medical monitoring, or other types of claims."[109]

These questions are all of serious concern, not just for the class members in receiving adequate relief, but also for the attorney who owes a duty of undivided loyalty to class members.[110] One way to ensure that these conflicts do not occur is to ask the class members to waive their right to monetary damages. One other thing to consider is that some courts, including the Ninth Circuit, have held that plaintiffs not included in the class seeking an injunction may still bring a claim for monetary damages on their own.[111] Courts have reasoned that to not do so would be a violation of the plaintiff's due process rights, as the plaintiffs seeking injunctive relief did not

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[102] *See* Gregory v. Mersol, *Ethical Issues in Class Action Employment Litigation*, 20 LAB. LAW. 55, 66 (2004).

[103] *See* Fed. R. Civ. P. 23(a)(2).

[104] Mersol, *supra* note 102.

[105] *See id.* at 59, 57–62 (discussing Amchem Prods. v. Windsor, 521 U.S. 591 (1997) and Ortiz v. Fibreboard Corp., 527 U.S. 815 (1999)).

[106] *Id.* at 66.

[107] *See id.* at 61.

[108] *See id.* (citing Ortiz v. Fireboard Corp., 527 U.S. 815, 849 (1999)).

[109] *See id.* at 59 (citing AmChem Prods. v. Windsor, 521 U.S. 591, 604 (1997)).

[110] David B. Parker et. al., *Ethical Issues in Class Actions and Derivative Litigation*, PARKER MILLS LLP,http://parkermillsllp.com/wp-content/uploads/2016/02/Ethical-Issues-in-Class-Actions-Derivative-Litigation.pdf (last visited Oct. 7, 2016).

[111] Andrew S. Tulumello & Mark Whitburn, *Res Judicata and Collaterol Estoppel Issues in Class Litigation*, *in* A PRACTITIONER'S GUIDE TO CLASS ACTIONS 605 (Mary Hogan Greer ed., 2010), http://www.gibsondunn.com/publications/Documents/TulumelloWhitburn-ResJudicataandCollateral EstoppelIssues.pdf (last visited Oct. 7, 2016).

have a chance to opt out of the class.[112] In this way, the moral considerations might not necessarily conflict with the practical outcome, provided one contains her class to plaintiffs who have experienced personal injury as a result of eating a sesame-filled product and are seeking injunctive relief.[113] These parameters of the class are assumed for the legal analysis that follows.

III. COMPARISON OF "NATURAL" LITIGATION TO A SESAME ALLERGY CLASS ACTION

A. Legal Guideposts: Common "Natural" Claims, Court Responses, and Planning for the Future

The history of "natural" class action litigation offers guidance for creating a new sesame allergy class action, both in terms of the subject-matter of the claim and in terms of legal issues to consider and navigate for successful litigation. In terms of subject-matter, mislabeling claims are a timely topic in the news. One lawsuit alleged that a product marketed as 100 percent pure olive oil misled consumers because it in fact was made from olive-pomace oil.[114] Another lawsuit alleged that a product marketed as grape seed oil was misleading to consumers because it contained "less than 25% grape seed oil."[115] Generally speaking, most food litigation, including "natural" litigation, has been brought under two broad categories: claims that, while legal or unregulated, are arguably misleading to consumers; and, claims that violate a state law codifying the FDCA, such as California's Sherman Law.[116] These substance groups offer some clue as to what legal issues emerge as most salient, especially given that the farthest any of these cases has proceeded is the class certification stage before the parties opt to settle: preemption, standing, the most common substantive claims utilized, and issues in class certification. Moreover, the substantive claims, mostly from California state law consumer protection statutes, lead to litigation filed in the federal courts in California. Therefore, the following is both a practical look at how the courts have handled each of the above legal issues within the context of the "natural" litigation and, based on this information, an imagining of how a court might handle a new sesame allergy class action claim brought against private parties under similar legal theories in similar legal venues. It will consider any other legal issues relevant to "natural" litigation claims as food for thought on taking a sesame allergy class action farther into the litigation process.

An initial question that arises is: Can one argue that sesame's omission from a label would be considered "false and misleading" under the FDCA? Case law on theories of false advertising based on omission are scarce, and there is a strong argument that

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[112] *Id.*

[113] The author notes that it is also analytically cleaner and simpler to use these parameters for this thought experiment.

[114] *See* Negowetti, *supra* note 76, at 10 (citing Ebin v. Kangadis Food Inc., No. 1:13-cv-2311 (S.D.N.Y. 2014)).

[115] *See id.* at 26, n.59 (citing Marquez v. Overseas Food Distrib., No. BC 535015 (Cal. Super., Los Angeles Cty. Jan. 32, 2014)).

[116] *See id.* at 10–11.

the real theory at issue is failure to warn. Each of these problems will be considered in turn, as each informs the discussion of how one might experiment with a class action theory to protect sesame-allergy sufferers.

B. Preemption and Standing

1. Preemption for "Natural" Litigation

One of the first responses a defense lawyer might have in this situation is that any claim regarding "natural" is preempted by the FDCA. While there is a presumption against preemption in food labeling litigation, courts have ruled for and against preemption.[117] Those that have ruled for preemption have done so where there has been a failure to meet required FDCA provisions[118] or where the judge thought that agency oversight would provide consistency and add competence to the decision.[119] Those that have ruled against preemption cite FDA's lack of a finalized rule through notice and comment rulemaking—and point to its choice to rely on an informal policy statement defining "natural"[120]—as reason not to apply the doctrine. Additionally, if the plaintiff alleges California statutory claims under the UCL, FAL, or CLRA as a violation of the California Sherman Food and Drug Act, their claims are not preempted because the state law claims are "identical" to the FDCA's claims, which is a way around preemption.[121] Given that FDA has closed its comment period for suggestions on defining the term "natural" as of May 10, 2016, it may not be long until the first of these ways around preemption may no longer be available to plaintiffs.[122] Something similar is true in the food allergy context: If, as a result of a lawsuit or other regulatory or legislative change, sesame were to be included as a "major allergen" or "non-major allergen," there would be a much stronger argument for preemption to apply to any claims that do not have another way around preemption.[123] Therefore, while the situations are not exactly analogous, false advertising claims in "natural" litigation that have circumvented preemption present a successful model to examine in a sesame allergy context. Specifically, statutory provisions that effectively use the "identical to" provisions of the FDCA, like the consumer protection statutes in California, merit exploration because they provide interesting alternatives to classic duty-to-warn theories of liability. The next section primarily considers if and how one might use these consumer protection statutes to avoid the express preemption clause in the

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[117] *See* Negowetti, *supra* note 76, at 14 (citing Holk v. Snapple Beverage Corp., 575 F.3d 329, 334–35 (3d Cir. 2009); *In re* Farm Raised Salmon Cases, 175 P.3d 1170, 1176 (Cal. 2008)).

[118] *See* Harrison, *supra* note 76, at 9 (citing Salazar v. Honest Tea, Inc., 74 F. Supp. 3d 1304, 1313–14 (E.D. Cal. June 10, 2014)).

[119] *See id.* at 13 (citing Saubers v. Kashi, Co., 39 F. Supp. 3d 1108, 1108 (S.D. Cal. 2014)).

[120] *See id.* at 2 (citing *In re* Hain Celestial Seasonings Prods. Consumer Litig., Case No. 8:13-cv-01757 (C.D. Cal. June 10, 2014)).

[121] Larsen v. Trader Joe's Co., 917 F. Supp. 2d 1019, 1023 (N.D. Cal. 2013).

[122] *"Natural" on Food Labeling*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm (last updated May 9, 2016).

[123] *See Sens. Blumenthal, Markey, Reps. Pallone, DeLauro Introduce Legislation to Modernize Food Labeling*, BLUMENTHAL.SENATE.COM (Nov. 23, 2015), http://www.blumenthal.senate.gov/newsroom/press/release/sens-blumenthal-markey-reps-pallone-delauro-introduce-legislation-to-modernize-food-labeling.

Nutrition Labeling and Education Act (NLEA) as it relates to "misbranding" under the FDCA.[124]

2. Preemption for Sesame Allergy Class Action: Express Preemption

Because FDA has broad federal jurisdiction over labeling food items to protect the health and safety of the public, no lawyer can move forward without due consideration of whether his or her claim will be federally preempted by FDA's authority under the FDCA.[125] Traditionally, FDA has regulated the back of the label, which contains the list of ingredients, much more stringently than the front of the label, which contains claims of a product being "natural" or "organic."[126] However, because allergy warnings appear on the back of the label, and this suit would ideally call for injunctive relief that would disclose sesame on the product, careful analysis of preemption issues is required.

Under the FDCA, "the adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce" is prohibited.[127] In order to clarify the term and to provide a "specific scheme for food labeling," Congress passed NLEA, which explains in greater detail the prohibitions on "misbranding."[128] Under NLEA, "there is a lengthy express preemption clause with five subparts" which prohibits "states from imposing 'requirements' relating to food that . . . are not 'identical' to an applicable federal food labeling standard."[129] Moreover, "for pre-emption purposes, 'not identical to' 'does not refer to the specific words,' but instead to state obligations that either 'differ' from or are 'not imposed' by federal law."[130] Preemption requires 'substantially the same language' and that 'any difference does not result in the imposition of materially different requirements.'"[131] Therefore, "the

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[124] *See* 21 U.S.C. § 343(1)(a) (2012); *see also* 21 U.S.C. § 331(b) (2012). Though implied preemption issues have arisen in this context, courts have generally held that the preemptive scope of 21 U.S.C. § 343 is limited to the language of the statute. *See* Pom Wonderful LLC v. Ocean Spray Cranberries Inc., 642 F. Supp. 2d 1112, 1122–23 (C.D. Cal. 2009); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 352 (2001). Therefore, this note focuses on express preemption, with a brief discussion of implied preemption.

[125] *See What We Do*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/ (last updated Dec. 27, 2015).

[126] James M. Beck, *Food Fight: FDA Preemption and Food Labeling Claims*, LAW360 (Jan. 27, 2011, 2:14 PM), http://www.law360.com/articles/221444/food-fight-fda-preemption-and-food-labeling-claims. Given how unregulated this area of law has been, it is unsurprising that so many "natural" and organic litigation suits have made their way through federal courts without pre-emption issues. *See id.*

[127] *See* 21 U.S.C. § 331(b) (2012).

[128] *See* Beck, *supra* note 126.

[129] *See id.* ("'labeling' has the same broad connotation in food as it does in other FDA regulated areas").

[130] *See* 21 C.F.R. § 100.1(c)(4) (2016).

[131] *Food Fight: FDA Preemption and Food Labeling Claims*, LAW360 (Jan. 27, 2011, 2:14 PM), http://www.law360.com/articles/221444/food-fight-fda-preemption-and-food-labeling-claims(citing Turek v. General Mills, Inc., 2010 WL 3527553, at *5 (N.D. Ill. 2010)). As an additional note, because *POM Wonderful v. Coca Cola* was about preclusion rather than preemption, there is nothing that it necessarily adds to the discussion of preemption of false advertising food labeling cases. *See* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228 (2014).

only state requirements that are subject to preemption are those that are affirmatively different from the Federal requirements."[132]

Additionally, FDA requires that FDCA violations be brought "'by and in the name of' the federal government" under its general exclusivity clause.[133] Despite FDA having sole authority over enforcement, the "identity" standard has been interpreted by some state courts as an exception to this general exclusivity clause.[134] As a result, as long as the state courts interpret their state statutes as having "identical" language to that in the FDCA, the statutes are not preempted.[135] States like California have done just that. The California Supreme Court ruled food claims brought under consumer protection statutes[136] as "identical to" the provisions in the FDCA under §343-1(a)[137]; therefore, food claims brought under these statutes or other state laws are not federally preempted under §337(a).[138] For the purposes of this case, this means that a claim brought under a consumer protection statute or even a state common law claim against the exposure to sesame, if such a claim is possible, would not be preempted by the FDCA.[139]

One major issue with using this approach to circumvent preemption is the concern that Congress has expressly preempted any state laws that might require allergen disclosure.[140] If the preemption clause applies to all potential allergens, sesame is not permitted to be disclosed as an allergen. The lawsuit is over.[141] However, if it is possible to create a claim where the problem with the omission of sesame was something other than the fact that it was an allergen—that, perhaps, not labeling it in and of itself is false and misleading in any particular[142]—then there might be a way to

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[132] *Id.* (quoting *In re* Pepsico Inc., 588 F. Supp. 2d 527, 532 (S.D.N.Y. 2008)).

[133] *Id.* (quoting Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4, 352 (2001)).

[134] *See* Beck, *supra* note 126.

[135] One article specifically references unfair competition statutes as an example of the kind of claims that should not be preempted, but this example is just one of many. *See id.*

[136] In California, the state ruled that bringing a consumer protection claim was part of the state's police powers, and thus state consumer protection statutes like the UCL, FAL, and CLRA are not preempted by federal law. *See In re* Farm Raised Salmon Cases, 175 P.3d 1170, 1176 (Cal. 2008) (citing *Florida Lime & Avocado Growers v. Paul*, 373 U.S. 132, 144 (1963)).

[137] *See* Beck, *supra* note 126 (quoting *In re* Farm Raised Salmon Cases, 175 P.3d 1170, 1176 (Cal. 2008)).

[138] *See* Beck, *supra* note 126.

[139] This gets around one major problem of trying to claim that sesame should be labeled as an allergen, as this would be preempted under the FDCA because FDA does not recognize sesame as an allergen.

[140] *See* 21 U.S.C. § 343(a)(2) (2012).

[141] This was the case in *Riegel v. Medtronic, Inc.*, where the Supreme Court held that an express preemption clause in the Medical Devices Amendments preempted the application of state tort law causes of action. Riegel v. Medtronic, Inc., 451 F.3d 104 (2008). Congress expressed its strong disapproval with the ruling and made ultimately unsuccessful efforts to pass legislation correcting the decision. *See* Medical Device Safety Act of 2008, H.R. 6381, 110th Cong. (2008); S. 3398, 110th Cong. (2008); *see also* Medical Device Safety Act of 2009, H.R. 1346, 111th Cong. (2009); S. 540, 111th Cong. (2009).

[142] This example is offered purely as a brainstorming hypothetical. According to CSPI, sesame is hidden in colorings, flavorings, and spices regularly. FDA does permit the general disclosure of spices, flavorings, colors, and incidental additives. See 21 U.S.C. 343(i) (2012); 21 C.F.R. § 101.100(a)(3) (2016). However, recently FDA acknowledged that sesame seeds specifically should not be considered "spices" and must be "declared on the label using common or usual names." *See FDA CPG Sec. 525-750 Spices –*

get around preemption. Because Congress defined "major allergens" by listing them (milk, wheat, soy, etc.), it is possible the preemptive effect of 21 U.S.C. § 343(1)(a)(2) applies specifically to state laws that would regulate these eight food items.[143] This argument may also hold true for non-major allergens promulgated under 21 U.S.C. § 343(x)—namely, cochineal extract and carmine.[144] Because sesame is not listed either as a major or non-major allergen in the FDCA, it might not be an agency-recognized "allergen" for purposes of the statute.[145] If this is the case, sesame might not be subject to the preemption on labeling,[146] though it is unlikely this could happen.[147]

One more promising avenue may provide a way around federal preemption. There is one uncodified law, NLEA § 6(c)(2),[148] that exempts "any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food" from preemption.[149] "Thus, NLEA preemption is not commonly encountered in personal injury litigation, but more often in consumer protection cases."[150] Therefore, the argument that labeling sesame is required in order

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Definitions, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074468.htm (last updated Mar. 3, 2015).

[143] 21 U.S.C. § 343(1)(a)(2) (2012).

[144] 21 U.S.C. § 343(x) (2012).

[145] This argument is grounded in how specific FDA was with its language on what makes a major food allergen, as well as FDA's hesitance to promulgate regulations on other, non-major food allergens. Because the statute named foods that were major allergens, rather than providing criteria by which FDA could evaluate these claims, those items not listed by Congress or promulgated by regulations by FDA might not be considered "food allergens" at all under the statute. If this is the case, one could argue the statute's preemptory effect would not apply to something like sesame that the populace recognizes as an allergen, but that is not legally recognized as such. The statute's "savings clause" also supports this interpretation. *See* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101–535, § 6(c)(1), 104 Stat. 2353, 2364 (1990) ("The [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [section 343–1] of the [FDCA].").

[146] In a note to the FDCA, Congress suggested that FDA still had the authority to label other food allergens than "major" ones. *See* Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, 118 Stat. 905 (codified as amended in scattered sections of title 21) ("amendments made…that require a label or labeling for major food allergens do not alter the authority of the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) to require a label or labeling for other food allergens").

[147] This would only work, then, if a court determined that the non-disclosure of sesame as an ingredient was false and misleading and led to a misbranding violation. There are a number of ways in which this could turn out the opposite way. One to keep in mind in this situation is that if sesame is only present in spices, flavorings, or the like, FDA may not require its disclosure because it is not a recognized major allergen. *See* 21 U.S.C. § 321(qq)(1) (2012); Specific Food Labeling Requirements, 21 C.F.R. § 101.22(a)(3) (2016); 21 C.F.R. § 101.100(a)(3) (2016). However, it is important to note that FDA has advised that sesame seeds must be declared on a label, even if they are included in spices. *See FDA CPG Sec. 525-750 Spices – Definitions*, *supra* note 141.

[148] *See* Beck, *supra* note 126 (citing Nutrition Labeling and Education Act, Pub. L. 101-535, 104 Stat. 2353).

[149] *Id.*

[150] *Id.*

to "provide a warning concerning the safety of a food or a component of the food" could provide another avenue to avoid preemption.[151] [152]

In all, then, there seem to be two helpful paths worth exploring to determine a way around preemption claims filed in California: (1) filing under consumer protection statutes and invoking the "identity" exception; and (2) claiming that the labeling did not "provide a warning concerning the safety of a food or a component of the food." Therefore, regardless of the claims an attorney might bring to achieve his or her goal, there might be room in the law to proceed.

3. Preemption for Sesame Allergy Class Action: Implied Preemption

Under NLEA, there is an express savings clause that the Act can only be interpreted to disallow state law that is expressly preempted.[153] However, given how specific Congress was in crafting FALCPA's language and delegation of authority to FDA in this area, a question remains as to whether the FDCA would impliedly preempt a California state law claim alleging the omission of sesame on an ingredient label is false or misleading advertising. Implied preemption is a doctrine with two major types: field preemption and conflict preemption.[154]

Field preemption "occurs when Congress, without expressly declaring that state laws are preempted, nevertheless legislates in a way that is so comprehensive as to occupy the entire field of an issue."[155] Given that Congress both enumerated which food allergens were considered "major allergens," and that it did not permit FDA to add to this major allergen list, there is a strong argument that Congress spoke so clearly

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[151] One reason why the argument that sesame in particular should be protected might be persuasive to a court is that it fits a "sweet spot" in past litigation that might merit judicial intervention. According to Roses, courts have held that judicial intervention to protect food allergy sufferers is not warranted when the allergen is generally known to the public and when the allergen is very rare. *See* Rosas, *supra* note 6, at 232 and 234. Roses also notes that an increase in the severity of the response to these allergens impacts this legal calculus. *See id.* at 234. Because sesame is not yet recognized by FDA as an allergen, it is not yet well-recognized in public despite its prevalence and severity, and the public may not be aware of the ingredients that might contain sesame, it may qualify as an item that merits protection via express labeling. *See Open Sesame*, *supra* note 11, at 4.

[152] Under past case law, this exception might be successfully used to circumvent preemption. The exception has been invoked where "safety" referred to cancer, but was denied where "safety" referred to gastrointestinal distress associated with lactose intolerance and BPA. *See* Skirtini v. Pepsico, Inc., 108 F. Supp. 3d 780, 801–802 (N.D. Cal. 2015) (insert parenthetical); Mills v. Giant of Maryland, LLC, 508 F.3d 11 (D.C. Cir. 2007) (not ruling on the District Court of the District of Columbia's ruling that flatulence and gastrointestinal distress did not qualify as conditions that triggered the "safety" exception in NLEA 6(c)(2)). See Mills v. Giant of Maryland, LLC, 441 F. Supp. 2d 104, 109 (Aug. 2, 2006)); *In re* Bisphenol-A (BPA) Polycarbonate Plastic Products Liability Litigation, 2009 WL 3762965, at *6 (W.D. Mo., Nov. 9, 2009). Given that anaphylactic shock is life-threatening, an advocate might have a stronger argument for categorizing sesame allergy along with "cancer" rather than "lactose intolerance." One district court even suggested that if "the harm to [lactose intolerant] plaintiffs was serious, it might weigh toward requiring a duty to warn." *See* Roses, *supra* note 6, at 234, FN. 79.

[153] Nutrition Labeling and Education Act of 1990 § 6(c)(1) Pub. L. No. 101–535, § 6(c)(1) (21 U.S.C. § 343-1 note).

[154] *See* HUTT, MERRILL & GROSSMAN, *supra* note 77, at 292.

[155] Stephen Wermiel, *SCOTUS for Law Students (Sponsored by Bloomberg Law): Preemption Again*, SCOTUSBLOG (March 11, 2013, 11:05 AM), http://www.scotusblog.com/2013/03/scotus-for-law-students-sponsored-by-bloomberg-law-preemption-again/.

as to the issue of food allergies that a claim like this in court might be preempted because it would encroach on Congress's intent and authority to protect Americans with food allergies. Moreover, Congress's intent for regulating food allergies is expressed in a statute rather than a regulation or a policy statement, as is currently still the case for natural food products.[156] That Congress spoke, rather than FDA, on this issue should serve as a thumb on the scale in favor of preemption. Should this occur, the case that may not proceed in court, but that could lead to other FDA action, is further explored in Part IV.

However, there is also a strong argument that the preemption doctrine does not apply to an allegation of the false or misleading labeling of sesame. Given that Congress was so specific with its delineation of the major allergens, its choice not to include sesame when it otherwise could have—either in the original statute or in an amendment, once relevant statistics of the rise of sesame allergy became apparent—perhaps takes it outside of the field of preemption. Moreover, field preemption in other contexts—such as the drug and device realms—is extremely rare, which may speak to its likely failure in the food context.[157] If this is the case, then the "identical" language in the UCL, FAL, and CLRA derived from the Sherman Act could thwart the doctrine of preemption.

Additionally, conflict preemption also does not present a strong case for preemption. Conflict preemption can be one of two types: obstacle or impossibility.[158] Under impossibility preemption, a state law is preempted when it is impossible for one to comply with both state and federal laws at the same time.[159] Here, because adding sesame allergy to a label would not negatively affect the disclosure of other major food allergens, an argument that sesame on a label would be preempted due to impossibility is weak.

Obstacle preemption is more challenging, but it produces the same result. Under obstacle preemption, a state law must yield to federal law when it stands as an "obstacle to the accomplishment of and execution of Congress' full purposes and objectives."[160] Two Supreme Court cases covering food law topics generally provide an explanation for what counts as an "obstacle." In *Florida Lime and Avocado Growers, Inc. v. Paul*, the Supreme Court found a California state law requiring that avocados shipped into the state "contain less than 8 per cent of oil, by weight . . . excluding the skin and seed"[161] was not an obstacle to accomplishing the full purposes of objectives of the similar federal law, which did not legally require any quantity of oil by weight for avocados.[162] The Court reasoned that there was no obstacle because there was a way to satisfy both standards—by having Florida avocado growers alter when they harvested and shipped the avocados to meet the California state law

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[156] *See* 21 U.S.C. § 343(w) (2012); *see also* Use of the Term ''Natural'' in the Labeling of Human Food Products; Request for Information and Comments, 80 Fed. Reg., 69,905 (Nov. 12, 2015) (to be codified at 21 C.F.R. pt. 101).

[157] *See* HUTT, MERRILL & GROSSMAN, *supra* note 77, at 292–99.

[158] *Id.* at 292.

[159] *See id.*

[160] *Id.*

[161] Florida Lime and Avocado Growers, Inc. v. Paul, 373 U.S. 132, 133 (1963); *see also* HUTT, MERRILL & GROSSMAN, *supra* note 77, at 292–302.

[162] *See Florida Lime and Avocado Growers, Inc.*, 373 U.S. at 141; *see also* HUTT, MERRILL & GROSSMAN, *supra* note 77, at 300.

requirement.[163] As a general principle to be applied in future cases, the Court explained that "federal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that Congress has unmistakably so ordained."[164] In this case, one might make the argument that "Congress had unmistakably so ordained" that food allergies be regulated by itself and FDA, rather than by states.[165] By the same token, there would not be an obstacle as defined under *Florida Lime and Avocado Growers* to include sesame regulation in addition to other major and non-major food allergen regulations.

By contrast, in *Jones v. Rath Packaging, Co.*, the Court held that a state requirement that the weight of an amount of flour be the same as the amount of flour on the label was an obstacle to the federal law that allowed for variations between the two values.[166] The Court explained that Congress' objective and purpose in allowing for variation was to account for natural processes like loss of moisture during good distribution practices, something the California state regulation did not do.[167] Thus, should consumers compare a California-regulated bag of flour to another state's bag of flour that followed federal law, they would be misled because the amounts would not be the same.[168] Therefore, because it was clear that "Congress had unmistakably so ordained"[169] that variation was to allow for natural processes, the state requirement was an obstacle, and thus preempted.[170] Unlike in this case, though, the general purpose of FALCPA is to protect the public from prevalent and severe food allergies.[171] Thus, adding one food to be disclosed on a label would likely not thwart the will of Congress in this respect. Therefore, under both doctrines of conflict preemption, a sesame allergy class action would likely move forward.

4. More Considerations: Preemption under a Failure to Warn Approach

One response to litigating under a theory of false and misleading advertising might be that a failure to warn theory of liability would prove more accurate and successful. Under this theory, a consumer-plaintiff could seek relief for a manufacturer's failure to warn consumers of the presence of sesame in a product that caused the allergic reaction(s). While a failure to warn claim might provide a stronger approach to litigating a food allergy class action, it too would encounter the preemption problem because this claim relies on categorizing sesame as a food allergen. Once sesame is

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[163] *Id.*

[164] *See Florida Lime and Avocado Growers, Inc.*, 373 U.S. at 142; *see also* HUTT, MERRILL & GROSSMAN, *supra* note 77, at 300.

[165] *Id.*

[166] *See* Jones v. Rath Packaging, Co., 430 U.S. 519, 540–43 (1977); *see also* HUTT, MERRILL & GROSSMAN, *supra* note 77, at 305–07.

[167] *Id.*

[168] *Id.*

[169] *See Florida Lime and Avocado Growers, Inc.*, 373 U.S. at 142; *see also* HUTT, MERRILL & GROSSMAN, *supra* note 77, at 300.

[170] *See* Jones v. Rath Packaging, Co., 430 U.S. at 540–43 (1977); *see also* HUTT, MERRILL & GROSSMAN, *supra* note 77, at 305–07.

[171] That sesame seeds did not make the list of FALCPA allergens does not mean their protection is against the intent of Congress.

categorized as a food allergen, the exception for "identical" regulations described above would not apply, as there would be a state law requirement (that sesame should be regulated as a food allergen) different from federal law requirements. The only way one might get around preemption, if this argument would persuade a court, would be to rely on the uncodified NLEA § 6(c)(2), arguing that labeling sesame was not preempted as a food allergen label because it provided "a warning concerning the safety of the food or a component of the food."[172] This is one advantage of taking the position that the omission of labeling sesame is misleading. As discussed above, alleging that the absence of labeling sesame is false and misleading to consumers, rather than alleging sesame must disclosed because it is an allergen, might allow for the intended effect—the labeling of sesame—without the preemptive effect of 21 U.S.C. § 343-1(a).

5. Conclusions

Preemption will be a tricky issue for plaintiff-side lawyers. There is a very real possibility that state law regulations are entirely preempted by Congress's act of granting FDA the jurisdiction over food allergies broadly. However, given the very specific language of the statute and the requirements of NLEA § (6)(c)(2), as well as NLEA's express savings clause, it is possible the state laws surrounding sesame regulation would not be preempted. Still, preemption remains the main hurdle a party would have to jump to even begin to think about relief on a class action, or even individualized, basis.

6. Standing: Doctrinal Requirements

To bring a case, a plaintiff-lawyer will have to satisfy Article III standing and prudential standing.[173] Article III standing requires an injury in fact, causation, and redressability.[174] Prudential standing, or requirements generally recognized by the courts, generally requires that: a grievance be particular rather than generalized; parties cannot raise the grievances of outside, third parties;[175] and the injury fall within the "zone of interest."[176] Because the cases below bring up unique standing issues, and because it does not appear that these initial standing concerns are addressed at length in relevant case law, the above tests will not be addressed further.[177] However, because

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[172] James M. Beck, *Food Fight: FDA Preemption and Food Labeling Claims*, LAW360 (Jan. 27, 2011, 2:14 PM), http://www.law360.com/articles/221444/food-fight-fda-preemption-and-food-labeling-claims (quoting uncodified NLEA § 6(c)(2)).

[173] *See* SARGENT SHRIVER NATIONAL CENTER ON POVERTY LAW, *Standing*, *in* FEDERAL PRACTICE MANUAL FOR LEGAL AID ATTORNEYS, http://federalpracticemanual.org/chapter3/section1 (last updated 2016). The author recognizes individual state court standing requirements may vary.

[174] For a few cases that explicate the standing requirements, see generally Allen v. Wright, 468 U.S. 737 (1984); Ass'n of Data Processing Serv. Org. v. ADAPSO Camp, 397 U.S. 150 (1970); Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992).

[175] *See* JOSEPH HAGE AARONSON LLC, *Prudential vs. Constitutional Standing*, COMPLEX LITIG. BLOG (Oct. 23, 2012), http://www.jha.com/us/blog/?blogID=2210.

[176] *See Ass'n of Data Processing Serv. Org.*, 397 U.S. at 150.

[177] *See, e.g.*, Hodsdon v. Mars, Inc., 162 F. Supp. 3d 1016 (N.D. Cal. 2016); Hinojos v. Kohl's Corp., 718 F.3d 1098, 1104 (9th Cir. 2013). This note will not weigh in on the circuit split regarding prudential standing or the debate of whether it is a true requirement for standing at all. *See generally* Joseph, *supra* note 175; S. Todd Brown, *Story of Prudential Standing*, 42 HASTINGS CONST. L.Q. 95 (2014); Micah Revell,

the preemption analysis above suggests that statutory claims under California's UCL, FAL, and CLRA would put a sesame allergy class action in a strong chance to succeed, one must also consider these particular statutes' standing requirements, which are modified by California's Prop 64.[178] To have standing under both the UCL and the FAL, one needs facts showing that someone "suffered injury in fact and lost money or property as a result of unfair competition."[179] In order to do this, one must "demonstrate actual reliance on the allegedly deceptive or misleading statements."[180] For the CLRA, one needs proof of actual reliance and economic injury.[181] Importantly for a food allergy class action, economic injury in the form of money that was paid for a product that a plaintiff would never have purchased had she known information qualifies as economic injury under all three statutes. Moreover, it would be simple enough to establish actual reliance, as if the person had not relied on the absence of a warning of sesame, she would not have purchased and consumed the product.

7. Standing: Considerations When Seeking Injunctive Relief under Statute

Most "natural" litigation questions of standing turn on whether one is seeking injunctive relief or monetary relief. Because this case is one in which injunctive relief is the goal, I have focused my analysis on the results of standing when the plaintiff seeks injunctive relief. [182]

First, in the most basic sense, plaintiffs typically needed to have purchased the product to be considered to have standing.[183] Some plaintiffs have alleged that their claims should extend to products that they have not purchased, but are "substantially similar" to those products.[184] Under these circumstances, courts have been hesitant to allow for relief.[185] Once it has been established that a plaintiff has purchased the product, most judges entertain whether injunctive relief is appropriate.[186] Second, only

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Prudential Standing, Zone of Interests, and the New Jurisprudence of Jurisdiction, 63 EMORY L.J. 221 (2013). It also will not address the recent discussion on standing in *Spokeo*. *See* Spokeo, Inc. v. Robins, 136 S. Ct. 1540 (2016).

[178] JULIA B. STRICKLAND ET AL., 2015 ANNUAL OVERVIEW OF CALIFORNIA'S UNFAIR COMPETITION LAW AND CONSUMER LEGAL REMEDIES ACT (2015), http://www.stroock.com/siteFiles/Publications/UCLAnnualUpdate2015.pdf.

[179] *See* CAL. BUS. AND PROF. CODE § 17204 (West, Westlaw through 2015–2016 Legis. Sess.); *id.* § 17536.

[180] *See* Kwikset Corp. v. Superior Court, 246 P.3d 877, 888 (Cal. 2011).

[181] Victor v. R.C. Bigelow, Inc., No. 13-CV-02976-WHO, 2014 WL 1028881, at *5 (N.D. Cal. Mar. 14, 2014).

[182] Again, one could argue here that a failure to warn claim is a more correct theory to apply. To continue the thought experiment of protecting sesame allergy through a misleading claim, a failure to warn claim will not be analyzed further in this note.

[183] *See* Maxwell v. Unilever United States, Inc., No. 5:12–CV–01736–EJD, 2014 WL 4275712, *4 (N.D. Cal. Aug. 28, 2014) (citing *Kwikset*, 246 P.3d at 884–85).

[184] *Id.* at *5.

[185] *See id.*

[186] *See, e.g.*, Hodsdon v. Mars, Inc., 162 F. Supp. 3d 1016, 1022 (N.D. Cal. 2016); Hinojos v. Kohl's Corp., 718 F.3d 1098, 1104 (9th Cir. 2013) (quoting Kwikset Corp. v. Superior Court, 246 P.3d 877, 890–91 (Cal. 2011)).

the class representative need meet the UCL's requirement for standing.[187] Third, claims that ask for injunctive relief for a product that a consumer has already purchased, found unacceptable, and presumably will not purchase again typically fail; courts have held that this knowledge that the product is not what the plaintiff thought it was (100% "natural," or something similar) bars the plaintiff from seeking injunctive relief.[188] Therefore, unless the plaintiff specifically alleges that he or she will continue to purchase the product after knowing it was not 100% "natural," or whatever the case may be—and thus alleging that future harm will continue to be incurred without the injunction—the claim for injunctive relief will likely fail.

However, recent case law demonstrates how to get around this specifically in the context of California's statutory consumer protection law claims. *Hodsdon v. Mars* does not seem to follow the above logic, allowing for consumer protection claims to move forward beyond standing after simply alleging economic injury.[189] With this in mind, this note will focus specifically on three consumer protection statute claims, the UCL, the FAL, and the CLRA, and their relation to a potential sesame allergy class action.[190]

C. What Claims Can One Bring?

1. Background on California Consumer Protection Statutes

The California Sherman Food, Drug, and Cosmetic Law (Sherman Law) is California's state statute codifying the FDCA. In other words, it "incorporates the requirements of the FDCA as the food labeling requirements of the state of California."[191] Violation of the Sherman Act itself is only one element in underlying state-law consumer protection statutes.[192] Thus, violations of the act can "give rise" to other causes of action,[193] including the UCL, the FAL, and the CLRA.[194] Because these three statutes make up the most common claims brought by food litigators, they will each be analyzed for their ability to provide a suitable cause of action for a sesame allergy case.[195]

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[187] *In re* Tobacco II Cases, 207 P.3d 20, 31–39 (Cal. 2009).

[188] *See* Harrison, *supra* note 76, at 2 ("courts have found that plaintiffs lack standing to pursue injunctive relief where they are either on notice that the "all-natural" labels are inaccurate or do not allege they will buy the product at issue in the future").

[189] Hodsdon v. Mars, Inc., 162 F. Supp. 3d 1016 (N.D. Cal. 2016).

[190] Readers should note some theories discussed here are currently on appeal in the Ninth Circuit, so this analysis may change in the near future.

[191] Bishop v. 7-Eleven, Inc., 37 F. Supp. 3d 1058, 1064 (N.D. Cal. 2014).

[192] *See California Adopts Narrow View of Implied Federal Preemption of State Law Claims*, BEVERIDGE AND DIAMOND, PC (Feb. 26, 2008), http://www.bdlaw.com/news-280.html. This is likely because there is no private cause of action in the statute. James T. O'Reilly, *Deregulation and Private Causes of Action: Second Bites at the Apple*, 28 WM. & MARY L. REV. 223, 252 (1987).

[193] *See* Beveridge, *supra* note 192.

[194] *See Bishop*, 37 F. Supp. 3d at 1064. This seems to function similarly to the FDCA itself, which does not provide a private cause of action. *See* O'Reilly, *supra* note 192.

[195] Note that these statutes allow a judge to grant injunctive and monetary relief in the same suit (at least with consumer protection law). Therefore, this statutory remedy provides the key required to make both a morally-correct and public impact litigation sesame class action work.

2. *Unfair Competition Claims: The UCL*

Under the UCL, "unfair competition" is defined as one of the following five "wrongs": (1) an "unlawful" business act or practice; (2) an "unfair" business act or practice; (3) a "fraudulent" business act or practice; (4) "unfair, deceptive, untrue or misleading advertising"; and (5) any act prohibited by sections 17500 through 17577.5.[196] Moreover, "each of the 'wrongs' operates independently from the others."[197] In this case, claims four and five are commonly referred to as the California False Advertising Law (FAL).[198] However, before even considering the case law on the subject, one doctrinal block prevents the case from moving forward if the case were to focus on anything other than already injured plaintiffs seeking injunctive relief.

3. *More Arguments for Choosing Injunctive Relief for an Already-Injured Class*

a. *Standing Under the UCL*

As explained above, standing under the UCL is modified by California's Prop 64, and is met when a plaintiff "has suffered an injury in fact and has lost money or property as a result of a violation of this chapter."[199] While this is not a problem for a class with presently-injured claimants who have purchased and consumed a product, it is a problem for future claimants seeking injunctive relief. Because future claimants who are at risk of suffering an allergic reaction have not likely experienced an "injury in fact,"[200] and even if they have, those who have not purchased a food product have not "lost money or property" because of the unfair competition, any class encompassing future claimants within this claim will likely fail on standing grounds. Thus, this group is not a good candidate to use to create a sesame allergy class action. Case law in the area, though scarce,[201] supports this contention, especially because plaintiffs who bring claims under the UCL must allege economic injuries.[202] If the case were to reach the merits, case law does not offer much guidance as to what a court might do. In most instances, plaintiffs allege that phrases like "no cholesterol" and "0g trans fat" are misleading or deceptive.[203] As long as there is nothing false about the

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[196] *See* CAL. BUS. & PROF. CODE § 17500–17577.5 (West, Westlaw through 2015-2016 Legis. Sess.); Strickland et al., *supra* note 177, at 1.

[197] Strickland et al., *supra* note 178, at 1.

[198] *See* CAL. BUS. AND PROF. CODE § 17200 (Unfair Competition), 17500 (False Advertising) (West, Westlaw through 2015–2016 Legis. Sess.).

[199] Strickland et al., *supra* note 178, at 5 (citing CAL. BUS. AND PROF. CODE §§ 17204, 17535).

[200] For case law on an injury in fact, see Allen v. Wright, 468 U.S. 737 (1984); Ass'n of Data Processing Serv. Org. v. Camp, 397 U.S. 150 (1970); Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992).

[201] Sherman Food, Drug, and Cosmetic Law, CAL. HEALTH & SAFETY CODE § 109875–111915 (West, Westlaw through 2015–2016 Legis. Sess.), http://www.cdph.ca.gov/services/Documents/fdbSFDCA.pdf.

[202] Bishop v. 7-Eleven, Inc., 37 F. Supp. 3d 1058, 1064 (N.D. Cal. 2014).

[203] *See generally id.*; Delacruz v. Cytosport, Inc., No. C11–3532 CW, 2012 WL 2563857 (N.D. Cal. June 28, 2012); Wilson v. Frito-Lay, North America, Inc., No. 12–1586 SC, 2013 WL 1320468 (N.D. Cal. April 1, 2013); Samet v. Procter & Gamble, Co., No. 5:12–CV–01891 PSG, 2013 WL 3124647 (N.D. Cal. June 18, 2013).

statements on their faces, courts have held that consumers' interpretations of the labels are not actionable under the UCL.[204] However, because at least one court noted it is possible for a label itself to mislead consumers,[205] if one could find a way around the standing issue, one could allege that an absence of sesame would be misleading to consumers who have a sesame allergy and who would not have purchased the item had they known that sesame was in the product.

b. Monetary v. Injunctive Relief under the UCL

Pursuing a UCL claim may or may not be worth it for monetary relief given the statute's provision regarding relief. The UCL does not permit monetary damages.[206] Rather, only injunctive relief and restitution are available in cases brought by private citizens.[207] Regardless of whether there will be a theoretical problem obtaining both forms of relief in one suit,[208] limiting the relief one who has experienced additional personal injury, pain, and suffering as a result of anaphylaxis can receive to restitution rather than damages does not seem to provide a fair remedy to those class members. Moreover, until recently, granting UCL injunctions seemed unpredictable and "highly case-specific."[209] In one case, a "court exercised its injunctive power to require a ten-year mandatory disclosure in the form of a warning on the defendant's future products."[210] But in another case:

> [A]n injunction requiring defendant to have appropriate policies and procedures to ensure that defendant and its dealers 'promptly' complied with 'replacement or restitution' remedy contained in the Song-Beverly Warranty Act was improper because: (1) injunctive relief under the UCL should be withheld where there is an adequate remedy at law; and (2) a court of equity 'should not intervene under the guise of the UCL where injunctive relief implicates matters of complex economic policy, where the injunction would lead to a multiplicity of enforcement actions, and/or result in ongoing judicial supervision of an industry.'[211]

Therefore, while it may turn out to be the case that a UCL claim would be the best option to seek relief that would suit all class members, further analysis is required to see if other options could produce better and fairer results. However, recent case law outside of the "natural" litigation world offers an interesting way to successfully assert

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[204] *See Bishop*, 37 F. Supp. 3d at 1066 (citing *Delacruz*, 2012 WL 2563857, at *8–10). *But see* Bishop v. 7-Eleven, Inc., 651 F. App'x 657, 658 (9th Cir. June 6, 2016) (overturning the district court's holding that the plaintiff "failed to allege facts sufficient to establish statutory standing" under the UCL, FAL, and CLRA).

[205] *See Bishop*, 37 F. Supp. 3d at 1066–67 (citing *Samet*, 2013 WL 3124647, at *8 (citing *Wilson*, 2013 WL 1320468, at *13)).

[206] Strickland, et al., *supra* note 177 at 38–39 (citing CAL. BUS. & PROF. CODE § 17203).

[207] *Id.*; *see also* Kwikset Corp. v. Superior Court, 246 P.3d 877, 894–95 (Cal. 2011) (explaining that a plaintiff without a right to restitution may nonetheless pursue a claim).

[208] Strickland et al., *supra* note 178, at 47.

[209] *Id.*

[210] *Id.*

[211] *See id.*

a UCL claim for injunctive relief with present, or already-injured, claimants in a context that could be utilized when litigating a sesame allergy class action case.

4. Substantive Consumer Protection Claims: UCL, FAL, and CLRA for both "Natural" and Sesame Allergy Litigation

a. UCL

California's unfair competition law provides two main avenues for thinking about a sesame allergy class action litigation claim seeking injunctive relief for injured claimants. The first is in the context of a theory of an omission. Typically a company cannot be sued for anything that is not explicitly stated on its label, but the company may have a duty to disclose information if there is a safety issue or product defect that a reasonable consumer would not be aware of without the warning.[212] The second is in the context of the "unfair" prong of the UCL, where if one can prove the conduct was "substantially injurious to consumers" or somehow against public policy, then it is a violation of the UCL.[213] Each of these violations will be considered in turn.

i. Omissions and the UCL

The Ninth Circuit has recognized that "'when analyzing a UCL, CLRA, or fraudulent concealment claim, California law instructs that a manufacturer's duty to consumers is limited to its warranty, unless a safety issue is present or there has been some affirmative misrepresentation.'"[214] Thus, if safety or an affirmative misrepresentation is at issue, a company will have a duty to disclose the information causing the safety risk or affirmative misrepresentation.[215] The test for determining when the information is enough of a safety hazard or an affirmative misrepresentation to require disclosure is a reasonable consumer test.[216] When members of the public are likely to be deceived by the absence of information on the labeling of a product, a company has the duty to disclose the information.[217]

Though the court does not make clear what threshold one must allege or obtain to achieve reasonableness in this context, a claim that a reasonable person would likely

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[212] Hodsdon v. Mars, Inc., 162 F. Supp. 3d 1016, 1022–23 (N.D. Cal. 2016). There "may" be a duty because other published cases come to the opposite conclusion. *See, e.g.*, Daugherty v. Am. Honda Motor Co., Inc., 144 Cal. App. 4th 824, 838 (2006) ("We cannot agree that a failure to disclose a fact one has no affirmative duty to disclose is 'likely to deceive' anyone within the meaning of the UCL.").

[213] Strickland, et al., *supra* note 177, at 20 (citing Cmty. Assisting Recovery, Inc. v. Aegis Sec. Ins. Co., 92 Cal. App. 4th 886, 894 (2001); Podolsky v. First Healthcare Corp., 50 Cal. App. 4th 632, 647 (1996). *See also* Bardin v. Daimler Chrysler Corp., 136 Cal. App. 4th 1255, 1270 (2006); Jolley v. Chase Home Fin., 213 Cal. App. 4th 872, 907–08 (2013) ("holding that although 'dual tracking'—pursuing mortgage foreclosure while negotiating loan modification—was not illegal when it occurred, legislature's subsequent prohibition supported grounds for allegation of 'unfair' conduct; 'while dual tracking may not have been forbidden by statute at the time, the new legislation and its legislative history may still contribute to its being considered 'unfair' for purposes of the UCL.'")).

[214] Gray v. Toyota Motor Sales, U.S.A., Inc., 554 F. App'x 608, 609 (9th Cir. Feb. 5, 2014) (quoting Daugherty v. Am. Honda Motor Co., 144 Cal. App. 4th 824, 834–35 (2006)).

[215] Willis v. Buffalo Pumps Inc., 34 F. Supp. 3d 1117, 1132 (S.D. Cal. 2014); *see Hodsdon*, 162 F. Supp. 3d at 1023.

[216] *See Hodsdon*, 162 F. Supp. 3d at 1023.

[217] *Id.*

be deceived into thinking that sesame was not present in a product when it actually was will likely qualify as enough to lead to a duty to disclose information about sesame.[218] Here, the safety risk at issue is that non-disclosure could cause a life-threatening anaphylactic reaction for those within the public with the allergy.[219] Whether this claim would be successful in court is outside the scope of this note, but in this context, this is likely a strong legal theory to consider.

ii. The Unfair Prong under the UCL

There is also a claim within the unfair prong of the UCL that could prove fruitful. In addition to its description as having five elements, the UCL is often also referred to as having three prongs, any one of which allows for a cause of action by a plaintiff: the unfair prong, the fraudulent prong, and the unlawful prong.[220] There are two tests that allow someone to allege a violation of the unfair prong.[221] The first defines a business practice as "unfair" when it "'offends an established public policy or when the practice is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers.'"[222] Here, the fact that sesame can cause anaphylactic shock is certainly "substantially injurious to consumers" with that food allergy; thus, the lack of information on or the omission of a label might be classified as an "unfair" business practice. The second test defines a business practice as "unfair" when it violates some form of public policy, i.e., the "UCL claim [must] be tethered to some 'specific constitutional, statutory, or regulatory provisions.'"[223] Though this claim might be harder to make, one could try to argue that, by not disclosing sesame on the label, one is violating the general purpose of FALCPA, even though sesame itself is not currently recognized as a major or non-major allergen. Given the unstable state of this area of law right now, and the fact that this case is currently on appeal in the Ninth Circuit, the unfair prong path for relief should be treated as more of a possibility for the time being.

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[218] This is provided that the disclosure of sesame on a product is not preempted, as discussed above.

[219] The author must also consider other facets of this reasonable consumer. Is the reasonable consumer someone who would presumptively not have food allergies? Does that even matter in this analysis, as even a reasonable consumer who did not have a sesame allergy would likely be deceived by a lack of sesame labeling on a product if the product does in fact contain sesame? These are all considerations for later with respect to the reasonable consumer test in this area of developing case law.

[220] Joseph G. Adams & Lindsay E. Martínez, *Welcome to California Business Litigation #7: Understanding California's Unfair Competition and False Advertising Laws*, WELCOME TO CALIFORNIA BUSINESS LITIGATION, 1, (Snell & Willmer, Phoenix, Ariz.), Dec. 27, 2013, 1, https://www.swlaw.com/assets/pdf/publications/2013/12/27/Understanding%20California%20Unfair%20Competition%20Laws.pdf.

[221] Currently, California law is in flux, and thus there are two tests for determining unfair conduct. *Hodsdon*, 162 F. Supp. 3d at 1024.

[222] *See Hodsdon*, 162 F. Supp. 3d at 1024 (quoting S. Bay Chevrolet v. Gen. Motors Acceptance Corp., 72 Cal. App. 4th 861, 886–87 (1999)).

[223] McVicar v. Goodman Global, Inc., 1 F. Supp. 3d 1044, 1054 (C.D. Cal. 2014) (citing Scripps Clinic v. Superior Court, 108 Cal. App. 4th 917, 940 (2003); Gregory v. Albertson's, Inc., 104 Cal. App. 4th 845, 854 (2002)).

b. CLRA

The California Consumer Legal Remedies Act (CLRA) "'was enacted in an attempt to alleviate social and economic problems stemming from deceptive business practices . . . .'"[224] The California legislature "intended that courts construe the CLRA liberally to 'protect consumers against unfair and deceptive business practices and provide efficient and economical procedures to secure such protection.'"[225] Moreover, the CLRA allows for legal and equitable relief, including actual damages,[226] restitution, injunctive relief, and punitive damages.[227]

Similarly to the UCL, the CLRA can be violated when a company had a duty to disclose information with respect to a safety issue or a product defect and it omitted that particular information on its packaging.[228] A similar theory would apply—here, a food company violated the UCL when it failed to disclose important information regarding sesame allergens on its labeling, thus risking the safety of the sesame-allergic consumer and/or friends and family who purchased those products for their sesame-allergic friends or family. Like with the first UCL claim, this is at least a plausible theory of liability, but time will tell whether it will stand up in court.

c. FAL

Under the California Food and Drug Sherman Act section 110390, "it is unlawful for any person to disseminate any false advertisement of any food, drug, device, or cosmetic."[229] "An advertisement is false if it is false or misleading in any particular."[230] In order for a sesame allergy claim to be successful under FAL, one would have to allege the omission of advertising and/or labeling led to injury. Though one might initially think that a false advertising claim might work well with the non-labeling of a sesame allergy class action, there is a split in case law as to what one should do if presented with an omission of a statement on a bottle that would be considered grounds for making a false advertising claim.[231] In one line of cases, an omission can never be recognized as a false advertising claim under the FAL.[232] In another line of cases, one can allege a false advertising claim based on an omission.[233] The District Court for the Northern District of California has characterized the difference between when one can and cannot allege a violation of false advertising law based on an omission. When one party makes no statement as to the alleged false advertising at all, there is no false advertising claim.[234] However, if one party makes a statement but then omits

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[224] *See* Strickland, et al., *supra* note 178, at 70.

[225] *Id.* (quoting CAL. CIV. CODE § 1760).

[226] Damages allow for a $1,000 minimum in class actions. *See id.* at 88.

[227] *Id.*

[228] Gray v. Toyota Motor Sales, U.S.A., Inc., 554 F. App'x 608, 609 (9th Cir. Feb. 5, 2014).

[229] Sherman Food, Drug, and Cosmetic Law, *supra* note 201.

[230] *Id.*

[231] *See* Hodsdon v. Mars, Inc., 162 F. Supp. 3d 1016, 1022–23 (N.D. Cal. 2016).

[232] *Id.* (citing Norcia v. Samsung Telecomms. Am., No. 14–CV–00582–JD, 2015 WL 4967247, at *8 (N.D. Cal. Aug. 20, 2015)).

[233] *See id.*

[234] *See Hodsdon*, 162 F. Supp. 3d at 1023.

"information that undercuts the veracity of the statement," then there is a false advertising claim.[235] For example, in *In re Sony Gaming Networks and Consumer Data Security Breach Litigation*, a computer network system manufacturer "had claimed to take reasonable steps to secure users' personal information, but omitted information about deficiencies in the product's security system."[236] This affirmative claim, followed by an omission of critical information with respect to deficiencies in the product, was enough to convince the court to deny defendant's motion to dismiss.[237] In *Tait v. BSH Home Appliances Corp.*, plaintiffs sued a home appliances manufacturer that had claimed that its washing machines were "Xxtra Sanitary" and had "high efficiency" because the machines "accumulated mold and bacteria and required extra cleaning."[238] Because the manufacturers had made some claim as to the cleanliness of its product, and this claim turned out to be misleading because the machines actually required *more* cleaning, a false advertising claim was appropriate.[239]

Based on this analysis and the scant case law surrounding this issue, it is difficult to determine whether a claim applied to sesame allergy might succeed. The case law does not flesh out how broad or narrow the scope of the claim can be to be viable. Accordingly, it is difficult to predict how a court would decide a claim alleging false advertising based on omission that falls outside of this developed schema. If the scope of the claim would have to be as narrow as saying that a person could only allege a sesame false advertising suit if the company had promised there was not sesame in a product, but there in fact was, then this would not be a useful claim. Very few if any companies explicitly state that they do not have sesame in them because it is not required by FALCPA. While one might think to broaden the claim to include a company that might allege its product to be "allergy-free," the claim would fall short, as again FALCPA currently does not cover sesame and it would not be logical or fair to the company to hold it accountable for every possible allergen that could exist.[240] Therefore, given recent court interpretations of which claims are acceptable and which ones are not under the FAL with respect to an omission, this will not be the most effective route to successfully litigate a sesame allergy class action.

D. Planning for the Future: Final Thoughts on "Natural" Litigation

This final section will briefly examine two other common problems that have arisen for plaintiff lawyers suing in "natural" litigation. They are the motion to dismiss and problems with ascertainability for class certification. While a comparison with a potential sesame allergy will not be examined, it is still important to see how past litigation could shape the present if one were to try litigating a sesame allergy class action.

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[235] *See id.*

[236] *Id.* (explaining *In re* Sony Gaming Networks and Customer Data Sec. Breach Litig., 996 F. Supp. 2d 942, 990 (S.D. Cal. 2014)).

[237] *Id.*

[238] *Hodsdon*, 162 F. Supp. 3d at 1023 (explaining Tait v. BSH Home Appliances Corp., No. SACV 10–00711 DOC (ANx), 2011 WL 3941387, at *1 (C.D. Cal. 2011)).

[239] *See Tait*, 2011 WL 3941387, at *2 (C.D. Cal. 2011).

[240] If anyone were to go that far, any ingredient in a company's product could lead to liability.

E. Evaluating Motions to Dismiss

Within the "natural" litigation world, as in other litigation, one of defense attorneys' favorite mechanisms to block a plaintiff suit is the motion to dismiss. There are two common legal theories used to demonstrate why the plaintiff's case should not survive the motion to dismiss.

The first theory is that the plaintiff did not adequately allege certain elements of the claim. As with other causes of action, plaintiffs must meet all elements of a particular claim in order to successfully pass a defendant's inevitable motion to dismiss. If they cannot meet these elements, the claim is dismissed. For instance, in *Kane v. Chobani*, the plaintiffs "failed to allege reliance and economic injury, which were required to be pled under the 'unlawful' prong of California's Unfair Competition Law."[241]

However, the second is more unique to the "natural" litigation. A few defendants have tried to allege that merely disclosing the items in question on the packaging information and ingredient list on the back of the label of any product—without any reference as to whether they are "natural" or unnatural"—frees them from any liability they might incur from stating their product, or certain ingredients in their products, are "natural" on the front of the label.[242] Courts have found this logic unpersuasive, and have consistently said that merely stating packaging information and ingredient lists cannot shield a plaintiff from liability.[243] While there is no way to know for sure what kinds of allegations defendants will make to dismiss the cases, these examples from "natural" litigation provide some idea of what issues may come up in other food-related contexts.

F. Class Certification: Eyes on Ascertainability

Once the lawsuit has made it past the initial concerns of bringing a claim and evaluating its legal worth, it stands to experience trouble at the class certification stage. While some of the "natural" class actions have been certified (even for injunctive relief),[244] one common roadblock has been problems with ascertainability.

Many successful defense-side lawsuits in the "natural" litigation world have turned on questions of ascertainability. "In the class action context, ascertainability means that the members of a certified class must be sufficiently definite," meaning that "class members can be easily ascertained or determined using objective criteria."[245] Though

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[241] Harrison, et al., *supra* note 76, at 2 (summarizing Kane v. Chobani, 973 F. Supp. 2d 1120 (N.D. Cal. 2014)). However, in March of 2016, the Ninth Circuit vacated the judgment of the district court, and remanded the case, and ordered a stay on the case until FDA had finished producing a final ruling on the term "natural." *See* Kane v. Chobani, No. 14–15670, 2016 WL 1161782 (9th Cir. March 24, 2016).

[242] *See* Harrison, et al., *supra* note 76, at 2–3 (summarizing, e.g., Hall v. Diamond Foods, Inc., 2014 WL 3779012 (N.D. Cal. July 31, 2014); Dye v. Bodacious Food Co., Case No. 14-cv-80627 (S.D. Fla. Sept. 9, 2014)).

[243] *See* Harrison, et al., *supra* note 76, at 2–3 (summarizing, e.g., *Hall*, 2014 WL 3779012).

[244] *See* Brazil v. Dole Packaged Foods, L.L.C., Case No.: 12–CV–01831–LHK, 2014 WL 2466559, at *15 (N.D. Cal. Nov. 6, 2014).

[245] JOHN H. BEISNER ET AL., THE IMPLICIT ASCERTAINBILITY REQUIREMENT FOR CLASS ACTIONS (2014),https://www.skadden.com/sites/default/files/publications/The%20Implicit%20Ascertainability%20Requirement%20for%20Class%20Actions.pdf.

in some instances, courts have found ascertainability arguments persuasive,[246] in most instances it stands as a significant roadblock to "natural" claim certification. In *Jones v. ConAgra Foods, Inc.*, a case filed in 2014, plaintiffs claimed "seven Hunt's canned tomato product labels read '100% natural' or 'Free of Artificial Ingredients and Preservatives' when, in fact, the products contained citric acid and/or calcium chloride."[247] The court held that "even assuming that all proposed class members would be honest, it is difficult to imagine that they would be able to remember which particular Hunt's brand products they bought from 2008 to the present, and whether those products contained the challenged statements."[248]

Other courts have followed a similar logic,[249] since ultimately one must show how class membership will be verified for the suit to be ascertainable.[250] Yet, as another court recognizes, because the ascertainability requirement is largely based on a requirement that comes before Rule 23, there is no clear method to achieving ascertainability.[251] Like with the most common reasons for a motion to dismiss to arise, this research provides some insight into what courts might reason with respect to ascertainability for a sesame allergy class action.[252]

IV. FDA'S AUTHORITY TO REGULATE SESAME ALLERGY

A. FDA's Authority to Regulate Sesame Allergy

A sesame allergy class action may or may not survive the many hurdles discussed above. However, even bringing the action would act as one additional incentive for FDA to act on CSPI's citizen petition and the urgings of senators who asked for sesame to be regulated via the Food Labeling Modernization Act in 2015.[253] Instead of going through litigation channels, FDA could use its authority under FALCPA to promulgate

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[246] *See* Harrison, et al., *supra* note 76, at 6 (summarizing Ebin v. Kangadis Food Inc., 297 F.R.D. 561 (S.D.N.Y. 2014)).

[247] *Id.* at 5.

[248] Jones v. ConAgra Foods, Inc., No. C 12–01633 CRB, 2014 WL 2702726, at *10 (N.D. Cal. June 13, 2014).

[249] *See* Harrison, et al., *supra* note 76, at 6 (summarizing Hernandez v. Chipotle Mexican Grill, Inc., No. CV 12–5543 DSF (JCx), 2013 WL 6332002 (C.D. Cal. Dec. 2, 2013) (denying ascertainability where there was a lack of records of low price transactions); Astiana v. Ben & Jerry's Homemade, Inc., No. C 10–4387 PJH, 2014 WL 60097 (N.D. Cal. Jan. 7, 2014) (denying ascertainability where the plaintiff was unable to prove which ice cream might contain chemicals)).

[250] *See* Harrison, et al., *supra* note 76, at 6 (summarizing Langendorf v. Skinnygirl Cocktails, L.L.C., No. 11 CV 7060, 2014 WL 5487670 (N.D. Ill. Oct. 30, 2014)).

[251] *See* Sethavanish v. ZonePerfect Nutrition Co., Case No. 12–2907–SC, 2014 WL 580696, at *4–6 (N.D. Cal. Feb. 13, 2014) (discussing a circuit split on how to demonstrate ascertainability).

[252] At the same time, ascertainability may not pose a problem for a sesame allergy class action, as these people presumably will have had anaphylactic responses before and will be able to document their symptoms and identify the food product that made them ill. But this is ultimately at the judge's discretion.

[253] *See Sens. Blumenthal, Markey, Reps. Pallone, DeLauro Introduce Legislation to Modernize Food Labeling*, *supra* note 123.

regulations on sesame as a non-major allergen, as suggested by CSPI's petition.[254] However, if sesame is a major allergen, FDA may be powerless to regulate sesame without Congress amending FALCPA.

B. Major or Non-Major: FDA's Likely Classification of Sesame as a Major Allergen

When Congress passed FALCPA in 2004 it defined a major food allergen as specifically one of the following eight allergens: "milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans."[255] As previously discussed, the statute was a response to the prevalence and severity of food allergy.[256] The eight major allergens were designated because, at the time, those combined allergens constituted over ninety percent of all food allergies in the United States and represented the foods most likely to cause severe, life-threatening reactions.[257] With sesame now recognized as the sixth or seventh most common food allergen in the country, it is arguable that sesame should be included in the major allergen category.[258] If this is the case, Congress will have to add sesame to the major allergen list for FDA to regulate it, as Congress has mandated FDA not to regulate major allergens, and FDA has shown in past circumstances that it is hesitant to do so.[259]

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[254] *See* Carla M. Davis et al., *Sesame Citizen Petition*, CTR. FOR SCI. IN THE PUB. INT., (Nov. 18, 2014), https://cspinet.org/new/pdf/11-18-sesame-petition.pdf.

[255] 21 U.S.C. § 321 (qq)(1) (2012). It was also determined that "a food ingredient that contains protein derived from a food specified [as a major allergen]" qualified as a "major allergen," unless that food was "[a]ny highly refined oil derived from a food specified [as a major allergen] and any ingredient derived from such highly refined oil." *See* 21 U.S.C. § 321 (qq)(2)(a) (2012).

[256] *See generally* Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108–282, 118 Stat. 905 (codified as amended in scattered sections of title 21); *see also* Laura Derr, *When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004*, 61 FOOD AND DRUG L.J., 65, 149 (2006) (citing 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)).

[257] *Id.*

[258] See *Common Food Allergens, Food Allergy and Anaphylaxis*, FAACT, http://www.foodallergyawareness.org/foodallergy/food_allergens-11/ (last visited Oct. 7, 2016) for percentages of common allergens. *See also Open Sesame*, *supra* note 11, at 1. There may be a question as to whether FDA can expand the existing categories to include sesame given that FDA has issued guidance documents on what items are included within the "e.g." group for some allergens. On the one hand, because clarifying or even expanding existing categories of allergens is not the same thing as adding an entirely new category of allergen, one could argue that Congress would be the only body with the power to add additional allergens. On the other hand, if FDA has the authority to clarify or expand what foods count as an allergen because of the language of "e.g.," it may also have the power to interpret another allergen as being a part of the "major" allergen list. If FDA were to take the second approach, there would likely be litigation to determine if FDA has that authority. See Guidance on Food Allergens, FDA (October 2006), http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM301394.pdf for an example when FDA has given guidance on food allergens in the past.

[259] *See* Listing of Color Additives Exempt From Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine Declaration, 21 C.F.R. §§ 73, 101 (2016), https://www.federalregister.gov/documents/2009/01/05/E8-31253/listing-of-color-additives-exempt-from-certification-food-drug-and-cosmetic-labeling-cochineal (responding to comments on final rule for major food allergen).

However, if sesame is a non-major allergen, FDA has the authority to promulgate regulations that could treat sesame as a non-major allergen.[260] 21 U.S.C. § 343(x) states that "a spice, flavoring, coloring, or incidental additive that is, or that bears or contains, a food allergen (other than a major food allergen), as determined by the Secretary by regulation, shall be disclosed in a manner specified by the Secretary by regulation."[261] FDA has previously used its statutory authority under this provision to promulgate regulations for cochineal extract and carmine.[262] While FDA chose to require only that carmine be "declared prominently and conspicuously at least once in the labeling" and that carmine be labeled by name in the ingredient list, rather than having it follow the major allergen provisions, there does not seem to be anything stopping it from requiring that of sesame.[263]

However, as the agency indicated in its responses to comments on carmine—one of which asked why carmine was not subject to the same or similarly-strict labeling requirements as the major food allergens—only major allergens are required to be listed under the allergen information on food labels.[264] Given this collated information, it does not appear as though FDA will want to regulate a food allergen that might be classified as a major allergen. If FDA will not take action to regulate sesame allergy, the burden falls on Congress to protect sesame-allergy sufferers.

V. CONCLUSION

Through an analysis of relevant case law and the most important legal issues to this particular set of facts, this note has argued that protection of the public health of sesame-allergy sufferers may be furthered through consumer class action litigation, resulting (ideally) in either large food companies having to indicate sesame on their products, and/or FDA or Congress taking appropriate action to regulate sesame. Though ultimately traditional methods of legislative change may be the best solution to regulating sesame as an allergy, this note showcases the potential of impact litigation to affect not only the duties of private parties involved, but also outside actors

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[260] 21 U.S.C. § 343(x) (2012).

[261] *Id.*

[262] Listing of Color Additives Exempt from Certification, 21 C.F.R. § 73 (2014); Food Labeling, 21 C.F.R. § 101 (2014).

[263] *Guidance for Industry: Chochineal Extract and Carmine: Declaration by Name on the Label of All Foods and Cosmetic Products that Contain These Color Additives; Small Entity Compliance Guide* U.S. FOOD & DRUG ADMIN. (April 2009), http://www.fda.gov/ForIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/ucm153038.htm. 21 U.S.C. § 343(x) grants FDA authority to regulate other food allergens like sesame in a "spice, flavoring, coloring, or incidental additive." 21 U.S.C. § 343(x) (2012). If a case were to arise where there were no spices, flavors, etc. with sesame in them, but there was til oil in a product, a consumer without the knowledge that til oil is derived from sesame may believe a product is sesame-free when it is not. *See Open Sesame*, *supra* note 11, at 4 (explaining that the public does not know that til oil and other products are derived from sesame). Ensuring the labeling of sesame in any of its forms and attaching enforcement provisions to a manufacturer's violation of FDA standards are two reasons to regulate sesame as a major, rather than a non-major, allergen. Additionally, 21 USC § 343(x) only addresses of labeling, which leaves open the question of whether enforcement provisions that are linked to major allergens in FALCPA might also be outside of FDA's authority. *See* Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, 118 Stat. 905 (codified as amended in scattered sections of title 21); 21 U.S.C. § 343(x) (2012).

[264] Listing of Color Additives Exempt from Certification, 21 C.F.R. § 73 (2014); Food Labeling, 21 C.F.R. § 101 (2014).

and the importance of thinking strategically to enhance consumer protection within the law.