Note

May Contain Peanuts, Eggs, and a "Natural" Solution: How to Challenge Food Manufacturers' Harmful Use of Precautionary Allergen Labels

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Food allergies are one of the most pressing health issues of our time. Around thirty-three million Americans currently have food allergies, thirteen million of which are severe or life-threatening. These numbers continue to increase at alarming rates, with an estimated one in thirteen children being diagnosed with food allergies every year. Despite this surge, much is still unknown about food allergies, including, most notably, the underlying causes and potential cures. Currently, the only recommended treatment method is strict avoidance, leaving those with food allergies almost completely dependent on food labeling.

Despite the importance of food labels for those with allergies, Congressional action in the area fails to properly protect those with food allergies. In 2004, Congress passed the Food Allergen Labeling Consumer Protection Act (FALCPA), which mandates clear disclosure of the eight major allergens on food labels.

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* J.D. Candidate 2025, University of Minnesota Law School. I would like to express my deepest gratitude to everyone who made this Note possible. As someone with peanut, dairy, egg, tree nut, shellfish, and legume allergies, I would first like to thank the Law Review for giving me the opportunity to share my message. To the Honorable Elizabeth G. Bentley, thank you for helping me find my voice. To Dr. Pat Ebeling, Evan Dale, Scott Dewey, and all the other staffers and editors who helped make this Note possible, thank you for your careful attention and support as I went through this process. To Charles and Diane Tremblay, thank you for always doing everything you can to keep me safe. To my brother, Nathan, for always believing in me, and to my sister, Liz, for inspiring me with your strength. To my dad, Brian, for always reassuring me when I needed it the most, and to my mom, Janet, for never giving up. From making pizzas in kindergarten to experimenting with egg replacers, you always made me feel included and ensured that allergies never held me back. Lastly, to my wife, Gabrielle. Meeting you was the best thing that ever happened to me. All mistakes are my own.

Without question, this requirement made life easier for those with food allergies. Nevertheless, the FALCPA still falls short because it does not cover precautionary allergen labels (PALs). These advisory labels are below the ingredient list and state something like "may contain [allergen]."

PALs were originally intended to warn consumers of the risk of cross-contamination, but their current use has strayed far from this intended purpose. Because of the economic incentive they provide—applying a PAL is cheaper than adhering to stringent manufacturing hygiene—food manufacturers are applying PALs in a pervasive, haphazard way. This has caused PALs to lose all credibility amongst those with food allergies. In fact, most consumers now ignore them, creating the potential for an allergic reaction—the very thing PALs were intended to prevent.

This Note provides a path to challenge food manufacturers' haphazard PAL use through litigation. This Note first urges Congress and the FDA to standardize them. Since this is unlikely, the Note then urges consumers to act by filing lawsuits. Though PALs seemingly shield manufacturers from liability under traditional common law theories, this Note articulates an alternative approach through California's consumer protection statutes. This approach draws heavily on one taken by consumers challenging manufacturer use of the term "natural," which is similarly unregulated. Most "natural" lawsuits settled, but consumer action created a powerful deterrent effect that caused a sharp decrease in the use of the term. This Note concludes that this litigation approach is the best—and perhaps only—way for consumers to reduce PAL use and return them to their intended purpose.

INTRODUCTION

> *Since there is currently no cure for food allergies, consumers need to be empowered to know whether or not food allerg[ens] are present in the food they consume.*[1]

"Is it really that important?" a parent asked after Paul Jakobson's teacher announced a nut-free classroom policy.[2] Jakobson suffers from peanut and tree nut allergies, and his mom, Paola, refused to remain silent after hearing this question.[3] She sprang up, seizing the opportunity to inform other parents about the seriousness of food allergies and the importance of recognizing the threat those with food allergies face daily.[4] This interaction represents a microcosm of the experience of living with food allergies. On one hand, food allergy awareness has never been higher, causing schools, restaurants, and airplanes to take precautionary measures.[5] On the other hand, much skepticism remains about the validity of these measures, and society still lacks an understanding of the burdens those with food allergies, like Jakobson, face.[6]

Fundamentally, a food allergy is a potentially catastrophic, life-threatening immune response to certain foods that are harmless to others in the population.[7] For example, peanuts are a staple at ballgames and restaurants, but for about two percent

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1. H.R. REP. NO. 108-608, at 3 (2004) (describing the purpose of the Food Allergen Labeling Consumer Protection Act).

2. *Personal Stories*, MICH. MED., https://medicine.umich.edu/dept/food allergy/outreach-advocacy/personal-stories [https://perma.cc/VQW7-THKB].

3. *Id.* This incident happened while Jakobson was in middle school. *Id.* Paola first learned about Paul's food allergies when he started vomiting while eating a piece of peanut butter toast. *Id.*

4. *Id.*

5. *See, e.g.*, *Why Are Food Allergies on the Rise?, with Ruchi Gupta, MD, MPH*, N.W. MED. (Jan. 17, 2023), https://www.feinberg.northwestern.edu/research/podcast/food-allergies-on-the-rise.html [https://perma.cc/FQ53-LLS6] (noting the increased awareness around children with food allergies).

6. *See Take Action to Raise Food Allergy Awareness*, KIDS WITH FOOD ALLERGIES (Apr. 27, 2023), https://community.kidswithfoodallergies.org/blog/take-action-to-raise-food-allergy-awareness [https://perma.cc/GHR2-HS3Q] ("[M]any people still don't understand what it's like to live with [food allergies].").

7. *See generally What Is a Food Allergy?*, FOOD ALLERGY RSCH. & EDUC., https://www.foodallergy.org/resources/what-food-allergy [https://perma.cc/43VY-KVXV] (describing the seriousness of food allergies). A food allergy is, in its simplest nature, an immune system overreaction to a harmless substance. *Id.*

of Americans, peanuts present a lethal toxin.[8] Food allergies are often confused with food intolerances, but the two are not the same.[9] Food intolerances are digestive in nature and result in mild symptoms that occur after a couple of hours.[10] Food allergies, however, are an immune response and involve immediate, severe symptoms such as hives, swelling of the lips/face, and vomiting.[11] In some cases, this immune response causes anaphylactic shock, a life-threatening reaction that involves constriction of the airways and a steep blood pressure drop.[12] Emergency medical treatment is crucial to secure the health and safety of the individual including, when available, the administration of an Epi-Pen.[13] To add to the seriousness of these

8. Nigel Mark Thomas, *Racial and Ethnic Data Reported for Peanut Allergy Epidemiology Do Little to Advance its Cause, Treatment, or Prevention*, 9 FRONTIERS PUB. HEALTH, 2021, at 1, 1; *see also* Press Release, Natl Ctr. for Health Stats., More than a Quarter of U.S. Adults and Children Have at Least OneAllergy (Jan. 26, 2023) [hereinafter More than a Quarter], https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/20220126.htm [https://perma.cc/Q88B-LDJL].

9. Mayo Clinic Staff, *Food Allergy*, MAYO CLINIC (Aug. 30, 2024), https://www.mayoclinic.org/diseases-conditions/food-allergy/symptoms-causes/syc-20355095 [https://perma.cc/E7PH-PFQX]. This conflation can have devastating consequences for those with food allergies. *See* Domenico Gargano et al., *Food Allergy and Intolerance: A Narrative Review on Nutritional Concerns*, NUTRIENTS, May 2021, at 1, 9 (noting the "nutritional harms" that could occur from erroneous diagnostic procedures).

10. *See generally Food Intolerance*, CLEVELAND CLINIC (Aug. 8, 2021), https://my.clevelandclinic.org/health/diseases/21688-food-intolerance [https://perma.cc/CF96-LB99] (describing the basics of food intolerances).

11. *See, e.g.*, Mayo Clinic Staff, *supra* note 9 (describing the symptoms of an allergic reaction). On a molecular level, an allergic reaction proceeds as follows: upon the first introduction of the allergen to the body, the immune system makes an antibody protein called IgE, which then circulates throughout the bloodstream and attaches to immune system cells; when a person with IgE antibodies ingests the same allergen again, the allergen binds to the antibodies attached to the immune cells which causes the cells to release huge amounts of chemicals, leading to the symptoms associated with allergic reactions. *Causes and Prevention of Food Allergy*, NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES (June 10, 2024), https://www.niaid.nih.gov/diseases-conditions/food-allergy-causes-prevention [https://perma.cc/HJ2K-XFVP].

12. Mayo Clinic Staff, *supra* note 9.

13. *E.g.*, *Food Allergies*, JOHNS HOPKINS MED. [hereinafter JOHNS HOPKINS MED.], https://www.hopkinsmedicine.org/health/conditions-and-diseases/food-allergies [https://perma.cc/XKQ7-SG79] (identifying self-injecting epinephrine as a treatment for anaphylaxis). If left untreated, anaphylaxis leads to death. Mayo Clinic Staff, *supra* note 9. EpiPen is the brand name for an auto-injector

situations, even the slightest cross-contamination could cause an allergic reaction.[14] This explains why allergic reactions occur so often, with one study estimating that someone in the United States goes to the emergency room for an allergic reaction every three minutes.[15]

Living with food allergies is therefore a full-time job for both the individual with food allergies and those who care for them, especially parents of young children.[16] Activities that should be enjoyable and routine, from a sleepover to eating at a restaurant, instead pose the potential for a life-threatening reaction.[17] This can lead to those with food allergies being isolated for their safety, much to their social and developmental detriment.[18] Jayden Johnson, a fourteen-year-old who suffers from a peanut allergy, put it this way: "It was hard for me . . . . As I got older, I realized how much I was missing out on, not just because I couldn't eat peanuts, but because I missed the opportunity to

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of epinephrine (adrenaline), which counteracts the effects of allergic reactions. *What Is an Epipen and Who Needs It?*, ATLANTA ALLERGY & ASTHMA (Sept. 3, 2024), https://www.atlantaallergy.com/posts/view/33-what-is-an-epipen-and-who-needs-it [https://perma.cc/PVA2-ZPMY]. While not a "cure," the administration of an EpiPen can buy the time needed to seek professional medical treatment. *Id*. This Note also seeks to raise awareness of allergic reactions and encourage third parties to spot and potentially treat allergic reactions when needed because not all who suffer allergic reactions may know their allergies or have epinephrine available. Matthew Shaker & David Corbin, *Bystander Epinephrine in Community Anaphylaxis,* J. OF EMERGENCY MED. SERVS. (Apr. 1, 2018), https://www.jems.com/patient-care/bystander-epinephrine-in-community-anaphylaxis [https://perma.cc/V446-YLV7].

14. JOHNS HOPKINS MED., *supra* note 13. In a highly allergic person, 1/44,000 of a peanut can cause a severe reaction. *Id.*

15. Sunday Clark, Letter to the Editor, *Frequency of US Emergency Department Visits for Food-Related Acute Allergic Reactions*, 127 J. ALLERGY & CLINICAL IMMUNOLOGY 682, 682 (2011).

16. *Peanut Allergy: Jayden's Story*, CHILD.'S MERCY KAN. CITY, https://www.childrensmercy.org/departments-and-clinics/allergy-and-immunology/jaydens-story [https://perma.cc/UD8L-C5JV].

17. *See id.* (highlighting that everything poses a risk, including "[l]unch time, snacks, sleepovers, birthday and holiday parties").

18. For example, some kids may be isolated at a "peanut-free" table during lunch. *Id.* See Linda L. Quach & Rita M. John, *Psychosocial Impact of Growing Up with Food Allergies*, 14 J. FOR NURSE PRACS. 477 (2018), for a more in-depth discussion of the social impacts of allergies.

gain important social skills at different developmental stages in my life."[19]

For those with food allergies, perhaps the most important––and most challenging—place is the grocery store.[20] Currently, there is no cure for food allergies, and the only widely accepted method of "treatment" is strict avoidance.[21] Thus, when shopping, those with food allergies must carefully read food labels to buy products that do not contain their allergens, implicitly relying on a manufacturer's assurance that the label is accurate.[22] In theory, a consumer's decision should be straightforward because a product either contains an allergen or it does not, and the manufacturer's label should reflect this black-and-white truth.

The reality, however, is far from that theory because some products contain "precautionary allergen labels" (PALs), which state something like "may contain [allergen]."[23] This sort of label

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19. *Peanut Allergy: Jayden's Story*, *supra* note 16. For more personal stories of growing up with food allergies and the need for greater awareness, see Zerrin Dulger et al., *Stressing the Importance of Food Allergies*, FOOD ALLERGY RSCH. & EDUC, https://www.foodallergy.org/resources/stressing-importance-food-allergies [https://perma.cc/VGW6-5L2J] ("I have lived with food allergies for my whole life and dealing with them definitely isn't easy, especially when people don't understand what you are going through." (quoting Catherine Walker, a sixteen-year-old allergic to dairy, egg, nuts, and quinoa)).

20. *See generally* Gillian Almeida et al., *Consumers with Food Allergies: A Growing Market Remains Underserved*, MCKINSEY & CO. (Sept. 22, 2020), https://www.mckinsey.com/industries/consumer-packaged-goods/our-insights/consumers-with-food-allergies-a-growing-market-remains-underserved [https://perma.cc/BJ69-79NK] ("Our new research shows that . . . trying to avoid allergens makes [those with food allergies] feel stressed in the grocery aisle. Many spend significant time reading labels, and some avoid entire categories of products.").

21. *E.g.*, *Food Allergies*, CDC (Aug. 23, 2022), https://www.cdc.gov/healthyschools/foodallergies/index.htm [https://perma.cc/PQ5B-VM8R] ("There is no cure for food allergies. Strict avoidance of the food allergen is the only way to prevent a reaction.").

22. *E.g.*, Almeida et al., *supra* note 20 ("[T]rying to avoid allergens makes [shoppers with allergies] stressed in the grocery aisle."); *Have Food Allergies? Read the Label*, FDA (Jan. 10, 2023) [hereinafter *Have Food Allergies?*], https://www.fda.gov/consumers/consumer-updates/have-food-allergies-read-label [https://perma.cc/5GS2-DE6B] (discussing how consumers should read all ingredients).

23. *E.g.*, Katrina J. Allen & Steve L. Taylor, *The Consequences of Precautionary Allergen Labeling: Safe Haven or Unjustifiable Burden?*, 6 J. ALLERGY & CLINICAL IMMUNOLOGY 400, 400–01 (2018).

neither indicates that the product is free from the allergen nor designates that the product contains the allergen.[24] For example:

> Contains: Coconut, milk, soy and wheat ingredients. May contain traces of peanut and other tree nuts.[25]

PALs were originally intended as a warning device to alert consumers of the risk of cross-contamination.[26] However, due to a variety of factors, including overuse, PALs no longer serve this purpose and have completely lost their credibility amongst those with food allergies.[27] Congress vested sole authority to regulate PALs in the Food and Drug Administration (FDA), and thus far the Agency has refused to do so despite constant cries from the food allergy community.[28]

This leaves those with food allergies in a precarious position when confronting a PAL.[29] On one hand, a consumer might interpret the label as indicating an unknown, but presumably small risk that the product will contain the allergen.[30] Out of an abundance of caution, this consumer chooses to avoid the

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24. *See* Carlo A. Marra et al., *Consumer Preferences for Food Allergen Labeling*, 13 ALLERGY, ASTHMA, & CLINICAL IMMUNOLOGY no. 19, 2017, at 1, 7 (noting the discretion the consumer has in deciding whether to eat a food product with PALs).

25. *Quaker Chewy Chocolate Chip Granola Bars*, TARGET, https://www.target.com/p/quaker-chewy-chocolate-chip-granola-bars-18ct-15-2oz/-/A-53141964 [https://perma.cc/RSR3-WCE4]. This quotation is from the label of a Quaker Chewy Chocolate Chip Granola Bar and is meant to be representative of the type of label one with food allergies would encounter while shopping.

26. *The Use of Food Allergen Precautionary Statements on Prepackaged Foods*, GOV'T OF CAN. (Apr. 27, 2012), https://www.canada.ca/en/health-canada/services/food-nutrition/food-labelling/allergen-labelling/use-food-allergen-precautionary-statements-prepackaged-foods.html [https://perma.cc/GPG8-6A6A] ("When used, precautionary statements aim to: (1) alert the consumer to the possible presence of an allergen in a food, and (2) prevent the consumption of products labelled with a precautionary statement by persons having a food allergy.").

27. *See infra* Part I (discussing issues with PALs in light of Congressional inaction).

28. *E.g.*, 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, 238 (2011) ("[N]either FDA nor Congress has taken action to regulate the use of [PALs].").

29. *See* Marra et al.*, supra* note 24 (noting the discretion the consumer has in deciding whether to eat a food product with PALs).

30. *See id.* ("Different precautionary expressions may be confusing and the level of allergic risk associated with each expression may be deemed unascertainable.").

product. On the other hand, a consumer may assume that, if the allergen was truly in the product, the label would state so definitively.[31] Accordingly, this consumer ignores the PAL and purchases the product, potentially risking an allergic reaction.

This Note argues that PAL overuse unnecessarily harms those with food allergies and that, because of FDA inaction, consumers should initiate a legal challenge to their use. Though helpful in some instances, food manufacturers mostly apply PALs in a nonsensical way that eradicates their credibility amongst those with food allergies.[32] For instance, even bags of peanuts utilize a "may contain peanuts" PAL.[33] In a world where scientists can detect water on other planets,[34] a food manufacturer's supposed "inability" to determine whether their products contain allergens, and the subsequent use of a "may contain [allergen]" label, is in most instances inexcusable and in some completely disingenuous.

This Note explores potential routes for relief to help those with food allergies return meaning to a PAL. Because the FDA has exclusive control over food labeling requirements, this Note—like other scholarship before it—implores the FDA to act and standardize these labels.[35] However, realizing that the FDA has so far refused to act and future action may be unlikely, this Note also articulates a novel alternative remedy to PAL overuse through consumer lawsuits.[36]

Throughout history, lawsuits have proven to be a powerful way to influence societal and corporate behavior.[37] This is especially true in the food context, as food labeling lawsuits have risen drastically in the last twenty years.[38] Much of this litigation alleges false or misleading advertising, including, and most

31. *See id.* ("[T]hese statements may be viewed as causing unnecessary diet restrictions . . . .").

32. *See infra* text accompanying note 99 (discussing the lack of trust consumers have in PALs).

33. Roses, *supra* note 28, at 238 n.110.

34. Lee Billings, *Astronomers Find Water on an Exoplanet Twice the Size of Earth*, SCI. AM. (Sept. 11, 2019), https://www.scientificamerican.com/article/astronomersfind-water-on-an-exoplanet-twice-the-size-of-earth [https://perma.cc/NXQ2-X3V4].

35. *See infra* Part II.A.

36. *See infra* Part III.

37. *See infra* Part II.B.

38. *See infra* Part III.A.

notably, deceptive use of the term "natural."[39] The word is currently undefined and unregulated by the FDA, giving food manufacturers an opening to apply the term as they see fit.[40] Amidst the obesity crisis, consumers began to look for healthier options like "natural" products, but manufacturer use of the term—in which seemingly everything became "natural"—frustrated their ability to make an informed decision.[41] Eventually, they began filing lawsuits against food manufacturers, which had a powerful deterrent effect and caused a steep reduction in the usage of the term.[42]

These lawsuits provide a blueprint for allergic consumers to challenge PAL use. Much like the term "natural," PALs are unregulated and mislead consumers.[43] Food manufacturers are exploiting their usage,[44] and those with food allergies—like "natural" consumers before them—must strike back to hold manufacturers accountable in the absence of regulatory supervision. Moreover, bringing an action through a consumer protection lens provides the best way to circumvent many of the common law obstacles to challenging PALs.[45] Through these lawsuits, consumers can reduce PAL usage and return PALs to their intended purpose as a warning device.[46]

This Note proceeds in three Parts. Part I provides the necessary background and context for this discussion by showing how the interaction between the rapid increase in food allergies and the current regulatory scheme around food labels has hurt allergic consumers. Part II argues first that the FDA should act and standardize these labels to eliminate PAL overuse. Because this appears highly unlikely, Part II then examines remedies available under federal statutes and state common law and finds that these avenues hold substantial obstacles that would defeat any lawsuit. Finally, Part III examines analogous caselaw around the term "natural" and compares it to the current situation facing those with food allergies. Part III then uses this

39. *See infra* Part III.A.

40. *See infra* Part III.A.

41. *See infra* Part III.A.

42. *See infra* Part III.A.

43. *See infra* Part III.

44. *See infra* Part I.B.

45. *See infra* Part III.B. For the common law obstacles that would potentially bar a PAL claim, see *infra* Part II.B.

46. *See infra* Part III.

background to assert a novel theory that allergic consumers should pursue relief by filing a lawsuit under California's Unfair Competition Law and Consumer Legal Remedies Act. This Note concludes that consumer lawsuits are the best route to reduce the overuse of PALs and promote more accurate food labels.

I. BOILING OVER: HOW THE RISE OF FOOD ALLERGIES AND CONGRESSIONAL INACTION HAVE CAUSED PALS TO BE ESPECIALLY HARMFUL TO ALLERGIC CONSUMERS

On the surface, it may seem rather strange that an advisory label could cause so much harm. After all, PALs are just a few words at most.[47] However, as seen through two converging issues, PALs are increasingly losing their purpose and harming allergic consumers. One, the unprecedented rise in food allergies without any available cure makes allergic consumers highly dependent on food labels.[48] Two, the omission of PALs from existing food labeling requirements gives food manufacturers an economic incentive to apply PALs instead of adhering to stringent and expensive manufacturing processes to protect those with food allergies.[49] This economic incentive explains why PAL use is so prevalent.[50] In turn, this prevalence causes consumers to distrust PALs, making the labels not only ineffective in their intended purpose as a warning device but also an unnecessary, harmful obstacle to those with food allergies.[51]

This Part will tell the story of how these warnings—short as they may be—have come to be so detrimental to consumers with food allergies. Section A will explore the relatively recent increase in the prevalence of food allergies and detail why avoidance of allergens is so important. Section B explains congressional legislation surrounding food labels and then discusses why this legislation and subsequent Congressional/FDA inaction allowed PALs to become an unnecessary and harmful obstacle to those with food allergies.

47. For example: "May Contain Eggs."
48. *See infra* Part I.A.
49. *See infra* Part I.B.
50. *See infra* Part I.B.
51. *See infra* Part I.B.

A. AN EPIDEMIC WITH NO CURE: THE RISE OF FOOD ALLERGIES AND LACK OF AVAILABLE TREATMENT METHODS

America is currently experiencing an epidemic of food allergies.[52] Surprisingly, however, reactions to food are a relatively recent phenomenon.[53] In fact, food allergies did not become common until the early 1990s,[54] but since then, they have increased at a shockingly fast rate.[55] Between 1997 and 2011, food allergies increased by almost fifty percent in children.[56] As of 2023, six percent of the population in the United States has a diagnosed food allergy.[57] Of these food allergies, over forty percent are anaphylactic or life-threatening.[58] Most alarmingly, there appears

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52. *See generally* M. Cecilia Berin & Hugh A. Sampson, *Food Allergy: An Enigmatic Epidemic*, 34 TRENDS IMMUNOLOGY 390 (2013) (detailing the "epidemic" of allergies).

53. Food allergies and their immunological basis were discovered in 1921. Hugh A. Sampson, *Food Allergy: Past, Present and Future*, 65 ALLERGOLOGY INT'L 363, 363 (2016). However, food allergies were not accepted as "real science" and received little scientific examination at that time. *Id.* at 364.

54. *E.*g., Thomas A.E. Platts-Mills, *The Allergy Epidemics: 1870–2010*, 136 J. ALLERGY & CLINICAL IMMUNOLOGY 3, 3–4 (2015) ("Since 1990, there has been a remarkable increase in food allergy, which has now reached epidemic numbers."). The relatively recent increase in the prevalence of allergies has caused some cross-generational tension. For example, some parents and grandparents may not believe in the seriousness of allergies because "'back in their day,' everyone ate everything and was fine." Theresa MacPhail, *How Modernity Made Us Allergic*, NOĒMA (Aug. 8, 2023), https://www.noemamag.com/modernity-has-made-us-allergic [https://perma.cc/4UP2-2PLW].

55. *E.g.*, Platts-Mills, *supra* note 54, at 3 (treating levels of allergies in the population as an epidemic).

56. Imad Neal Saab & Wendelyn Jones, *Trends in Food Allergy Research, Regulations and Patient Care*, 57 NUTRITION TODAY 64, 64 (2022). Similar trends are likely occurring in adults. *See* Andrew Van Dam, *The Real Reason(s) Food Allergies Are on the Rise*, WASH. POST (Sept. 8, 2023), https://www.washingtonpost.com/business/2023/09/08/real-reasons-food-allergies-are-rise [https://perma.cc/X7YR-K3WK] (highlighting that other research reinforces the trend of increasing rates of allergies in the adult population).

57. More than a Quarter, *supra* note 8.

58. *Facts and Statistics*, FOOD ALLERGY RSCH. & EDUC., https://www.foodallergy.org/resources/facts-and-statistics [https://perma.cc/XHK5-H2YM]. Unsurprisingly, this has led to a corresponding increase in hospital visits, with at least one source reporting that hospital admissions for anaphylaxis increased by more than 600% between 1992 and 2012. Vybarr Cregan-Reid, *Allergies: The Scourge of Modern Life?*, GUARDIAN (Oct. 20, 2018), https://www.theguardian.com/society/2018/oct/20/allergies-the-scourge-of-modern-living-hay-fever-ashtma-eczema-food-peanuts-dairy-eggs-penicillin [https://perma.cc/L8TB-TRW8].

to be no sign of this trend reversing or slowing down, making allergies a clear public health crisis that is here to stay.[59]

Naturally, this sort of increase has led to considerable scientific inquiry into the underlying causes.[60] The current leading theory is the "hygiene hypothesis," which argues that society's growing cleanliness is to blame.[61] Through the elimination of various pathogens and diseases over the course of the past century, our bodies and immune systems do not face the constant threats they once did.[62] This leads the immune system to turn and attack harmless substances—or allergens—as if they are dangerous pathogens.[63] For example, at a molecular level, a shellfish closely resembles a dust mite.[64] Over time, society has significantly reduced the amount of dust mites present in various locations, and this lack of exposure causes an individual's immune system to mistakenly attack a shellfish as if it were a dust mite.[65] While the hygiene hypothesis is supported with worldwide evidence,[66] some scientists have criticized the theory's application to food allergies, arguing that it better explains

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59. *See* Bee Wilson, *'It's One of the Great Mysteries of Our Time': Why Extreme Food Allergies Are on the Rise – And What We Can Do About Them*, GUARDIAN (July 15, 2023), https://www.theguardian.com/society/2023/jul/15/its-one-of-the-great-mysteries-of-our-time-why-extreme-food-allergies-are-on-the-rise-and-what-we-can-do-about-them [https://perma.cc/8BUA-PLYG] ("Whatever the causes of the allergy epidemic . . . it will only get worse . . . .").

60. *See FAIR Health Reports That Food Allergy Prevalence, Treatment and Costs Have Skyrocketed in Past Decade*, FOOD ALLERGY RSCH. & EDUC. (Nov. 22, 2017), https://www.foodallergy.org/media-room/fair-health-reports-food-allergy-prevalence-treatment-and-costs-have-skyrocketed-past [https://perma.cc/M26X-YADH] (noting the growing list of studies examining food allergy-related issues).

61. *See, e.g.*, Van Dam, *supra* note 56 (highlighting that society's eradication of certain parasites and threats has led to our immune systems going "haywire").

62. *Id.*

63. *See id.* ("Without those actual threats, our immune system downshifts to tackle the biggest possible threat on the horizon.").

64. *Id.* ("If you put a shrimp and a dust mite like face to face, they look pretty darn similar . . . ." (quoting Christopher Warren, Dir. of Population Health Rsch. at the Nw. Univ. Allergy Ctr.)).

65. *Id.*

66. This can be seen through the increasing prevalence of auto-immune disorders in Western countries and not in other areas of the developing world, which presumably lack the cleanliness Western countries possess. H. Okada et al., *The 'Hygiene Hypothesis' for Autoimmune and Allergic Diseases: An Update*, 160 CLINICAL & EXPERIMENTAL ALLERGY 1, 2 (2010).

seasonal allergies and asthma.[67] In any event, more research is needed to better understand the reasons for the current allergy epidemic and to prevent its seemingly inevitable upward march.[68]

While scientists may disagree about the theories underlying this uptick, one point on which there is widespread agreement is on the "cure"—or lack thereof—for food allergies.[69] Strict avoidance of potential allergens is the only widely-recommended "treatment" method for those suffering from food allergies.[70] Research into oral immunotherapy[71] offers some hope for a better future, but its efficacy is nowhere near the level needed for those with severe food allergies.[72] Additionally, the FDA recently approved Xolair to treat food allergies—the first approved

67. *See, e.g.*, Ruchi S. Gupta et al., *Hygiene Factors Associated with Childhood Food Allergy and Asthma*, 37 ALLERGY & ASTHMA PROC., at e140, e145 (2016) (documenting that the associations between food allergies and hygiene factors were "less profound" than the influence of hygiene factors on asthma). Other scientists see a stronger link between food allergies and eczema, a chronic inflammatory skin condition. *E.g.*, Teresa Tsakok et al., *Does Atopic Dermatitis Cause Food Allergy? A Systematic Review*, 137 J. ALLERGY & CLINICAL IMMUNOLOGY 1071, 1071 (2016) ("[Eczema] is often associated with other atopic diseases, such as IgE-mediated food allergy (FA)."); P.E. Martin et al., *Which Infants with Eczema Are at Risk of Food Allergy? Results from a Population-Based Cohort*, 45 CLINICAL & EXPERIMENTAL ALLERGY 255, 255 (2014) ("Food allergy has been linked to eczema, a common paediatric [sic] condition with a spectrum of severity."). In Martin et al.'s study, one in five children with eczema would develop a food allergy, compared to one in twenty-five without. *Id.* at 255. In addition, 50.8% of children with early onset eczema would go on to develop a food allergy. *Id.*

68. *See generally* Wilson, *supra* note 59 (calling the current allergy epidemic "one of the great mysteries of our time").

69. *E.g.*, Mayo Clinic Staff, *supra* note 9 ("[T]here isn't any proven treatment that can prevent or completely relieve symptoms.").

70. *E.g.*, JOHNS HOPKINS MED., *supra* note 13 ("The goal of treatment is to stay away from the food that causes the allergic symptoms. There is no medicine to prevent food allergies . . . .").

71. Oral immunotherapy involves the "administration of small, gradually increasing doses of the food to which patients are allergic, with the aim to enable them to eat varying amounts of the allergenic food without reaction." Aikaterini Anagnostou, *Weighing the Benefits and Risks of Oral Immunotherapy in Clinical Practice*, 42 ALLERGY & ASTHMA PROC. 118, 118 (2021).

72. *See* Sayantani B. Sindher et al., *Treatment of Food Allergy: Oral Immunotherapy, Biologics, and Beyond*, 131 ANNALS ALLERGY, ASTHMA & IMMUNOLOGY 29, 29 (2023) ("[Oral immunotherapy] has several limitations that weaken its success. Limitations include a long duration of buildup, especially when used for multiple allergens, and a high rate of reported adverse events.").

medication for multiple allergens—but this drug only reduces the severity of a reaction from accidental exposure and avoidance is still recommended.[73] Thus, despite skyrocketing rates of food allergies, scientists have yet to identify any widespread successful treatment method, leaving those with food allergies on their own to avoid their potential allergens.

B. ONE LABEL FORWARD, TWO LABELS BACK: HOW THE FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT FAILED TO PROVIDE TRUE RELIEF FOR THOSE WITH ALLERGIES BY FAILING TO REGULATE PALS

The increasing prevalence of food allergies and lack of any recommended treatment method other than avoidance explains why it is so important for those with food allergies to make informed, safe choices at the grocery store. Left to their own devices, those with food allergies must carefully read every food label, as this is the only way to ensure that their potential allergens are not in the product.[74] However, this process hinges not only on the individual's obligation to read the food label but also on the label's *accuracy*.[75]

The main way Congress ensures this accuracy is through the Food Allergen Labeling and Consumer Protection Act

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73. Press Release, FDA, FDA Approves First Medication to Help Reduce Allergic Reactions to Multiple Foods After Accidental Exposure (Feb. 16, 2024), https://www.fda.gov/news-events/press-announcements/fda-approves-first-medication-help-reduce-allergic-reactions-multiple-foods-after-accidental [https://perma.cc/7V58-G7NL]; Liz Scherer, *Xolair a New Weapon Against Food Allergies, but Questions Remain*, WEBMD (Mar. 4, 2024), https://www.webmd.com/allergies/news/20240304/xolair-a-new-weapon-for-food-allergies [https://perma.cc/W9QB-RZ8W].

74. *See* Jen Jobrack, *When Food at the Grocery Store Isn't Labeled for Top Allergens*, ALLERGIC LIVING (Feb. 23, 2021), https://www.allergicliving.com/2021/02/23/when-ingredient-labels-at-the-grocery-store-dont-list-top-allergens [https://perma.cc/ME5F-BCY6] (describing how those with food allergies must rely on labels of grocery products for accurate and complete information).

75. For some, an accurate food label can mean the difference between life and death. Laura E. Derr, *When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004*, 61 FOOD & DRUG L.J. 65, 66 (2006). One thing that this Note does not address—but is still a pressing issue for those with allergies—is the readability of the food label. For more, see W. Marty Blom et al., *Allergen Labelling: Current Practice and Improvement from a Communication Perspective*, 51 CLINICAL & EXPERIMENTAL ALLERGY 574, 577–80 (2021).

(FALCPA).[76] Recognizing both the prevalence of allergies and the lack of available treatment methods, Congress passed the FALCPA in 2004 to address food labels.[77] The Bill amended the Food, Drug, and Cosmetic Act (FDCA) by requiring food

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76. Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), Pub. L. No. 108-282, 118 Stat. 905 (2004) (codified as amended in scattered sections of 21 U.S.C. and 42 U.S.C.). Since the passage of the FALCPA, Congress has continued to remain active in this area. In 2010, Congress passed the Food Allergy and Anaphylaxis Management Act as part of the Food Safety Modernization Act, which required the Secretary of Health and Human Services to develop voluntary guidelines to avoid allergic reactions in schools. Roses, *supra* note 28, at 229. In 2013, President Obama signed the School Access to Emergency Epinephrine Act. *Epinephrine in Schools and Public Places*, ASTHMA & ALLERGY FOUND. OF AM., https://aafa.org/advocacy/key-issues/access-to-medications/epinephrine-stocking-in-schools [https://perma.cc/N5M4-XJ9X]. This encouraged "states to implement policies requiring schools to stock undesignated epinephrine auto-injectors for use in emergencies." *Id.* Finally, in April of 2021, Congress signed the Food Allergy Safety, Treatment, Education and Research Act, or FASTER Act, which added sesame to the list of major allergens. Kristen Rogers, *Sesame Joins the Major Food Allergens List, FDA Says*, CNN HEALTH (Jan.2, 2023), https://www.cnn.com/2023/01/01/health/sesame-joins-major-food-allergens-list-fda-wellness/index.html [https://perma.cc/3RYR-9MAZ]. One disappointing consequence of the FASTER Act was that certain food manufacturers started adding sesame to their products because it's "easier to add sesame and note it on the label than to try to keep the ingredient out of other foods and away from equipment." Jonel Aleccia, *Sesame Is Being Newly Added to Some Foods. The FDA Says It Doesn't Violate an Allergy Law*, ASSOCIATED PRESS (July 26, 2023), https://apnews.com/article/sesame-food-allergy-fda-7a3e1fbf6abbb5073a491e46a4ccec2d [https://perma.cc/8G33-ESFA]. The FDA has stated that this does not violate the law, leaving those with sesame allergies with *fewer* food choices than before the Act. *Id.*

77. FALCPA § 202, 118 Stat. at 905–06. The text of the Bill reads:

> Congress finds that—
>
> (1) it is estimated that—
>
> (A) approximately 2 percent of adults and about 5 percent of infants and young children in the United States suffer from food allergies; and
>
> (B) each year, roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food;
>
> (2)
>
> (A) eight major foods or food groups—milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans— account for 90 percent of food allergies;
>
> (B) at present, there is no cure for food allergies; and
>
> (C) a food allergic consumer must avoid the food to which the consumer is allergic.

Id.

manufacturers to list the eight major allergens on their food labels.[78] Under the new requirements, a product containing a major allergen is mislabeled unless it lists the allergen on the food label in one of three ways.[79] One, the "allergen may be declared in the ingredient list by the recognized name of the food source. . ." (ex: salt, *peanuts*, sugar).[80] Two, if the product contains the allergen but none of the ingredients include the allergen's name, then the allergen may be indicated by inserting a parenthesis after the substance that contains the allergen (ex: salt, whey *(milk)*, sugar).[81] Three, a manufacturer may provide a "contains" statement at the end of the ingredient list (ex: Contains: *peanut*).[82] Congress vested sole power in the FDA to enforce the FALCPA and ensure food manufacturers comply with its guidelines.[83]

Without question, the passage of the FALCPA made life for those with food allergies significantly easier.[84] Allergic consumers hailed the victory, as now they had access to information about their allergens in a simple, easily-understood manner, allowing them to make informed decisions about the products they buy.[85] The Act had an immediate effect, as accidental ingestion

78. FALCPA § 202, 118 Stat. at 906. Interestingly, the Bill received bipartisan support and the food industry's endorsement. Derr, *supra* note 75, at 66.

79. Dana Shaker, Note, *An Analysis of "Natural" Food Litigation to Build a Sesame Allergy Consumer Class Action*, 72 FOOD & DRUG L.J. 103, 108 (2017); 21 U.S.C. § 343(w).

80. Shaker, *supra* note 79, at 108; 21 U.S.C. § 343(w)(b)(i)–(ii). This includes situations in which an ingredient's name identifies the allergen (ex: salt, *peanut butter*, sugar). Shaker, *supra* note 79, at 108.

81. Shaker, *supra* note 79, at 109; 21 U.S.C. at § 343(w)(b).

82. Shaker, *supra* note 79, at 109; 21 U.S.C. at § 343(w)(a). If a food label does utilize a "contains" statement, then all allergens must be listed in this statement. *Have Food Allergies?*, *supra* note 22. In other words, a food label cannot list some allergens in the "contains" statement and not others.

83. *See Food Allergies*, FDA (Sept. 17, 2024), https://www.fda.gov/food/food-labeling-nutrition/food-allergies [https://perma.cc/2A4K-U2SW] ("The FDA enforces the provisions of this law . . . .").

84. *See, e.g.*, *Labeling That Saves Lives: Understanding FALCPA*, FOOD INSIGHT (Feb. 5, 2021), https://foodinsight.org/labeling-that-saves-lives-understanding-falcpa [https://perma.cc/U67M-GRCX].

85. *See* Roses, *supra* note 28, at 229 ("In this way, FALCPA dramatically decreased information costs for food allergic consumers, making foods containing the eight major allergens readily identifiable in a way they might not have been before.").

of food allergens decreased by 24.4% in the two years after the passage of the FALCPA.[86]

Yet, despite this widespread success, the Act still fell short in several key areas.[87] One, the Act regulates only prepackaged food and does not cover restaurants, a place of significant anxiety for those with food allergies.[88] Two, the FALCPA does not cover alcohol products,[89] some of which are derived from major allergens.[90] Three, and perhaps most importantly, the Act left PALs unregulated.[91] This was an especially striking exclusion because the FDA had previously expressed concern about the use of PALs in a letter to food manufacturers eight years prior to the FALCPA's passage.[92]

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86. Susan Liebert, The Effect of the Food Allergen Labeling and Consumer Protection Act (FALCPA) on the Accidental Food Allergen Ingestion Rate in Adults with Self-Reported Food Allergies (May 12, 2008) (M.S. thesis, Eastern Michigan University) (on file with Minnesota Law Review).

87. *See, e.g.*, Roses, *supra* note 28, at 225 (noting that the FALCPA falls short because it does not apply to PALs and only regulates package foods).

88. *See id.* at 225–26 ("FALCPA also falls short because it only regulates packaged food, and fails to regulate allergen labeling in restaurants. Restaurants present an even greater danger to food allergy sufferers . . . ."). By contrast, the European Union mandates all restaurants to disclose the presence of the fourteen major allergens on their menus. A. Bryan Endres et al., *Restaurant Disclosure of Food Allergens: Analysis and Economic Implications*, 21 TOURISM & HOSP. RSCH. 202, 202 (2020).

89. Nicole Smith, *Food Allergy and Alcohol: How to Socialize Without Brewing up Trouble*, ALLERGIC LIVING, https://www.allergicliving.com/2018/12/06/food-allergy-and-drinking-how-to-socialize-without-brewing-up-trouble [https://perma.cc/PR88-F9XS].

90. For example, Screwball Whiskey is made from peanuts. Liza Weisstuch, *Believe It or Not, This Peanut Butter Whiskey Is Legitimately Good*, BON APPETIT (May 29, 2023), https://www.bonappetit.com/story/skrewball-peanut-butter-whiskey [https://perma.cc/Q9CP-9FAB].

91. *See* Roses, *supra* note 28, at 225 ("FALCPA left unregulated the use of precautionary statements that warn consumers about the possibility of allergen contamination."); Sarah Besnoff, Comment, *May Contain: Allergen Labeling Requirements*, 162 U. PA. L. REV. 1465, 1469 (2014) ("However, the Act left one important concern for food allergy sufferers untouched: advisory label warnings.").

92. *See* Roses, *supra* note 28, at 227–28 ("[T]he 1996 Allergy Warning Letter . . . makes the important declaration that . . . 'precautionary statements are not an alternative to adhering to good manufacturing practices (GMPs)' and . . . manufacturers '[must] take all steps necessary to eliminate cross-contamination and to ensure the absence' of allergens in foods."). One might wonder why, if the allergen is in the food, it is not required to be disclosed in the "contains" statement. Put simply, the FALCPA applies only to ingredients, or those

Unlike the other two, Congress's exclusion of PALs is potentially understandable because they are beneficial in certain circumstances.[93] Food manufacturing, especially in large plants, is an incredibly complex system.[94] Allergens may be used only in some products, and it might be infeasible—both mechanically and monetarily—to clean the machines after every single production to prevent cross-contamination.[95] In these circumstances, the food manufacturer may truly be unable to tell whether there is cross-contamination between products.[96] To protect the allergic consumer, the food manufacturer applies a PAL to signify this risk. Herein lies the power of a PAL: in just a short phrase, the allergic consumer understands—at least in part—the unique risk the product presents.[97] In other words, the PAL provides more information than would otherwise be present on the food label, helping the allergic consumer make a more informed choice.[98]

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things "intentionally" added. Conversely, cross-contaminants, even if they end up in the product, are not an ingredient and therefore do not have to be disclosed under the FALCPA. *See* Kathleen Doheny, *The Confusing State of Food Allergy Labels*, CBS NEWS (Nov. 2, 2016), https://www.cbsnews.com/news/the-confusing-state-of-food-allergy-labels [https://perma.cc/65JN-WQMX] ("Under the U.S. Food Labeling and Consumer Protection Act, food companies must identify major allergens if that food is an *intended* ingredient." (emphasis added)). Thus, a food product that contains peanuts may not be mislabeled if the peanuts are an unintended addition.

93. *E.g.*, Nick Hughes, *Are PALs Really a Consumer's Best Friend?*, SAFE FOOD, (June 30, 2023) https://www.safefood.net/professional/food-safety-news/pals [https://perma.cc/R7KQ-PDVB] ("Used appropriately, precautionary allergen information or labelling can be hugely beneficial to consumers . . . .").

94. *See* Damini, *Foods Manufacturing: Critical Issues and Challenges*, DESKERA, https://www.deskera.com/blog/foods-manufacturing-critical-issues-and-challenges [https://perma.cc/B6JJ-94QV] (noting the numerous obstacles food manufacturers face).

95. However, the food manufacturer could always use dedicated allergen-free production lines. *Id.*

96. Pablo Coronel, *Allergens in Food Manufacturing: Best Practices in Facility Design*, CRB, https://www.crbgroup.com/insights/food-beverage/allergens-food-manufacturing [https://perma.cc/3NWF-Y8T8] (discussing situations in which it is impossible to guarantee complete sanitation and segregation).

97. *E.g.*, Hughes, *supra* note 93 ("[P]recautionary allergen information or labelling can be hugely beneficial to consumers when it clearly tells them about an unavoidable risk of allergen cross-contamination.").

98. *See* A. DunnGalvin et al., *Precautionary Allergen Labelling: Perspectives from Key Stakeholder Groups*, 70 EUR. J. ALLERGY & CLINICAL IMMUNOLOGY 1039, 1040 (2015) ("Precautionary allergen labelling is meant to inform consumers with food allergy about a significant risk of reacting to a product.").

This all depends, however, on a PAL's ability to communicate risk to consumers. When viewed in this way, PALs clearly fail. They lack any credibility amongst allergic consumers and are now more harmful than beneficial.[99] Though the exact causes of PALs' downfall are many, three main issues explain how they lost their effectiveness and benefit to allergic consumers.

The first problem with PALs is that they are not regulated or standardized.[100] Since the passage of the FALCPA, the FDA has only released advisory, non-binding guidance on PAL usage that states that PALs cannot be used as a substitute for "good manufacturing practices."[101] This policy lacks the force of law and has little enforcement effect.[102] Moreover, the FDA has never standardized PALs' language, leaving food manufacturers free to apply them in their own way.[103] To make matters worse, most individuals with food allergies wrongly assume that PALs are regulated.[104] One study estimates that thirty-seven percent of consumers with allergies believe that PAL language corresponds to the amount of risk.[105] This explains why many consumers avoid products with a "may contain" label while at the

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99. *See infra* notes 100–45 (identifying the reasons consumers cannot trust PALs).

100. *E.g.*, *This Blog Post May Contain: Food for Thought About Precautionary Allergen Labeling,* FOOD ALLERGY RSCH. & EDUC. BLOG (Mar. 20, 2018) [hereinafter *This Blog Post May Contain*], https://www.foodallergy.org/fare-blog/blog-post-may-contain-food-thought-about-precautionary-allergen-labeling [https://perma.cc/J7DM-49W3]. The European Union, United Kingdom, Canada, and United States all do not regulate PALs. Katrina J. Allen et al., *Precautionary Labelling of Foods for Allergen Content: Are We Ready for a Global Framework?,* 7 WORLD ALLERGY ORG. J., 2014, at 1, 5.

101. *E.g.*, *This Blog Post May Contain*, *supra* note 100 ("FDA advises only that precautionary allergen labeling 'should not be used as a substitute for adhering to current Good Manufacturing Practices' and 'must be truthful and not misleading.'"). "Good Manufacturing Practices" are a general set of procedures—rife with exceptions and exemptions—that govern the production of food and drugs. U.S. FOOD & DRUG ADMIN., SEC. 555.250 MAJOR FOOD ALLERGEN LABELING AND CROSS-CONTACT DRAFT COMPLIANCE POLICY GUIDE 7 (2023) [hereinafter FDA COMPLIANCE GUIDE].

102. *See generally This Blog Post May Contain*, *supra* note 100 (noting the advisory only guidance on PALs).

103. *E.g.*, *id.* ("[P]recautionary labels that warn about unintentional inclusion of allergens are voluntary and not regulated. Laws do not require these statements or govern how they are worded.").

104. *See, e.g.*, *id.* (reporting that about half of consumers thought precautionary labels were regulated by law).

105. *Id.*

same time buying products with a "manufactured in a facility" label.[106] Yet, there is no law or regulation that mandates or governs this difference in language.[107] In fact, both labels indicate the same level of risk.[108] Therefore, even though the consumer believes they are making a smart decision by avoiding certain PAL-products, they are not actually doing so and are subjecting themselves to the potential for a serious allergic reaction.[109] This lack of regulation makes avoiding PALs in their entirety the most prudent course of action for an individual with food allergies, as one cannot rely on the language of the PAL itself.[110]

This would not be a problem if PALs were sparingly used, but the second problem with PALs are the incentives they create, which leads to their widespread use throughout the food industry.[111] Quite simply, PALs are a cost-saving measure because they provide a cheaper alternative than using good manufacturing practices to eliminate the risk of cross-contamination.[112] Said another way, PALs' economic benefits outweigh any incentives

106. Julie Barnett et al., *Using 'May Contain' Labelling to Inform Food Choice: A Qualitative Study of Nut Allergic Consumers*, 11 BMC PUB. HEALTH, 2011, at 1, 4 (2011). One respondent in Barnett et al.'s study said: "'May contain nuts' is . . . well, I wouldn't eat it, because that means it could contain nuts. 'May contain traces of nuts' is different." *Id.* (quoting a respondent). Another said: "If it says 'May contain traces', I'm okay with that—I'll buy that. But if it says quite specifically 'May contain traces of peanut', then I won't buy it, because I think that's the . . . I feel like—I don't feel so confident I think, because I think that's a little bit too specific, you know?" *Id.* (quoting a respondent).

107. *See, e.g.*, *This Blog Post May Contain*, *supra* note 100 ("Laws do not require these statements or govern how they are worded.").

108. *See, e.g.*, *id.* ("In North America, the wording of precautionary labeling is not based on the amount of allergen present.").

109. *See* Besnoff, *supra* note 91, at 1485 ("The label may not reflect the true probability of exposure.").

110. *E.g.*, Ruchi Gupta et al., *Understanding Precautionary Allergen Labeling (PAL) Preferences Among Food Allergy Stakeholders*, 9 J. ALLERGY & CLINICAL IMMUNOLOGY 254, 258 (2021) ("When asked if they discussed PAL with their health care provider, 32% of individuals with [food allergies] were instructed to avoid . . . . Of parents with children with [food allergies], 50.5% were instructed to avoid all PAL labels . . . ."); *see* Doheny, *supra* note 92 ("I advise my patients to avoid foods with any label stating 'may contain' an allergen . . . ." (quoting Dr. Vivian Hernandez-Trujillo, Head of Pediatric Allergy and Immunology, Nicklaus Children's Hospital, Miami, Fla.)).

111. *See* Besnoff, *supra* note 91, at 1486 ("[T]he possibility of reducing or eliminating contamination may be in reach, but may be deemed less attractive than the cheaper alternative of using advisory labeling.").

112. *See id.* (identifying the favorable economics of widespread use of PALs).

food manufacturers have to protect their consumers or comply with FDA guidance.[113] This explains why their use is so prevalent.[114] According to a 2009 study, almost seventeen percent of all grocery store products in the United States contained PALs, but for certain categories the number was well over fifty percent.[115] Though conducted over fifteen years ago, this appears to be the most recent comprehensive study done in the United States.[116] More recent international studies—while conducted in countries not subject to the FALCPA—are thus especially illuminating in highlighting the *current* overuse of PALs.[117] For example, a 2018 study in Australia revealed that sixty-five percent of all products at grocery stores contain some sort of PAL.[118] In a comparable 2015 study in England, the number was fifty percent.[119]

Increased PAL use makes sense if current food manufacturing processes contaminate more products than in the past, but research shows that the opposite is true. For example, one study found that only one of fifty-seven products with an egg PAL contained egg.[120] For peanuts, the number was only slightly higher at five out of one hundred and twelve.[121] Other studies reveal similar results, and these numbers have remained relatively constant over time.[122] Therefore, it seems likely that food

113. *Id.* This economic incentive could change if most allergic consumers forego purchasing the product, but there is no research doing this analysis.

114. *Id.*

115. Allen et al., *supra* note 100, at 4.

116. *See generally id.* (compiling a list of all the recent studies done in this area).

117. For a summary of some of the studies done, see *id*.

118. Giovanni A. Zurzolo, *Precautionary Allergen Labelling Following New Labelling Practice in Australia*, 49 J. PAEDIATRICS & CHILD HEALTH, at E306, E308 (2013).

119. B.C. Remington et al., *Unintended Allergens in Precautionary Labelled and Unlabelled Products Pose Significant Risks to UK Allergic Consumers*, 70 EUR. J. ALLERGY & CLINICAL IMMUNOLOGY 813, 813 (2015).

120. Lara S. Ford et al., Letter to the Editor, *Food Allergen Advisory Labeling and Product Contamination with Egg, Milk, and Peanut*, 126 J. ALLERGY & CLINICAL IMMUNOLOGY 384, 384 (2010). Notably, in products with no PALs at all, the allergen could be detected in 2.6% of products. *Id.*

121. *Id.*

122. *See* Allen & Taylor, *supra* note 23, at 402.

manufacturers are using PALs because of their economic incentives and not due to increased cross-contact.[123]

In turn, this unjustified prevalence limits the options of those with food allergies even further, making avoidance of all PAL-products nearly impossible. Before an individual with food allergies even walks into the grocery store, their options are already limited, often severely.[124] The lack of regulation and the incentives for food manufacturers to overuse PALs only limits these options further, especially if the consumer must avoid PAL-products in their entirety.[125] For example, consider an individual with severe food allergies to several major food allergens. This person automatically loses over forty percent of all items in the store due to products that actually contain their allergens.[126] Then, because of PALs, this person could lose an additional fifty percent of the *remaining* products available to them.[127] This leaves the consumer with few, if any, remaining options and makes avoiding PAL-products altogether untenable.

The third problem with PALs, and the most significant, is that PALs have completely lost their credibility amongst consumers with food allergies.[128] The combination of their overuse

123. *See generally* Sébastien La Vieille et al., *Precautionary Allergen Labeling: What Advice Is Available for Health Care Professionals, Allergists, and Allergic Consumers?*, 11 J. ALLERGY & CLINICAL IMMUNOLOGY 977, 977 (2023) (discussing the lack of actual risk PALs convey).

124. *See, e.g.*, ABC 7 Chicago Digital Team, *Grocery Shopping with Food Allergies Can Be Easier with New Technology*, ABC 7 (May 15, 2021), https://abc7chicago.com/grocery-shopping-food-allergies-sifter-judy-seybold/10632063 [https://perma.cc/6C2V-ZUMR] (highlighting the difficulty of finding safe foods when shopping to avoid allergens).

125. *E.g.*, Allen & Taylor, *supra* note 23, at 404 ("Avoidance of foods with PAL places an additional burden on the allergic consumer . . . .").

126. This number was estimated using Sifter, a technology that filters out products containing the user's allergens, and Walmart.com. SIFTER, https://fare.sifter.shop/products [https://perma.cc/2LGW-EXWK]. It is based on the Author's allergen profile of allergies to dairy, egg, peanuts, and shellfish. For more on Sifter, see *FARE and Sifter Announce Grocery Shopping Technology for the Food Allergy Community*, FOOD ALLERGY RSCH. & EDUC. (Nov. 10, 2022), https://www.foodallergy.org/media-room/fare-and-sifter-announce-grocery-shopping-technology-food-allergy-community [https://perma.cc/7URS-TPWY].

127. If they lived in the United Kingdom, for example, this would be the case. *See* Remington et al., *supra* note 119, at 813 (finding that fifty percent of all products in UK grocery stores contained PALs).

128. *E.g.*, Allen & Taylor, *supra* note 23, at 405 ("Consensus has been achieved among various stakeholders, including consumers, food industry

and lack of association with actual risk has caused many with food allergies to disregard them.[129] In one study, close to two-thirds of individuals with food allergies ignored PALs at some point.[130] This number is likely to continue to rise as food manufacturers increasingly use PALs instead of good manufacturing practices, leaving consumers little choice but to try the PAL-product and hope for the best.[131] Shockingly, a majority of healthcare professionals even recommend that consumers ignore them in certain instances.[132] By disregarding PALs, a consumer increases their chances of encountering food allergens—the very opposite of what PALs were intended to do.[133]

Perhaps the biggest reason that PALs lack credibility is that consumers see them as a shield against lawsuits.[134] One allergic consumer put it this way: "I can understand why (the 'may contain' messages) are there, because it's a backside-covering

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management professionals, health care professionals, psychologists, food industry auditors, analysts, and regulatory professionals, that PAL has lost its credibility because of its inconsistent application and lack of association with the actual risk.").

129. *See, e.g.*, *This Blog Post May Contain*, *supra* note 100 ("[M]any people managing food allergies ignore some or all precautionary allergen labeling, including a majority of young adults . . . ."); Barnett et al., *supra* note 106, at 7–8 (documenting that many participants did not believe that the "may contain" message was credible or desirable and ignored it when making food choices).

130. Stella Anne Cochrane et al., *Characteristics and Purchasing Behaviours of Food-Allergic Consumers and Those Who Buy Food for Them in Great Britain*, 3 CLINICAL & TRANSLATIONAL ALLERGY, 2013, at 31, 31 ("Only a third of respondents always avoided products with 'may contain' labels.").

131. *See* Bregje C. Holleman et al., *Poor Understanding of Allergen Labelling by Allergic and Non-Allergic Consumers*, 51 CLINICAL & EXPERIMENTAL ALLERGY 1374, 1375 (2021) (highlighting that consumers with food allergies decide whether or not to use a PAL-product based on experience or other heuristics).

132. *See, e.g.*, DunnGalvin et al., *supra* note 98, at 1041 ("Only one-third [of physicians] would advise patients with tree nut allergy to avoid all foods with PAL relating to tree nuts.").

133. This is a serious issue, as a recent study in Canada documented that eight percent of all allergic reactions can be attributed to the ignoring of a PAL-product. *This Blog Post May Contain*, *supra* note 100.

134. *E.g.*, Jan Mei Soon & Louise Manning, *"May Contain" Allergen Statements: Facilitating or Frustrating Consumers?*, 40 J. CONSUMER POL'Y 447, 451 (2017) ("Indeed, it has been suggested that the use of PAL is an intentional strategy to mitigate multiple levels of risk (on the spectrum from low to high) and thus is used to cover the manufacturers' back and/or to protect supply chain actors against product liability claims."); DunnGalvin et al., *supra* note 98, at 1040 ("[S]ome consumers may consider the change has been made purely for liability reasons to protect the food manufacturer and so ignore the warning.").

exercise for the manufacturers, because they can say 'Well we put it may contain traces of nuts in it, and he died, so it's not our fault.'"[135] Healthcare professionals also share this perspective.[136] Temporarily putting aside the validity of this belief,[137] the fact that consumers believe manufacturers apply PALs for improper reasons illustrates just how far PALs have strayed from their intended goal.

When entering a grocery store, an allergic consumer facing a PAL- product faces four scenarios, only one of which provides them with any benefit from PAL use. One, the consumer may see a PAL and choose to avoid a product that does, in fact, contain the allergen. This is the only scenario in which the PAL benefits the consumer. Two, the consumer may see a PAL and choose to avoid a product that, like most products with PALs, does not contain the allergen. As a result, the allergic consumer chooses to forego a legitimate option for them to eat. Three, a consumer may see a PAL and, whether because the consumer distrusts the PAL or has no other available options, choose to consume the product. Because most products that utilize PALs do not contain the allergen, the consumer will *likely* be okay. However, this scenario only reinforces the belief that PALs are not to be heeded, leading to the last, and worst, scenario. In this fourth scenario, the consumer takes the same action as scenario three, but this time the product contains the allergen. As a result, the consumer may experience a life-threatening allergic reaction, resulting in hospitalization and even death. Because of the current pattern and overuse of PALs, this situation is becoming far too common.[138]

These problems, and the situations they create for consumers, reveal that PALs are failing their intended purpose as a

135. Barnett et al., *supra* note 106, at 4.

136. Derr, *supra* note 75, at 88 (noting that physicians view PALs not as a device to protect consumers but as a method to protect manufacturers).

137. The extent to which PALs shield manufacturers will be addressed in Part II.

138. According to one study, nearly eighteen percent of children experienced allergic reactions to products containing PALs. François Graham et al., Letter to the Editor, *Real-life Evaluation of Tolerance to Foods with Precautionary Allergen Labeling in Children with IgE-mediated Food Allergy*, 78 EUR. J. ALLERGY & CLINICAL IMMUNOLOGY 2558, 2559 (2023).

warning device.[139] A good warning should have specific, standardized language and be limited in use, but PALs currently lack all these attributes. Their lack of regulation leads consumers to wrongly choose one PAL-product over another, exposing themselves to danger.[140] In addition, their prevalence eradicates consumer trust in them, causing consumers to disregard them.[141] This leads to dangerous and life-threatening situations.[142] Instead of providing a consistent benefit to the consumer, PALs are frequently detrimental.[143] The seriousness of this situation for those with allergies demands action.[144]

II. ~~DIETARY~~ SOLUTION RESTRICTIONS: FDA INACTION AND PALS' EFFECTIVENESS AS A LIABILITY SHIELD GIVES CONSUMERS LITTLE RECOURSE

The problem is evident: PALs no longer serve their intended purpose, making the current scheme untenable for those with food allergies. The solution, however, is more complicated. Only Congress can amend the FDCA, and it has vested sole authority in the FDA to enforce the law.[145] Action at the federal level is therefore the easiest solution, as it would provide uniformity to the food label landscape. However, consumers with food allergies have been waiting for almost twenty years for FDA action on PALs, receiving little to no relief.[146] While the FDA recently

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139. *See, e.g.*, DunnGalvin et al., *supra* note 98, at 1039 (noting that PAL use is counterproductive for those with food allergies in its current form); Barnett et al., *supra* note 106, at 2 ("The prevalence and variation of precautionary labelling, although intended to assist the consumer in their food choices, is increasingly considered as problematic for food allergic consumers.").

140. *See supra* notes 91–99 and accompanying text (discussing the lack of PAL regulation).

141. *See supra* notes 118–27 and accompanying text (discussing the overuse of PALs and the corresponding effect on consumers with food allergies).

142. A recent fatality in Poland can also be attributed to a PAL-product. *This Blog Post May Contain*, *supra* note 100.

143. *Id.* (explaining the burdens PALs place on consumers with food allergies).

144. *See* DunnGalvin et al., *supra* note 98, at 1047 (noting that stakeholders agree that the situation regarding PALs needs to be "urgently" addressed).

145. *E.g.*, Shaker, *supra* note 79, at 122 (noting that the FDA has sole authority over enforcement of the FDCA).

146. *See, e.g.*, Roses, *supra* note 28, at 225 (noting that the FALCPA does not address PALs). *See generally* FDA COMPLIANCE GUIDE, *supra* note 101 (providing nonbinding recommendations on the use of PALs). Shockingly, even though

proposed expansive new guidance that addresses PALs and cross-contaminants,[147] this draft guidance does little to establish mandatory standards of care and instead contains non-binding recommendations/suggestions, causing many to remain skeptical about its actual effects.[148] If the FDA is not going to act, or even if it does act but in an insufficient way, then those with food allergies should take action to promote better food labeling practices. The best, and perhaps only, way for those with food allergies to act on their own is through filing lawsuits against food manufacturers.[149] However, PALs, even if not intended to be a liability shield, are quite effective at protecting against any consumer action.[150]

Section A argues that the most efficient and comprehensive solution to current PAL issues is for the FDA to regulate the use of PALs and examines possible avenues for doing so. Concluding, however, that this sort of action is unlikely due to practical and political constraints, Sections B and C turn to lawsuits consumers could bring to try and change this practice. Section B examines possibilities for relief at the federal level, including action under the FALCPA, Americans with Disabilities Act, and

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food manufacturers started adding sesame to products after the passage of the FASTER Act, the guidance does not address this issue. *See id.* (omitting a discussion on manufacturers' use of sesame).

147. Martin Hahn et al., *FDA Releases Draft Guidance on Food Allergen Programs Under the Preventive Controls Rule*, ENGAGE (Nov. 27, 2023), https://www.engage.hoganlovells.com/knowledgeservices/news/fda-releases-draft-guidance-on-food-allergen-programs-under-the-preventive-controls-rule [https://perma.cc/FN6Q-UV7N] ("The U.S. Food and Drug Administration (FDA) recently issued a new food allergen-focused chapter . . . [that] addresses allergen cross-contact controls, label controls, allergens controlled under a supply-chain program, and allergen advisory statements."). This appears to be the best hope yet for FDA action on PALs because it encourages testing as part of the advisory process and recommends safety procedures beyond what many food manufacturers do today. *Id.*

148. *E.g.*, Adrienne Crezo, *Have a Food Allergy? What to Know About FDA's New Guidance*, CTR. FOR SCI. IN THE PUB. INT. (Mar. 20, 2024), https://www.cspinet.org/cspi-news/have-food-allergy-what-know-about-fdas-new-guidance [https://perma.cc/RC35-3LLA] ("Newest guidance is no improvement[.]"). Comments will close on August 2, 2024, with the final rule coming after that. U.S. FOOD & DRUG ADMIN., HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD: GUIDANCE FOR INDUSTRY (2024).

149. *See infra* Part II.B (discussing avenues for individuals with food allergies to seek remedies through the court system).

150. *See infra* Parts II.A–II.B (explaining the complications consumers with food allergies face when filing lawsuits).

Lanham Act. Finding that these provide no relief, Section C looks to state common law to see if any remedy lies in a failure to warn or a similar negligence claim. Ultimately, this too will likely fail because of preemption and failure to warn defenses, and this Part concludes by highlighting the seemingly impenetrable nature of PALs and the need for novel solutions.

A. ALLERGIC TO ACTION: HOW THE FDA COULD REGULATE PALS AND WHY IT IS UNLIKELY TO HAPPEN

Because Congress vested sole power in the FDA to enforce the FDCA, the simplest solution to the current PAL situation is for the FDA to regulate them and provide uniformity to food labels.[151] Other countries demonstrate two effective ways the FDA could do this. The first is to ban them entirely.[152] The rationale behind this solution is simple: either the product contains the allergen or not.[153] The second is to establish thresholds for when a PAL may be used[154]—a plan of action the FDA encouraged food manufacturers to take in its most recent proposed guidance.[155] Standardizing the labels and providing a comprehensive framework for PAL use could bring meaning back to the specific words.[156] For instance, under Australia's voluntary scheme for food manufacturers, the application of PALs corresponds to their likelihood of causing an allergic reaction.[157] This scheme utilizes

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151. *See, e.g.*, Besnoff, *supra* note 91, at 1486 ("The FDA can make advisory labeling more helpful to consumers."). Even if it chooses not to adopt standards for PALs, the FDA should enforce its guidance that PALs should not substitute for good manufacturing practices (GMPs). *See id.* at 1488 (arguing that the current GMP scheme lacks enforcement and accountability).

152. Allen et al., *supra* note 100, at 5. Japan and Argentina are the only countries to ban PALs. *Id.*

153. Reed Baker, *The Global Status of Food Allergen Labeling Laws*, 54 CAL. W. L. REV. 293, 318 (2018).

154. *See, e.g.*, Besnoff, *supra* note 91, at 1486 ("[PALs] should be standardized both in language and content to reflect the thresholds . . . that the FDA develops.").

155. Crezo, *supra* note 148 ("The FDA's recent draft guidance . . . suggests that companies can use such 'thresholds' in designing preventive controls to protect against allergen cross-contamination.").

156. *See* Besnoff, *supra* note 91, at 1492 ("The ideal label would thus provide standardized language that appropriately warns consumers of the risks of allergic reaction.").

157. *See generally* Alessandro Fiocchi et al., *Food Labeling Issues for Severe Food Allergic Patients*, WORLD ALLERGY ORG. J., Oct. 2021, at 1, 5 (describing this framework and its general approach and purposes).

results from oral food challenges, in which patients—under the close watch of medical professionals—ingest the product to see if it causes an allergic reaction.[158] The scheme then generalizes these results to the broader population and recommends that a "may contain" label be used only if the product causes a reaction in one or more percent of allergic people.[159] Consumers prefer this scientific, risk-based approach because it returns the power of choice and evaluation of risk to them.[160]

While either method would provide substantial benefits, each suffers from its own flaws that might prevent the FDA from adopting the measure. For complete PAL bans, the data is insufficient as to whether they benefit consumers.[161] Moreover, setting aside the data, a complete ban is flawed because it is over-inclusive—it covers both the improper and proper use of PALs. While consumers would benefit from PAL-less products in most circumstances, they would also be deprived of this information when a PAL is truly needed, creating a less-informed allergic consumer.[162] A PAL solution, therefore, should reflect this nuance of PAL use, which a complete ban fails to do. As for thresholds and standardizing PALs, this approach does not account for the individualized nature of food allergies.[163] A safe amount for one person may not be safe for another, and the possible standardization may give consumers with severe food allergies a false

158. *See id.* (discussing how oral food challenges are used to make recommendations).

159. *Id.* The number may be as high as five percent for certain allergens. *Id.*

160. *See* Yvette F.M. Linders et al., *Precautionary Allergen Labeling: Current Communication Problems and Potential for Future Improvements*, FOOD CONTROL, May 2023, at 1, 6 ("Almost all interviewees would prefer to work with [Australia or an Australian-like] system.").

161. *See* Allen et al., *supra* note 100, at 11 (noting the need for more research to determine the efficacy of the measures).

162. *See generally* DunnGalvin et al., *supra* note 98, at 1045 (discussing how PALs help consumers make more informed choices).

163. *See* Besnoff, *supra* note 91, at 1491 (explaining the difficult task the FDA has when determining thresholds). Food Allergy Research and Education (FARE) recommends that the FDA establish thresholds for allergies only if the FDA "is in possession of reliable scientific data that clearly identifies a quantity of the allergen that is so small that it will not cause an allergic reaction in even the most sensitive individuals, and also a reliable analytical method for determining compliance with the threshold that can be easily used by food companies and the FDA." *This Blog Post May Contain*, *supra* note 100.

sense of security.[164] In addition, detecting compliance and enforcement would be challenging because there is currently no universally agreed upon allergen detection method.[165]

These flaws, combined with the food industry's interest in preserving PAL use, indicate that the FDA is unlikely to act. The original text of the FALCPA contained language restricting the use of PALs, but the food industry lobbied successfully to remove it, presumably because of the economic benefit PALs provide.[166] It is simply much cheaper for food manufacturers to apply a PAL than adhere to rigid manufacturing guidelines.[167] Thus, food manufacturers, a group whose resources and lobbying power vastly outweigh those of any individual or advocacy group,[168] would likely meet any attempted action by the FDA with swift opposition.[169]

Nevertheless, the FDA should still act to solve the PAL problem because they alone have the power to bring uniformity to food labels. While none of the proposed solutions are perfect, the benefits of FDA regulation would outweigh the drawbacks and return choice to the consumer.[170] Yet, these drawbacks and the food industry's interest in preserving the current scheme

164. One way around this is by publishing the threshold levels and encouraging those with food allergies to visit their allergist for their own oral challenge. Besnoff, *supra* note 91, at 1492.

165. *See, e.g.*, Allen et al., *supra* note 100, at 10 ("Similarly, public health agencies in various countries have not provided guidance to industry on preferred approaches and as yet there is no universally-agreed method for allergen detection.").

166. *See* Derr, *supra* note 75, at 112–13 (noting the compromises the food industry and Congress reached).

167. *See supra* Part I.B (discussing why food manufacturers prefer using PALs).

168. In 2023, the food and beverage industry spent almost 28 billion on lobbying. *Industry Profile: Food & Beverage*, OPEN SECRETS (last updated July 24, 2024), https://www.opensecrets.org/federal-lobbying/industries/summary?cycle=2023&id=N01 [https://perma.cc/P59G-4PEM].

169. *See generally* Besnoff, *supra* note 91, at 1486 (noting that the "possibility of reducing or eliminating contamination may be in reach, but may be deemed less attractive [to food manufacturers] than the cheaper alternative of using advisory labeling.").

170. *See* Allen et al., *supra* note 100, at 12 (arguing that, at the very least, regulating PALs "would be a significant early step forward for improved utility and safety for the allergic consumer").

indicate that the FDA is not likely to act in the near future.[171] Consumers, then, must seek an alternative solution through the judiciary.

B. FEDERAL CAUSES OF ACTION: CONTAINS THE FALCPA, AMERICANS WITH DISABILITIES ACT, LANHAM ACT, AND NO SOLUTION

Because the FDA is unlikely to provide any relief for consumers, individuals with food allergies should seek relief through the courts. Throughout history, litigation has shown the ability to generate change.[172] For example, lawsuits caused the end of school segregation[173] and established the right to gay marriage.[174] More recently, schools and states have utilized lawsuits to sue Juul for false advertising and reduce the use of e-cigarettes by almost ninety-five percent.[175] Lawsuits, or the threat of

171. To further evidence the ineffective bureaucracy of the FDA, consider the fact that it took the agency *twelve* years to standardize the definition of peanut butter. Editorial Staff, *Why Midcentury Lawyers Spent 12 Years Arguing About Peanut Butter*, MENTAL FLOSS (Feb. 9, 2016), https://www.mentalfloss.com/article/71698/why-midcentury-lawyers-spent-12-years-arguing-about-peanut-butter [https://perma.cc/W348-CCVA].

172. *See generally* Timothy D. Lytton, *Using Tort Litigation to Enhance Regulatory Policy Making: Evaluating Climate-Change Litigation in Light of Lessons from Gun-Industry and Clergy Sexual-Abuse Lawsuits*, 86 TEX. L. REV. 1837, 1841 (2008) ("[L]itigation . . . shapes public opinion, which in turn creates pressure for reform."); Gregory Briker, *The Anatomy of Social Movement Litigation*, 132 YALE L.J. 2304, 2306 (2023) ("[L]itigation can also shape social movements . . . . Legal concepts like rights can frame grievances and unite activists around particular goals."). Additionally, litigation could also bring awareness to the issue. Lytton, *supra*, at 1841 ("[L]itigation can provide a new venue for policy issues, framing them in new ways . . . . [L]itigation also attracts press coverage . . . .").

173. *See generally* Brown v. Bd. of Educ., 347 U.S. 483 (1954) (holding that "separate but equal" violated the U.S. Constitution). Sadly, the Brown decision did not immediately end segregation, as it took several years and more Court decisions to implement its central holding. *Brown v. Board of Education: The Case that Transformed America*, LEGAL DEF. FUND, https://www.naacpldf.org/brown-vs-board [https://perma.cc/ZY83-A27S].

174. Obergefell v. Hodges, 576 U.S. 644 (2015).

175. *E.g.*, Annika Kim Constantino, *Juul to Pay $462 Million to Settle Youth Vaping Claims from Six States, D.C.*, CNBC (Apr. 13, 2023), https://www.cnbc.com/2023/04/12/juul-to-pay-462-million-settlement-to-six-states.html [https://perma.cc/98Y3-LG7L] (discussing the effects of Juul settlements on underage use of their products).

them, have even changed large businesses' behavior,[176] something that would be especially important when suing food manufacturers. An allergic consumer challenging PAL usage could sue under federal or state law, but neither provides an easy route for potential plaintiffs.

Under federal law, the FALCPA and its enforcement mechanisms provide no relief for consumers. The law does not provide a private right of action for individuals, instead vesting sole enforcement power in the FDA.[177] This means that, even if a consumer knew of a violation and could prove it, the consumer would have to pursue enforcement through the FDA and not the courts.[178] Relatedly, a consumer cannot induce the FDA to take action on PALs, as agencies generally cannot be forced to act by private parties.[179] In other words, courts do not have the power to hear lawsuits asking the FDA to take action.[180]

Although other federal laws address food labeling and food allergies, none provide a viable route for the consumer. The Americans with Disabilities Act (ADA) is a broad regulatory scheme that aims to protect those with disabilities against

176. *See, e.g.*, Taylor Telford, *Law Firm Opens Diversity Fellowship to All Students After Lawsuit*, WASH. POST (Sept. 6, 2023), https://www.washingtonpost.com/business/2023/09/06/morrison-foerster-diversity-lawsuit-white-applicants [https://perma.cc/7Y2D-PRJ2] (describing how a large law firm ended its diversity program after a recent lawsuit).

177. *See* Nicole E. Negowetti, *Food Labeling Litigation: Exposing Gaps in the FDA's Resources and Regulatory Authority*, BROOKINGS INST. 10 (June 2014), https://www.brookings.edu/wp-content/uploads/2016/06/Negowetti_Food-Labeling-Litigation.pdf [https://perma.cc/4FUF-LNUZ] (noting that the FDCA does not provide for a private right of action).

178. *Id.* at 3 (describing how the FDA is responsible "for enforcing labeling regulations"). Unless, of course, the individual has a parallel right to relief under state law. *See infra* Part II.C (describing options to challenge food labelling practices under state law). Other issues abound with FDA enforcement. One, the FDA lacks the resources to effectively monitor labeling violations. Negowetti, *supra* note 177, at 2. Two, it does not exercise its authority enough to sufficiently deter manufacturers from false labeling practices. *Id.* at 3–4. While it does have the authority to seize products and impose fines, the FDA's main mechanism of compliance is a warning letter. *Id.*

179. *See, e.g.*, Heckler v. Chaney, 470 U.S. 821, 821–22 (1985) (holding that a federal agency's decision to not take an enforcement action is presumptively unreviewable by the courts).

180. An individual could, however, petition the FDA to pursue regulation of PALs, but this is highly unlikely to be successful because of the current landscape of PALs and the manufacturing lobbying power behind their use. *See supra* Part II.A (noting FDA's reluctance to regulate PALs).

discrimination.[181] Unlike the FALCPA, the ADA contains a private right of action and, as amended in 2008, covers individuals with food allergies.[182] However, the ADA only applies to places of public accommodation, and a food label on a product is almost certainly not a place of public accommodation.[183] In the advertising realm, the Lanham Act creates a private cause of action for competitors who suffered harm from false or misleading advertising practices.[184] For example, Novartis sued Johnson & Johnson (their competitor) for making unsubstantiated and misleading promises about their antacid tablet.[185] While the FDCA does not preclude suits under the Lanham Act,[186] a competitor would be unlikely to bring a PAL-related lawsuit because most, if not all, food manufacturers reap the benefits of PAL use.[187] This gives them little incentive to challenge PAL use by a competitor. Thus, federal law, even when it does provide for a cause of action,

181. *See generally Americans with Disabilities Act*, U.S. DEP'T OF LAB., https://www.dol.gov/general/topic/disability/ada [https://perma.cc/SM47-447L] (outlining the purpose of the ADA).

182. The private right of action is codified at 28 C.F.R. § 36.501 (1991). As originally passed, the ADA did not cover those with food allergies. Jason Mustard, Comment, *Nothing to Sneeze at: Severe Food Allergy as a Disability Under the ADA Amendments Act of 2008*, 45 GOLDEN GATE U. L. REV. 173, 174 (2015). After the Amendments in 2008, it became clear that those with severe food allergies were included in the definition. *See id.* (noting court decisions that indicated that the ADA applied to those with severe food allergies).

183. While there has been an expansion in the definition of "place of public accommodation," it seems unlikely that even the broadest definition would reach a food label. A website is potentially the most analogous medium that has been held to be a place of public accommodation, but the distinctions between a website and a food label are readily apparent. *See generally* Tavarez v. Moo Organic Chocolates, LLC, 623 F. Supp. 3d 365, 367 (S.D.N.Y. 2022) (holding that a website is a place of public accommodation even if it is not tethered to a public-facing physical location). Much like a store or a more "traditional" place of public accommodation, a website is a place where users interact, and products are bought. A food label, however, is found on a physical food product and provides neither of these things.

184. 15 U.S.C. § 1125; POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102, 106 (2014). ("[The Lanham Act] allows one *competitor* to sue another if it alleges unfair competition arising from false or misleading product descriptions." (emphasis added)).

185. Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Pharms. Co., 290 F.3d 578 (3d Cir. 2002) (affirming preliminary injunction).

186. POM Wonderful LLC, 573 U.S. at 121 ("Congress did not intend the FDCA to preclude Lanham Act suits . . . .").

187. See *supra* Part I.B, for a discussion of the prevalence of PAL use.

is not a viable route for an individual to challenge the use of PALs.

C. STATE COMMON LAW CAUSES OF ACTION: CONTAINS TWO OBSTACLES AND NO SOLUTION

Despite the soaring number of food allergies, there is a surprising dearth of caselaw involving food allergies and inadequate food labels.[188] Recently, there has been an explosion in state lawsuits challenging the use of food labels more generally, especially for nutritional and health claims, but there is no similar uptick in food allergy lawsuits.[189] Why this disparity exists is somewhat unclear, but the challenging nature of bringing a claim for a faulty food label that led to an allergic reaction explains a large part of it.[190] One significant hurdle in allergy cases is proving causation, something that can be especially difficult if all of the suspect product was consumed, leaving nothing but the food label—which presumably states that the product does not contain the allergen—as evidence.[191] This, along with the complicated

188. *See* Roses, *supra* note 28, at 231 ("Despite the prevalence of food allergies, there is little history of food allergen litigation in the United States."). This could be evidence that the law currently does not sufficiently protect consumers with allergies. *Id.* at 241.

189. *See* Negowetti, *supra* note 177, at 1 (noting the "unprecedented surge" in lawsuits against the makers of products such as Naked Juice, Fruit Roll-Ups, Bear Naked Granola, and Wesson Oil (quoting *The New Lawsuit Ecosystem: Trends, Targets, and Players*, U.S. CHAMBER INST. FOR LEGAL REFORM (Oct. 2013), https://instituteforlegalreform.com/wp-content/uploads/media/The_New_Lawsuit_Ecosystem_pages_web.pdf [https://perma.cc/45S6-XA6X])). For example, Pinnacle Foods settled a potential lawsuit for marketing its waffles as "blueberry waffles" despite the fact that the waffles contained no blueberries. *Id.* at 7.

190. *See* Roses, *supra* note 28, at 226 ("[L]itigation has been sparse and success for plaintiffs rare due to challenges in proving causation and prevalence of their allergic condition."). *Ruff v. Perfetti Van Melle USA Inc.*, a recent case, further drives this point home. Civil Action No. 23-70, 2024 WL 329525 (E.D. Ky. Jan. 27, 2024). In *Ruff*, the plaintiff suffered an allergic reaction to Airheads, relying on the package's "tree nut free" statement to conclude that the product did not contain tree nuts. *Id.* at *1–2. The Court dismissed the suit, concluding that it was not reasonable for the plaintiff to rely on such a statement because the product's ingredient list noted the presence of tree nuts, which the plaintiff should have read. *Id.* at *4–5.

191. In *Moore v. P.F. Chang's China Bistro, Inc.*, a case analogous to the hypothetical described above, the plaintiff suffered an allergic reaction after consuming a dish at P.F. Chang's. No. B193396, 2007 WL 2121240, at *1 (Cal. Ct. App. July 25, 2007). She claimed it had shellfish in it. *Id.* The Court dismissed

nature of the defendant's manufacturing processes and procedures, makes proving that the product contained the allergen and that it was the manufacturer's negligence that caused the allergen's presence especially difficult.[192]

As it relates to a hypothetical suit brought against a food manufacturer for PAL misuse, the claim falls under state common law theories of products liability.[193] More specifically, the suit would allege a failure to warn because the food label's deficiency caused the harm.[194] Any plaintiff bringing such a suit would have to overcome the challenges noted above, along with two specific, formidable obstacles unique to a PAL claim: (1) preemption and (2) adequate warning/assumption of risk. As demonstrated below, these obstacles/defenses would likely result in the dismissal of the plaintiff's claim. Therefore, a different approach is needed.

This section proceeds in two subsections. Subsection 1 details preemption and its inevitable applicability to a common law PAL lawsuit. Subsection 2 examines PALs as a warning device and finds that manufacturers can defend against a common law claim by arguing that the plaintiff assumed the risk by ignoring the PAL and consuming the product.

1. Copycat Recipe: Preemption's Preemptive Strike

Preemption doctrine holds that when federal and state law or authority conflict, federal trumps its state equivalent.[195] There are two types.[196] The first is express preemption, which occurs when Congress explicitly states that federal law trumps state law in a certain area.[197] In the context of the FDCA,

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the suit, holding that it was her blood pressure medication that caused the reaction. *Id.* at *5–7. Crucially, there was nothing left of the dish to test. *Id.* at *4.

192. *See generally id.* at *5–7 (dismissing the case because plaintiff could not meet her burden).

193. *See* Roses, *supra* note 28, at 226 (noting that most food allergy consumer lawsuits have been filed under "common law products liability causes of action").

194. *See id.* at 230 ("[T]he greatest source of litigation for food allergies has been common law, mostly based on the tort doctrines of failure to warn . . . .").

195. *See generally* Kellen Norwood, *Federal Preemption of State and Local Law*, *in* MUNICIPAL LAW DESKBOOK 1, 1–9 (William Scheiderich, ed., 2015).

196. *Id.* at 9 ("Preemeption may be either expressed or implied . . . .").

197. *See id.* ("Congress expressly preempts state law when it includes language like this in a statute: 'No state shall adopt or enforce any law, rule,

Congress provided an express preemption clause that forbids states from establishing any requirements that differ from the FDCA.[198] The second type is implied preemption, a more challenging subset in which courts must determine whether Congress has regulated so heavily in an area so as to preclude any state regulation.[199] In the context of the FDCA, courts have held that state negligence claims premised on a violation of FDCA obligations are not impliedly preempted if the state duties do not add to federal labeling requirements.[200] Said another way, states can enact parallel, equivalent duties to federal law but any regulations that go beyond them will be impliedly preempted.[201] Thus, though different, both types of preemption apply if adjudicating the lawsuit requires adding new requirements to current federal law.

A food manufacturer defending a PAL lawsuit would argue that the claim is both expressly and impliedly preempted because the lawsuit seeks to impose additional PAL requirements. The central problem for a PAL plaintiff is that the FDCA permits PALs.[202] Consequently, any court-imposed remedy would necessarily demand additional requirements beyond the FDCA, triggering preemption.[203] Unlike a PAL suit, most food allergy labeling claims avoid preemption by alleging breaches of duty for violations of the FDCA.[204] For example, in *Spano ex rel. C.S. v.*

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regulation, standard or other provision having the force and effect of law relating to . . . ."').

198. Spano *ex rel.* C.S. v. Whole Foods, Inc., 65 F.4th 260, 262–63 (5th Cir. 2023) ("The express preemption clause of the FDCA provides . . . that 'no State . . . may directly or indirectly establish . . . any requirement for the labeling of food of the type required by section . . . 343(w) . . . that is not identical to the requirement of such section.'" (quoting 21 U.S.C. § 343–1(a))).

199. *See* Norwood, *supra* note 195, at 10–12 (discussing the different types of implied preemption).

200. *Spano*, 65 F.4th at 264.

201. For example, California has enacted its own version of the FDCA. *See infra* Part III.B (noting the advantages of California consumer protection statutes for PAL litigation).

202. *See supra* Part I.B (discussing the background and requirements of the FDCA).

203. *See id.*; *Spano*, 65 F.4th at 261 (discussing when preemption is triggered).

204. *E.g.*, Cline v. Publix Super Mkts., Inc., No. 3:15–0275, 2015 WL 3650389 (M.D. Tenn. June 11, 2015) (alleging that defendant's failure to warn of peanuts in a cookie caused plaintiff's allergic reaction and death); *See Spano*, 65 F.4th at 260 (explaining when FDCA violations may be presented).

Whole Foods, Inc., a plaintiff sued after suffering an allergic reaction to a "vegan" cupcake that allegedly contained dairy.[205] If true, the cupcake was mislabeled under the FDCA because it failed to list one of the eight major allergens on its label.[206] Therefore, the food manufacturer potentially violated a pre-existing federal duty to list all major allergens, a duty all other food manufacturers presumably follow, and the Court held it was not preempted for these reasons.[207] Conversely, in a PAL suit, a court finding for a plaintiff would necessarily impose a duty beyond the FDCA, subjecting food manufacturers to different standards.[208] This directly runs afoul of preemption principles and would likely cause a court to dismiss the suit as expressly and impliedly preempted.

2. Buyer Beware: PAL as a Warning and Assuming the Risk

Another, more obvious, defense for a PAL suit is that the food manufacturer warned the consumer of the risk that the product contained the allergen, and they chose to disregard the warning in consuming the product. Broadly speaking, a manufacturer's failure to warn of the dangers associated with a product could constitute a basis for relief for a potential litigant.[209] As noted above, a manufacturer has a duty to warn about the presence of a food allergen in its product.[210] Without delving too deep into failure to warn specifics, an obvious problem emerges for a plaintiff seeking relief for a PAL-labeled product: the PAL

205. *Spano*, 65 F.4th at 261.

206. 21 U.S.C. § 343(w) (describing "[m]ajor food allergen labeling requirements").

207. *Spano*, 65 F.4th at 264 (noting that the requirements for preemption are not met).

208. *See generally Spano*, 65 F.4th at 261 (discussing when preemption can be triggered).

209. Richard E. Kaye, *Manufacturer's Failure to Warn Consumer of Allergenic Nature of Product* ("The failure of a manufacturer or seller to provide an adequate warning as to the dangers associated with its product may serve as the basis for a cause of action against the manufacturer or seller."), *in* 139 AMERICAN JURISPRUDENCE: PROOF OF FACTS 573, 580 (3d series 2014).

210. Cline v. Publix Super Mkts., Inc., No. 3:15–0275, 2015 WL 3650389, at *4 (M.D. Tenn. June 11, 2015) ("Generally, the FDCA and FALCPA require that manufacturers or sellers of food products label food with information related to the food products' ingredients and any allergens that the products may contain . . . .").

is a warning.[211] By consuming the product with the PAL, the plaintiff chose to ignore the warning and assumed the risk that their allergens would be in the product.[212] While claimants have pursued failure to warn claims against food manufacturers for allergic reactions, almost all have done so when the product is mislabeled.[213] In these cases, the consumer is unaware of the risk in consuming the product because the label does not communicate the proper allergens. Conversely, the PAL label is "correct" in that it properly communicates the risk of present allergens to the consumer, who then can choose to disregard the warning.[214] It is the consumer's decision, not the manufacturer's error, that causes the allergic reaction, and this should free a food manufacturer from liability from a failure to warn claim.[215]

As an alternative, a plaintiff could challenge the adequacy of the warning, but this too will likely fail. An inadequate warning does not free a food manufacturer from liability,[216] and a plaintiff could argue that the warning is inadequate because the PAL does not definitively state that the product contains the allergen.[217] However, the main flaw with this argument is that the

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211. Though a PAL has never been held to be a warning, food labels generally have consistently been construed as warnings. *See, e.g.*, *id.* at *5 (holding that a bag that contained no warning of the potential allergens of a cookie should not be dismissed by the Court because the producer had a duty to warn and failed to do so).

212. *See* Roses, *supra* note 28, at 225 ("[F]ood allergic consumers may waive any right to litigate allergic reactions if they consume foods bearing precautionary warnings.").

213. *E.g.*, *Spano*, 65 F.4th at 262 (bringing suit for a mislabeled vegan cupcake under a failure to warn theory); *see also* Mills v. Giant of Md., LLC, 508 F.3d 11, 12 (D.C. Cir. 2007) (alleging a failure to warn for a lack of warning about lactose intolerance on a carton of milk).

214. Unless, of course, the PAL lists the wrong allergens.

215. *See* Kaye, *supra* note 209, at 611 ("The defense of assumption of risk—that one who voluntarily assumes the risk of injury from a known danger is barred from recovery—might be available to a manufacturer if, for example, the plaintiff used the product despite knowledge that the product could cause the plaintiff to suffer an allergic reaction to it.").

216. *See generally* Bryant v. Tech. Rsch. Co., 654 F.2d 1337, 1345–46 (9th Cir. 1981) (detailing standards for reviewing the adequacies of warnings).

217. For example, a "contains" statement definitely tells a consumer whether the allergen is in the product. A "may contain" statement, on the other hand, indicates that there is a possibility that the allergen might not be in the product.

FDA accepts this type of warning.[218] Most courts would likely find this highly persuasive.[219] Thus, PALs are an adequate warning, making a manufacturer's defense of assumption of the risk highly likely to succeed.

Frustrated allergic consumers are seemingly out of options. The FDA is unlikely to provide any substantial relief on its own, so consumers should begin to file lawsuits to change current PAL use. But federal laws provide no viable route to do so, and state common law does not either, especially when considering the defenses of preemption and assumption of the risk. A different, more creative approach is needed to address these issues and provide relief for those with food allergies.

III. A NATURAL PARALLEL: HOW "NATURAL" LITIGATION CAN SERVE AS A BLUEPRINT FOR CHALLENGING THE USE OF PALS AND CREATING CHANGE

While seemingly out of options, those with food allergies are not without precedent for changing harmful labeling practices through lawsuits. Throughout the 2000s, frustrated consumers sued food manufacturers under California's consumer protection statutes for false and misleading application of the term "natural" to food products.[220] These lawsuits, and the threat of them, caused a sharp decrease in the use of the term—presumably because food manufacturers started using the word only when their products were in fact "natural."[221] Consumers with food allergies should take a similar approach. Just like the term "natural," PALs are applied in a haphazard, meaningless way,[222] and consumer lawsuits may be the only way to hold food manufacturers accountable in the likely absence of FDA action. Lawsuits

218. *See, e.g.*, FDA COMPLIANCE GUIDE, *supra* note 101, at 8 (discussing PALs and their accepted status).

219. *See* Spano *ex rel.* C.S. v. Whole Foods, Inc., 65 F.4th 260, 264–65 (5th Cir. 2023) (discussing how FDA violations could be evidence that the defendant is liable under a state law duty and implying that FDA compliance is evidence of nonliability).

220. *See infra* Part III.A (noting food litigation trends in California related to the use of consumer protection statutes).

221. *See infra* Part III.A (discussing the decline of the use of the word "natural" on food labels).

222. *See supra* Part I.B (identifying the shortcomings of PALs).

under these statutes provide the best route to reduce PAL use and generate the change allergic consumers need and deserve.[223]

This Part proceeds in two sections. Section A examines caselaw regarding the term "natural" and argues that the cases' ability to reduce the term's use makes it an ideal blueprint for lawsuits challenging the use of PALs. Section B then analyzes how such a claim would work. It first details California's consumer protection statutes and then argues that the Unfair Competition Law and Consumer Legal Remedies Act provide the best route through which consumers could change current PAL practices for the betterment of those with food allergies.

A. A STORY OF ONE WORD: LITIGATION AROUND THE TERM "NATURAL" AND WHY ITS ABILITY TO CREATE CHANGE IS A MODEL FOR PAL CHALLENGES TO FOLLOW

The story of "natural" lawsuits begins in the early 2000s with the start of the American obesity epidemic. As Americans increased their appetites but decreased their exercise, obesity rates began to skyrocket in 2004 and continued to rise for the next several years.[224] Alarmed, consumers began to look for ways to eat healthier by focusing on healthy, fresh food.[225] "Organic" products became consumers' new favorites, as did anything like them, such as "natural" foods.[226]

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223. Though many have identified the need for a solution to the PAL problem, none have articulated a coherent theory of how to do so other than FDA/congressional action. *See, e.g.*, Roses, *supra* note 28, at 226 ("Congress should rectify this situation and better protect food allergic consumers by further amending the FD&C Act . . . ."). This Part appears to be the first to assert a solution that would empower individuals to reduce PAL use and promote better and more accurate food labels.

224. *State of Obesity 2023: Better Policies for a Healthier America*, TRUST FOR AM.'S HEALTH (Sept. 21, 2023), https://www.tfah.org/report-details/state-of-obesity-2023 [https://perma.cc/4VK5-7JMC] ("Over the past two decades obesity rates have climbed for all population groups . . . ."); *Obesity in America*, PUBLICHEALTH.ORG, https://publichealth.org/public-awareness/obesity [https://perma.cc/JG8Y-C5L7] ("[T]he preponderance of evidence points to the two causes most people already suspect: too much food and too little exercise.").

225. *E.g.,* Negowetti, *supra* note 177, at 5 ("As the American obesity 'epidemic' has become one of the most pressing public health issues, consumers have been increasingly demanding healthier food products." (footnote omitted)).

226. *Id.* at 6 (noting that food labeled "natural" or "organic" constituted fifteen percent of all food products sold in 2013).

However, the term "natural," unlike "organic," lacks any regulatory definition.[227] The FDA has never defined the term; the Agency has only published informal guidance that states that a product is "natural" if "nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food."[228] This policy lacks the force of law,[229] but even if it did not, the definition completely disregards food production and processing methods,[230] as well as the supposed health benefits of the food.[231] Consequently, manufacturers are almost entirely free to apply the term "natural" at their discretion, and they began doing so to try and capitalize on shifting consumer preferences.[232]

In turn, consumers, believing the term signified a healthier product, started purchasing these products in large numbers—only to find out there was nothing "natural" about them.[233] The label lacked any real meaning and covered nearly every kind of

227. *E.g.*, Joyanna Hansen, *Interpreting Food Labels: Natural Versus Organic*, AM. SOC'Y FOR NUTRITION (Feb. 2, 2013), https://nutrition.org/interpreting-food-labels-natural-versus-organic [https://perma.cc/4H23-SK5Z] ("[T]he U.S Food and Drug Administration (FDA), responsible for regulating and supervising food production, does not define or regulate the label 'natural' on food products.").

228. *Use of the Term Natural on Food Labeling*, FDA (Oct. 22, 2018), https://www.fda.gov/food/food-labeling-nutrition/use-term-natural-food-labeling [https://perma.cc/6GRM-2D24].

229. Negowetti, *supra* note 177, at 11 ("Although the FDA has seemed to recognize the importance of formally defining this term and has recognized that an adequate definition could prevent consumer confusion, the agency nevertheless has declined to adopt a formal definition." (footnote omitted)).

230. *What is "Natural"?*, FOOD INSIGHT (Nov. 10, 2021), https://foodinsight.org/what-is-natural [https://perma.cc/8ZCY-8YDG] ("[T]his FDA policy on 'natural' only covers part of the picture; it is not meant to address food production, processing or manufacturing.").

231. *Id.* (noting that the FDA's policy on the term "natural" is not indicative of the nutritional benefit of the food).

232. In 2009, 30.4% of all new products introduced contained the "natural" label. Mike Esterl, *Some Food Companies Ditch 'Natural' Label*, WALL ST. J. (Nov. 6, 2013), https://www.wsj.com/articles/SB10001424052702304470504579163933732367084 [https://perma.cc/G8C7-PGBP].

233. In 2013, consumers spent nearly forty million dollars on products that used the word "natural." Christy Wyatt, Note, *The Case Against La Croix: Moving Beyond the Ingredient List in "Natural" Litigation*, 89 U. CIN. L. REV. 231, 231 (2020).

product, from La Croix[234] to ice cream,[235] regardless of their "natural" or health properties. This partly explains why obesity rates continued to climb even though access to "healthy" or "natural" foods increased.[236] To add insult to injury, consumers often paid more for these "natural" products than they would have for other, non-natural products.[237]

Frustrated with this haphazard approach, and facing little prospect of FDA action, consumers began to file lawsuits.[238] These suits alleged false/misleading advertising and involved products that, while compliant with the FDA's loose guidance, were not "natural" in the ordinary sense.[239] For example, in 2007, a group of plaintiffs brought a lawsuit against Snapple for claiming that their products were "100% natural" when the product contained high-fructose corn syrup,[240] a heavily processed liquid sweetener derived from corn.[241] In another similar

234. *See id.* at 238–48 (discussing lawsuits brought against La Croix for describing its drink as "natural").

235. Negowetti, *supra* note 177, at 14 (detailing lawsuits brought against Ben & Jerry's "all natural" ice cream). For more illustrative examples of the term "natural," see Andrea Rock, *Peeling Back the 'Natural' Food Label*, CONSUMER REPS. (Jan. 27, 2016), https://www.consumerreports.org/food-safety/peeling-back-the-natural-food-label [https://perma.cc/6ND2-XC7P].

236. *See US Obesity Rates Have Tripled Over the Last 60 Years*, USAFACTS (last updated Mar 21, 2023), https://usafacts.org/articles/obesity-rate-nearly-triples-united-states-over-last-50-years [https://perma.cc/ZW6J-CEYV] (illustrating the rise in obesity in the last sixty years).

237. Fred Kuchler & Megan Sweitzer, *Prevalence of the "Natural" Label Varies by Food Category*, U.S. DEP'T AGRIC. (Aug. 30, 2023), https://www.ers.usda.gov/amber-waves/2023/august/prevalence-of-the-natural-label-varies-by-food-category [https://perma.cc/HVR2-EJ92] ("U.S. food suppliers use packaging labels to make claims that highlight production-process attributes some consumers want, often charging a higher price for those products than for products without label claims.").

238. The consumer advocacy group Center for Science in the Public Interest's litigation department mostly filed the lawsuits, attempting to "fill the void left by the inactive government agencies by using state and federal courts to correct corporate misbehavior." *Negowetti, supra* note 177, at 7.

239. *See id.* at 11 (discussing the liability theories of plaintiffs in food labeling lawsuits).

240. Holk v. Snapple Beverage Corp., 575 F.3d 329, 332 (3d Cir. 2009) ("[Plaintiff] argued that . . . Snapple products were not 'All Natural' because they contained [high-fructose corn syrup] . . . .").

241. WebMD Editorial Contributor, *What to Know About High-Fructose Corn Syrup*, WEBMD (July 14, 2023), https://www.webmd.com/diet/what-to-know-about-high-fructose-corn-syrup [https://perma.cc/HAL2-5R6A].

example, plaintiffs sued Kashi for labeling products "all-natural" even though they contained genetically-modified organisms.[242]

The results of these lawsuits were highly varied, but the two most common outcomes were court dismissal or settlement.[243] The main reason that courts decline to hear these cases is primary jurisdiction.[244] A cousin of preemption, this doctrine expresses deference to the FDA and allows a court to stay or dismiss a case while it waits for FDA action.[245] While it does not appear that any of these cases made it to trial,[246] plaintiffs still found success through lucrative settlements.[247] For instance, PepsiCo settled claims about its Naked Juice product for nine million dollars.[248]

Most importantly, use of the term "natural" has declined since the start of these lawsuits, evidencing the impact litigation can have. Following the initiation of these claims, food and drink manufacturers started voluntarily removing the term "natural"

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242. Garcia v. Kashi Co., 43 F. Supp. 3d 1359, 1368 (S.D. Fla. 2014). For more examples of claims brought against companies who used the "natural" label for products with artificial ingredients and preservatives, see Negowetti, *supra* note 177, at 13–15.

243. *See* Negowetti, *supra* note 177, at 11–15 (describing reasons for dismissal of cases and settlements).

244. Note, *A "Natural" Stand Off Between the Food and Drug Administration and the Courts: The Rise in Food-Labeling Litigation & the Need for Regulatory Reform*, 60 B.C. L. REV. 271, 297 (2019) [hereinafter *A "Natural" Stand Off*].

245. *See, e.g.*, Kane v. Chobani, LLC, 645 Fed. App'x 593, 594 (9th Cir. 2016) ("The delineation of the scope and permissible usage of the terms 'natural' and 'evaporated cane juice' in connection with food products 'implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch.'").

246. Stephen P. Safranski & Adam Welle, *Natural-Labeling Litigation: Preparing for the Next Five Years*, ROBINS KAPLAN (Apr. 8, 2014), https://www.robinskaplan.com/resources/publications/2014/04/natural-labeling-litigation-preparing-for-the-next-five-years [https://perma.cc/89KX-WYJ8] (highlighting that there have been no trials regarding the use of the term "natural"). This article was written in 2014, but as far as research shows it still rings true today.

247. Some false and misleading settlements have gone as high as forty-five million dollars. *See* Negowetti, *supra* note 177, at 9 (detailing a 2010 settlement with Dannon regarding false claims of the digestive benefits of their yogurt).

248. Ben Bouckley, *PepsiCo Brand Naked Juice Cuts 'All Natural' Claim After $9m US Payout*, FOOD NAVIGATOR (July 17, 2023), https://www.foodnavigator-usa.com/Article/2013/07/17/PepsiCo-brand-Naked-Juice-cuts-all-natural-claim-after-9m-US-payout [https://perma.cc/W3NR-G3EC].

from their packages.[249] From 2009 to 2013, usage of the term "natural" declined by eight percent in food products and eleven percent in beverages.[250] Presumably, this decline is due to food manufacturers removing the term from products that might not be "natural"—products that would be the subject of a lawsuit.[251] In other words, the cost incentive now weighs in favor of omitting the word from products that are not "natural" because of the potential of a lawsuit.[252] This decrease, in turn, provides consumers the opportunity to make more informed choices at the grocery store because the word "natural" is now being used how most people understand it, i.e., free of harmful, ultra-processed ingredients.[253]

The possibility of similar change explains why allergic consumers should use the "natural" cases as a blueprint. Much like the term "natural," food manufacturers are exploiting a regulatory loophole to apply PALs in a pervasive, haphazard way that obscures an allergic consumer's ability to make an informed choice.[254] Change is needed, as PAL overuse harms those with food allergies by sharply reducing their available options or putting them at risk for an allergic reaction if the consumer (understandably) disregards the PAL.[255] But, just as in the "natural" context, the FDA seems unlikely to act, and food manufacturers seem equally unlikely to stop this practice on their own.[256] Allergic consumers, then, must act on their own through filing lawsuits against food manufacturers to reduce PAL use. As shown by "natural" litigation, lawsuits, and the potential of them, can

249. *See, e.g.*, Esterl, *supra* note 232 ("A growing number of food and drink companies including PepsiCo Inc. and Campbell Soup Co. are quietly removing these claims from packages amid lawsuits challenging the 'naturalness' of everything from potato chips to ice cream to granola bars.").

250. *Id.*

251. *See generally id.* (discussing the decline in "natural" usage and reasons for it).

252. *Id.* (noting that food manufacturers don't think the term is "worth it" now).

253. For example, "Goldfish" will no longer be "All-Natural Goldfish" because they contain genetically-modified soy. *Id.*

254. *See supra* Part I.B (discussing carelessness and shortcomings in food labels).

255. *See supra* Part I.B (identifying risks to consumers arising from issues with PALs).

256. *See supra* Part II.A (giving reasons for the FDA's reluctance to regulate PALs).

lead to a reduction in the use of PALs. Those with food allergies deserve to know whether a PAL actually signifies a risk of an allergen, just like "natural" consumers deserve a truthful label that does not deceive them, and PAL lawsuits—following the blueprint of their "natural" predecessors—provide the best way to accomplish it.

B. NOT UNFAIR ANYMORE: HOW CALIFORNIA'S CONSUMER PROTECTION STATUTES COULD PROVIDE A ROUTE FOR PLAINTIFFS TO CHALLENGE PAL USE

While the ability to create change makes the "natural" blueprint important by itself, the lawsuits also highlight three reasons why California's consumer protection statutes are well-suited for a PAL claim. One, PALs, much like the term "natural," mislead consumers, making them ripe for a consumer protection lawsuit.[257] Additionally, unlike traditional common law claims, consumer protection statutes potentially circumvent the defenses of preemption and assumption of risk. Two, the statutes are unparalleled in their breadth, something that would be especially helpful when pursuing a novel claim for PALs.[258] The statutes' broadness is why California has become the battleground for most food labeling lawsuits.[259] Three, this litigation history, including "natural" lawsuits, provides food-labeling precedent, giving plaintiffs a unique insight into how courts would treat a PAL claim.[260] Under this consumer protection umbrella, a lawsuit challenging the use of PALs can succeed in changing current PAL practices to promote better and more accurate food labels.

This section proceeds in two subsections. Subsection 1 provides an in-depth examination of California's three consumer protection statutes. Subsection 2 then applies this law to a hypothetical case challenging PALs and shows how a lawsuit filed under these statutes could succeed.

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257. *See supra* Part I.B (noting potential legal issues surrounding PALs).

258. *See generally An Overview of California Consumer Protection Law*, CONN LAW, PC (Feb. 9, 2023), https://connlawpc.com/blog/an-overview-of-california-consumer-protection-laws [https://perma.cc/PL49-H9QH] (discussing the robustness of California's consumer protection laws).

259. *See* Negowetti, *supra* note 177, at 1 (noting that the majority of cases challenging food labels have been filed in California).

260. *See infra* Part III.B.2 (relating California's Unfair Competition Law and Consumer Legal Remedies Act to PAL litigation).

1. The Plaintiff's Trilogy: California's Three Consumer Protection Statutes

The three statutes plaintiffs mostly used to challenge the term "natural"—and ones that could serve as the basis for a lawsuit challenging the use of PALs—are California's Unfair Competition Law (UCL), False Advertising Law (FAL), and Consumer Legal Remedies Act (CLRA).[261]

Enacted to "promot[e] fair competition," the UCL applies broadly to prohibit various types of unfair behavior.[262] To succeed on a UCL claim, a plaintiff must satisfy one of two pathways by showing either: (1) an "unlawful, unfair, or fraudulent business act or practice," or (2) "unfair, deceptive, untrue or misleading advertising."[263] Thus, on its face, the UCL prohibits three types of behavior in the first pathway and four in the second, denoting its expansive nature for plaintiffs seeking remedies.

Before reaching the merits, however, a plaintiff must satisfy the rigorous standing requirements of the statute.[264] A plaintiff has standing under the UCL by establishing both a (1) loss or deprivation of money or property sufficient to qualify as injury in fact, i.e., economic injury, and (2) that the economic injury was the result of, i.e., caused by, the unfair business practice or false

261. *E.g.*, Negowetti, *supra* note 177, at 11 ("Most of the food labeling lawsuits filed in California allege violations of the Unfair Competition Law . . . predicated on violations of the False Advertising Law . . . or the Consumer Legal Remedies Act . . . ." (footnotes omitted)). The UCL can be found at CAL. BUS. & PROF. CODE §§ 17200–10 (West 2024). The FAL can be found at CAL. BUS. & PROF. CODE §§ 17500–57.2 (West 2024). The CLRA can be found at CAL. CIV. CODE §§ 1750–84 (West 2024).

262. The purpose of the UCL is "to protect both consumers and competitors by promoting fair competition in commercial markets for goods and services." Kwikset Corp. v. Superior Ct., 246 P.3d 877, 883 (Cal. 2011). Courts have repeatedly stated that the UCL applies broadly. *E.g.*, Cel-Tech Comms., Inc. v. Los Angeles Cellular Tel. Co., 973 P.2d 527, 540 (Cal. 1999) ("The unfair competition law, which has lesser sanctions than the Unfair Practices Act, has a broader scope for a reason."); *In re* Tobacco II Cases, 207 P.3d 20, 33 (Cal. 2009) (highlighting the "broad remedial purpose" of the UCL).

263. *See, e.g.*, Lippitt v. Raymond James Fin. Servs., 340 F.3d 1033, 1043 (9th Cir. 2003) (quoting BUS. & PROF. § 17200).

264. *See* BUS. & PROF. § 17203 ("Any person may pursue representative claims or relief on behalf of others only if the claimant meets the standing requirements of Section 1704 . . . .").

advertising.[265] Courts have interpreted the "economic injury" language narrowly by limiting it to circumstances involving the purchase of a product.[266] The "caused by" element is easier to satisfy, as plaintiffs need not prove that the unfair business practice was the sole cause of the injury, only that it was a "substantial part."[267] For example, plaintiffs in "natural" litigation satisfied both UCL standing requirements by alleging that they would not have bought the product had it not been advertised as "natural" or that they paid more because of the term.[268] The difference in price or purchasing of a product constitutes the economic injury, and the plaintiff's (misplaced) reliance on the term "natural" satisfies the "caused by" element.[269]

As for the actual elements of a claim, a plaintiff may succeed in the first pathway by showing an "unfair business practice," which California courts use two competing tests to determine.[270] The first test states that an "unfair" practice is one that "offends established public policy" because "it is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers."[271] For example, Hertz's disclosure of a refueling charge in small, hard-to-read font on their main rental document was considered an unfair practice.[272] The second test states that a plaintiff must show that the "unfair" practice is tied to some specific

265. BUS. & PROF. § 17204 ("Actions for relief pursuant to this chapter shall be prosecuted . . . by . . . a person who has suffered injury in fact and has lost money or property as a result of the unfair competition."); *Kwikset*, 246 P.3d at 884 (noting that the UCL restricts standing to those who were "actually injured" by the company's business practice).

266. *See* Arroyo v. TP-Link USA Corp., No. 5:14-CV-04999, 2015 WL 5698752, at *4 (N.D. Cal. Sept. 29, 2015) (dismissing claims for products that the plaintiff did not purchase or whose marketing he did not view).

267. *In re Tobacco II*, 207 P.3d at 39.

268. *See, e.g.*, Jones v. ConAgra Foods, Inc., 912 F. Supp. 2d 889, 901 (N.D. Cal. 2012) ("[E]vidence that plaintiffs would not have purchased a product if the product had been labeled accurately is sufficient to establish injury under California's consumer laws.").

269. *See generally id.* (discussing standing requirements).

270. Jolley v. Chase Home Fin., LLC, 153 Cal. Rptr. 3d 546, 574–75 (Cal. Ct. App. 2013) (noting the split in courts regarding the proper test); Shaker, *supra* note 79, at 133 (explaining the two tests).

271. Podolsky v. First Healthcare Corp., 58 Cal. Rptr. 2d 89, 98 (Cal. Ct. App. 1996); Shaker, *supra* note 79, at 133.

272. Schnall v. Hertz Corp., 93 Cal. Rptr. 2d 439, 455–56 (Cal. Ct. App. 2000).

constitutional, statutory, or regulatory provision.[273] Accordingly, it was not an unfair business practice for lenders to tell a customer that a (arguably bad) loan was "good for [them]" because this conduct is not tethered to some other regulatory provision.[274] When the California Supreme Court first articulated this test, it said that a violation of the "spirit of the law" would suffice to satisfy the requirements.[275]

Another way to succeed in the first pathway is by showing that the defendant engaged in a "fraudulent business act or practice."[276] Unlike common law fraud, this does not require proof that the alleged business had any knowledge of the falsity.[277] Rather, a plaintiff need only show that an ordinary consumer acting reasonably under the circumstances would be misled by the conduct.[278] For example, Bayer marketing their vitamins as "One-A-Day" even though consumers actually had to take them

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273. *See, e.g.*, Graham v. Bank of Am., N.A., 172 Cal. Rptr. 3d 218, 234 (Cal. Ct. App. 2014) ("Moreover, where a claim of an unfair act or practice is predicated on public policy, we read *Cel-Tech* to require that the public policy which is a predicate to the action must be 'tethered' to specific constitutional, statutory or regulatory provisions."); Shaker, *supra* note 79, at 133 (describing how this second test is used by California courts). Some courts prefer the first test because it is less rigid than the second test's focus on tying the claim to some provision or regulation. Camacho v. Auto. Club of S. Cal., 48 Cal. Rptr. 3d 770, 776 (Cal. Ct. App. 2006) ("'[T]ethering' a finding of unfairness to 'specific constitutional, statutory or regulatory provisions' does not comport with the broad scope of section 17200.").

274. *Graham,* 172 Cal. Rptr. 3d at 221, 234 (holding that homeowners must show future appraisals about the value of their home were tethered to some regulatory provisions to constitute an unfair practice).

275. Cel-Tech Comms., Inc. v. L.A. Cellular Tel. Co., 973 P.2d 527, 566 (Cal. 1999) ("[T]he word 'unfair' in that section means conduct that threatens an incipient violation of an antitrust law, or violates the policy or spirit of one of those laws . . . ."). Spirit of the law, as opposed to letter of the law, is its "perceived intention." Stephen M. Garcia et al., *The Letter Versus the Spirit of the Law: A Lay Perspective on Culpability*, 9 JUDGMENT & DECISION MAKING 479, 479 (2014) (detailing the relationship between the "spirt of the law" and culpability). It does not appear that any California case has ever held that a violation of the "spirit of a law" suffices for relief under the UCL.

276. *See, e.g.*, Lippitt v. Raymond James Fin. Servs., 340 F.3d 1033, 1043 (9th Cir. 2003) (quoting CAL. BUS. & PROF. CODE § 17200 (West 2024)).

277. *See* Day v. AT&T Corp., 74 Cal. Rptr. 2d 55, 59 (Cal. Ct. App. 1998) (distinguishing the UCL showing of fraudulent business practice from the common law requirements of fraud which include intent and/or knowledge).

278. *E.g.*, Williams v. Gerber Prods. Co., 552 F.3d 934, 938 (9th Cir. 2008) ("Appellants' claims under these California statutes [UCL, FAL, and CLRA] are governed by the 'reasonable consumer' test.").

twice a day—a fact disclosed only in fine print on the back of the label—could be a fraudulent business practice because consumers do not generally read all the words on a label and therefore could be misled by the branding.[279] It was not, however, a fraudulent business practice for a company to label their products as "diet" even though the soda contained sugar and calories because "no reasonable consumer would assume that Diet Dr Pepper's use of the term 'diet' promises weight loss or management."[280]

The second pathway of the UCL borrows the ordinary consumer test and applies it to advertisements. A plaintiff can succeed in showing "unfair, deceptive, untrue or misleading advertising" by demonstrating that the advertisement would mislead an ordinary consumer.[281] Thus, the analysis is largely the same as "fraudulent business act or practice," except that the conduct in question must be an advertisement.[282]

The second statute, the FAL, prohibits false advertisements and imposes a knowledge or reasonable inquiry requirement for liability.[283] The FAL forbids any advertising "which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."[284] The FAL applies the same "reasonable consumer" test as the UCL,[285] but the statute is different from the UCL because it requires that the potential offender knew or should have known

279. Brady v. Bayer Corp, 237 Cal. Rptr. 3d 683, 688–89 (Cal. Ct. App. 2018) (holding plaintiff's claims survive the motion to dismiss stage).

280. Becerra v. Dr Pepper/Seven Up, Inc., 945 F.3d 1225, 1229 (9th Cir. 2019).

281. BUS. & PROF. § 17200; *see, e.g.,* Townsend v. Monster Beverage Corp., 303 F. Supp. 3d 1010, 1044 (C.D. Cal. 2018) (noting that a plaintiff must prove that the ordinary consumer would be misled to succeed on their UCL false advertising claims).

282. BUS. & PROF. § 17200. In practice, most cases do not discuss the pathways separately when the conduct in question is an advertisement. *E.g.*, *Brady*, 237 Cal. Rptr. 3d at 695–98.

283. BUS. & PROF. § 17500.

284. *Id.*

285. *E.g.*, Williams v. Gerber Prods. Co., 552 F.3d 934, 938 (9th Cir. 2008). One potentially unsettled issue is who the applicable ordinary person would be and whether it would be comprised solely of persons with allergies. Some language in *Lavie v. Procter & Gamble Co.* suggests that courts apply the reasonable person of a targeted audience if the ad sufficiently targets that group, but that decision applied only the reasonable person standard. 129 Cal. Rptr. 2d 486, 494 (Cal Ct. App. 2003). It seems that no other case has applied a targeted standard.

that the advertisement was false or misleading.[286] In other words, it imposes a duty on the advertising business to ensure that their materials are not false.[287]

The CLRA is the third statute and, while similar to the UCL and FAL, differs by enumerating actionable conduct and giving wider latitude to plaintiffs seeking standing. Much like the UCL and FAL, the CLRA was enacted to declare unlawful several "methods of competition and unfair or deceptive acts," but it goes a step further and defines twenty-four categories of actionable conduct.[288] Of these categories, most relevant to a PAL lawsuit is number five, which prohibits "representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or qualities that they do not have."[289] For example, Carmax violated this subsection for advertising that a car passed its 125-point inspection test without disclosing that the car was the subject of an active recall.[290] Along with the enumeration of prohibited conduct, another crucial distinction between this and the other statutes is that it broadens the standing requirement to "any damage[s]."[291] Along with traditional

286. BUS. & PROF. § 17500 ("It is unlawful for any person . . . to make or disseminate or cause to be made or disseminated before the public in this state . . . any statement . . . which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known. . . .").

287. People v. Forest E. Olson, Inc., 186 Cal. Rptr. 804, 806 (Cal. Ct. App. 1982) ("[S]ection 17500 imposes a duty of investigation . . . ."). In *Forest*, the Court found the defendants guilty of violating the FAL for disseminating false advertisements about homes it had sold. *Id.* at 806. The advertisements stated that the homes had been sold and that they were located in Riverside and Orange Counties, neither of which was completely true. *Id.* at 805–06. Because the defendant had all the information in its possession to verify its advertisement, it should have known the information was false. *See id.* at 806 ("The facts here show the need for an attempt to verify the computer printout, the light burden such an attempt would create and the probable success of an investigation.").

288. CAL. CIV. CODE § 1770 (West 2024). The CLRA is meant to be construed broadly. CIV. § 1760 ("This title shall be liberally construed and applied to promote its underlying purposes, which are to protect consumers against unfair and deceptive business practices and to provide efficient and economical procedures to secure such protection.").

289. CIV. § 1770.

290. Gutierrez v. Carmax Auto Superstores Cal., 248 Cal. Rptr. 3d 61, 69–70, 76–84 (Cal. Ct. App. 2018).

291. CIV. § 1770; *see, e.g.*, Meyer v. Sprint Spectrum L.P., 200 P.3d 295, 299 (Cal. 2009) (noting that "any damage" signifies a less stringent requirement than "actual damages" which generally means only economic injuries). *Compare*

economic harms,[292] the CLRA makes transactional and opportunity costs actionable.[293] However, there appears to be no case alleging these sorts of damages only, as most of the CLRA-specific caselaw examines unconscionability clauses in contracts.[294]

In summary, a PAL plaintiff has three potential statutes to choose from. The UCL requires an economic injury for standing but contains two broad pathways for recovery.[295] Most relevant to this case are the first pathway's prohibitions on "unfair business practices," which are determined two ways, and "fraudulent business practices," which are examined through the eyes of the reasonable consumer.[296] The FAL, like the second pathway of the UCL, outlaws false advertising.[297] Unlike the UCL, however, the FAL requires that the advertiser have knowledge of falsity.[298] Finally, the CLRA defines twenty-four specific categories of actionable behavior, including representing that a good has an ingredient or characteristic it does not.[299]

CIV. § 1770 (making a loss of "any" damage actionable), *with* BUS. & PROF. § 17204 (requiring that actions be brought by "a person who has suffered injury in fact and has lost money or property as a result of the unfair competition").

292. *See* Takahashi-Mendoza v. Coop. Regions of Organic Producer Pools, 673 F. Supp. 3d 1083, 1093–94 (N.D. Cal. 2023) (holding that buying milk because of false advertising is enough to satisfy UCL and CLRA standing).

293. *Meyer*, 200 P.3d at 299 ("'[A]ny damage' may encompass harms other than pecuniary damages, such as certain types of transaction costs and opportunity costs."). The Court defined transaction costs as "costs associated with the formation and maintenance of economic relationships, including the costs of enforcing contracts." *Id.* at 299 n.1. Opportunity costs are "the potential benefits that a business, an investor, or an individual consumer misses out on when choosing one alternative over another." Jason Fernando, *Opportunity Cost: Definition, Formula, and Examples*, INVESTOPEDIA (Aug. 29, 2024), https://www.investopedia.com/terms/o/opportunitycost.asp [https://perma.cc/85CV-QE9A].

294. *See, e.g.*, *Meyer*, 200 P.3d at 301–04. This action arises from Subsection (19) of the CLRA: "Inserting an unconscionable provision in the contract." CIV. § 1770.

295. BUS. & PROF. § 17200, 17204.

296. BUS. & PROF. § 17200.

297. BUS. & PROF. § 17500.

298. *Id.*

299. CIV. § 1770. It is worth noting briefly that the "unlawful" UCL subpart provides relief for violations of other laws. *See* Cel-Tech Comms., Inc. v. L.A. Cellular Tel. Co., 973 P.2d 527, 539–40 (Cal. 1999) ("By proscribing 'any unlawful' business practice, 'section 17200 "borrows" violations of other laws and treats them as unlawful practices' that the unfair competition law makes independently actionable." (quoting State Farm Fire & Casualty Co. v. Superior Ct., 53 Cal. Rptr. 229, 234 (Cal. Ct. App. 1996), *abrogated by Cel-Tech*, 973 P.2d at

2. The Golden Ticket(s): Utilizing the UCL and CLRA to Challenge PAL Use

The UCL is the best option for a PAL lawsuit, though the suit should also allege violations of the CLRA. The UCL is the best option because of its broad applicability and relatively nebulous tests. This is essential for plaintiffs pursuing a novel PAL claim. In contrast, the FAL and the second subsection of the UCL are not applicable because a PAL is not an advertisement. Finally, the CLRA is a good option because its broad standing requirements can serve as a "backup" to the UCL's stringent standing demands, and PAL use arguably falls within the statute's enumerated prohibited behaviors.

Starting first with UCL standing, any potential claimant challenging PALs could utilize a similar approach to that of "natural" litigants to satisfy both elements. The comparison and subsequent decision to forego one PAL-labeled product for a similar, more expensive, PAL-free product could constitute an economic injury. To illustrate this, consider an allergic consumer who wants to buy Oreos.[300] The cheaper, generic brand contains a PAL, whereas the more expensive, name-brand Oreo does not. A wise consumer must purchase the name-brand product to be safe, costing the consumer more money and causing an economic injury. This largely mirrors "natural" plaintiffs, who chose to purchase a more expensive "natural" product instead of a cheaper, unnatural alternative.[301] Granted, this scenario does not exactly parallel the "natural" cases because here the PAL leads to the purchase of a different, PAL-free product, whereas in "natural" cases the term induced the purchase of the "natural"

543–44)). This is not a good option for a PAL claim because, as discussed, food manufacturers are not breaking the FDCA or Sherman Act. *See supra* Part I.B (discussing the current state of the law and PALs).

300. This example is lifted from the Author's own experience and tends to be quite common for those with food allergies.

301. *See supra* Part III.B.1 (outlining natural litigants' tactics); *see also* Jones v. ConAgra Foods, Inc., 912 F. Supp. 2d 889, 901 (N.D. Cal. 2012) ("For each consumer who relies on the truth and accuracy of a label and is deceived by misrepresentations into making a purchase, the economic harm is the same: the consumer has purchased a product that he or she paid more for than he or she otherwise might have been willing to pay if the product had been labeled accurately." (quoting Degelmann v. Advanced Med. Optics, Inc., 659 F.3d 835, 839 (9th Cir. 2011), *vacated*, Degelmann v. Advanced Med. Optics Inc., 699 F.3d 1103 (9th Cir. 2012))).

product itself.[302] However, plaintiffs should argue that what matters is that the PAL forced them to spend more money, i.e., an economic injury, and not that the consumer purchased a separate product from the one at issue. If the individual could establish an economic injury, the "caused by" element would be satisfied because the PAL was a "substantial part" of the decision and its subsequent consequences.[303]

As for the actual merits of a UCL claim, a plaintiff challenging the use of PALs would have a good argument that PAL use is "unfair" under both tests. Under the first test,[304] PAL use is "substantially injurious" to consumers because it is so widespread and unnecessarily reduces those with food allergies' already-limited options.[305] Like Hertz disclosing their refueling charge in a hard to read font, food manufacturers are keeping consumers in the dark about certain facts like allergens in their products.[306] Unlike the *Hertz* case, however, there may be instances in which food manufacturers truly do not know whether their products contain the allergen, but this should not justify the incoherent application of PALs and its disparate impact on those with food allergies.[307]

Under the second test for an "unfair" practice, plaintiffs should be able to show that PAL use is tethered to some specific statutory provision. California has expressly adopted the FDCA

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302. *See supra* Part III.A (summarizing litigation around the term "natural" on food labels).

303. *In re* Tobacco II Cases, 207 P.3d 20, 39 (Cal. 2009). One additional advantage of the UCL worth noting is that only the named plaintiff in a class action needs to satisfy the standing requirements in a class-action lawsuit. *Id.* at 34. However, because of the individualized nature of allergies, it remains unclear how a class-action would work in this context. For a discussion of class requirements and considerations under California law, see Shaker, *supra* note 79, 115–19. "Natural" litigants were able to achieve positive results without class actions, and there is no reason to doubt the same couldn't happen here. *See generally* Negowetti, *supra* note 177, at 13–15 (summarizing the various claims "natural" plaintiffs brought and only noting a few class actions).

304. *See, e.g.*, Podolsky v. First Healthcare Corp., 58 Cal. Rptr. 2d 89, 98 (Cal. Ct. App. 1996).

305. *See supra* Part I.B (noting the unnecessary restrictions PALs can place on those with allergies).

306. Schnall v. Hertz Corp., 93 Cal. Rptr. 2d 439, 455–56 (Cal. Ct. App. 2000).

307. *See supra* Part I.A (providing an overview of current PAL use in the United States and the effects it has on those with allergies).

through the Sherman Act,[308] and plaintiffs should argue PALs violate the spirit of the FALCPA, which amended the FDCA.[309] At its core, the FALCPA promises those with food allergies a right to know about any potential allergens in their foods.[310] PALs frustrate this intent by introducing uncertainty into the equation. Much like having no label to read at all, a consumer faced with a "may contain" label has little ability to determine whether the product contains allergens. This lack of clarity directly conflicts with their right to make an informed decision under the FALCPA.[311] Thus, regardless of what test a reviewing court applies, plaintiffs should be able to show how PAL use is "unfair" under both.

The third and final UCL route for plaintiffs is to prove a "fraudulent" business practice. Here, plaintiffs could satisfy the ordinary consumer test by (1) finding products with especially misleading PALs and (2) presenting objective evidence on the confusing nature of PALs. Addressing the former first, Plaintiffs should strategically choose products with PALs that are especially misleading. For instance, Ghirardelli, a California-based

308. Negowetti, *supra* note 177, at 11 (noting how California's Sherman law expressly adopts the FDCA); *see also* CAL. HEALTH & SAFETY CODE § 110390 (West 2024) ("It is unlawful for any person to disseminate any false advertisement of any food, drug, device, or cosmetic. An advertisement is false if it is false or misleading in any particular.").

309. *See supra* Part I.B (describing the history of the FALCPA and the purposes of regulating PALs).

310. *See* H.R. REP. NO. 108-608, at 3 (2004) (highlighting that the lack of cures for food allergies means that those with allergies should be "empowered" to know whether the allergens are present in the foods they consume).

311. *See generally* Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, § 202, 118 Stat. 905, 906 (2004) (describing congressional findings and purposes of the FALCPA).

corporation,[312] makes a "non-dairy" line of chocolate chips.[313] The front of the package says "non-dairy,"[314] and it is advertised as such on the website,[315] but the product nevertheless contains a dairy PAL.[316] Arguably, one of the two labels is misleading. If the "non-dairy" label is correct, then there should never be dairy in the product, but the PAL suggests the opposite—that dairy could be in the product—directly contradicting the front of the package. A court should deem this misleading and actionable under the UCL, much like it did with Bayer's supposed "One-A-Day" vitamins that in reality had to be taken twice a day.[317] Plaintiffs can further bolster their ability to satisfy the ordinary consumer test by presenting objective evidence on the misleading nature of PALs. Quite simply, research indicates PALs mislead consumers.[318] In particular, they believe that PALs are regulated and that a "may contain" label means more of a risk than a "made in a facility" label.[319] A court should find this evidence

312. *Ghirardelli Careers – Corporate*, GHIRARDELLI CHOCOLATE, https://www.ghirardelli.com/careers-corporate [https://perma.cc/CNH8-HXVJ] ("Our Company Headquarters is located in San Leandro, California . . . ."). Suing a California corporation would resolve any potential jurisdictional issues because corporations are subject to personal jurisdiction in states where their principal place of business is located. *See* Daimler AG v. Bauman, 571 U.S. 117, 137 (2014) ("With respect to a corporation, the place of incorporation and principal place of business are 'paradig[m] . . . bases for general jurisdiction.'" (quoting Lea Brilmayer et al., *A General Look at General Jurisdiction*, 66 TEX. L. REV. 721, 728 (1988))).

313. Brian Amick, *Ghirardelli Launches First Plant-Based, Non-Dairy Dark Chocolate Baking Chips*, BAKE (Sept. 21, 2022), https://www.bakemag.com/articles/16595-ghirardelli-launches-first-plant-based-non-dairy-dark-chocolate-baking-chips [https://perma.cc/2EB6-K46Q].

314. *Ghirardelli 52% Cacao Non-Dairy Dark Chocolate Chips (Case of 12)*, GHIRARDELLI CHOCOLATE [hereinafter *Ghirardelli*], https://www.ghirardelli.com/ghirardelli-52-percent-cacao-non-dairy-dark-chocolate-chips-case-of-12 [https://perma.cc/9BL7-AUY6].

315. *Id.*

316. *Id.* ("Ingredients: Unsweetened chocolate, cane sugar, cocoa butter, soy lecithin, vanilla extract. *May contain milk*." (emphasis added)).

317. *See supra* text accompanying note 279 (discussing the standards for an actionable claim in the case of Bayer's vitamins).

318. *See, e.g.*, *This Blog Post May Contain*, *supra* note 100 (detailing how consumers falsely believe that the language used in a PAL corresponds to risk).

319. *See, e.g.*, Allen et al., *supra* note 100, at 6 (highlighting consumer preference for a "shared facility" PAL as opposed to "may contain" PAL).

highly probative of whether an ordinary consumer would be misled by the statements.[320]

As for the UCL's advertisement prohibition and the FAL, any such claim would not succeed because a PAL is not an advertisement. Unlike the term "natural," which manufacturers use to induce customers to buy the product, a PAL is not an advertisement.[321] It is (intended to be) a warning of risk and not a term used to sell a product.[322] Thus, even under the broadest conception of "advertisement," a PAL would not qualify, making the FAL and the advertising pathway of the UCL inapplicable to this case.[323]

The CLRA contains some merit, however, because of its broad standing requirements and definitions of actionable behavior. If the plaintiff fails to satisfy UCL standing requirements, purchasing a more expensive, PAL-free product could potentially qualify as an opportunity or transaction cost sufficient for CLRA standing.[324] In this sense, the CLRA serves as a standing "backup plan." In addition, the CLRA flatly prohibits "representing that goods or services have . . . characteristics, ingredients . . . they do not have."[325] Arguably, a product such as Ghirardelli's "non-dairy" chocolate chips that contain a milk PAL violates the CLRA because Ghirardelli is representing its good (chocolate chips) has characteristics ("non-dairy") it does not

320. This would be direct evidence that "it is probable that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled." Lavie v. Procter & Gamble Co., 129 Cal. Rptr. 2d 486, 495 (Cal. Ct. App. 2003). In *Becerra v. Dr. Pepper/Seven Up, Inc.*, the Ninth Circuit considered survey evidence as one factor that could be used to evaluate the reasonableness of a claim. 945 F.3d 1225, 1230–31 (9th Cir. 2019).

321. The word "advertisement" has been interpreted broadly to include statements made in connection with the sale of goods, but a PAL is not used to sell a good. Algarin v. Maybelline, LLC, 300 F.R.D. 444, 452 (S.D. Cal. 2014).

322. Plaintiffs could, however, consider suing for "dairy free" packaging like Ghirardelli's if the product contained a PAL with the same allergen. The "dairy free" labeling is an advertisement, unlike the PAL.

323. The Ninth Circuit has extended the word "advertisement" to pictures on a label, but this likely represents the outer reaches of the term. Williams v. Gerber Prods. Co., 552 F.3d 934, 939 (9th Cir. 2008). Thus, even under this broad conception, it is highly doubtful a PAL is an advertisement.

324. *See* Meyer v. Sprint Spectrum L.P., 200 P.3d 295, 299 (Cal. 2009) (noting that transactional costs are sufficient for CLRA standing).

325. CAL. CIV. CODE § 1770 (West 2024).

have.[326] Plaintiffs should try to target products like this in which the PAL conflicts with other labeling because these present the best likelihood of success under the CLRA.

If products like these cannot be utilized or found, plaintiffs should highlight the context of PALs to argue that they are still representing that a product has characteristics or ingredients it does not.[327] Technically speaking, a PAL that states a product "may contain" an allergen is not a false representation about a product because this phrase could not possibly be proven false.[328] Even if a plaintiff could show that there are no peanuts in a product, a "may" contain label is still literally a true statement because the word "may" encapsulates a possibility that peanuts are not present.

However, viewing a PAL in this technical, superficial way ignores the function of PALs because food manufacturers could still be falsely representing a PAL-product's characteristics and/or ingredients.[329] When a food manufacturer applies a PAL, they do so because there is a risk of cross-contamination, which they want to signal to the consumer.[330] But if there is no risk of cross-contamination present, such as a completely peanut-free facility, then a food manufacturer's application of a PAL is a false representation about the characteristics of a product.

Similarly, plaintiffs could take it a step further and argue that a PAL-labelled allergen functions much the same as an ingredient because those with food allergies must avoid PAL-products as if the allergen is present.[331] For example, an allergic consumer with an egg allergy avoids all products with an egg-PAL

326. *Ghirardelli*, *supra* note 314.

327. CIV. § 1770.

328. Though the phrase is literally true, the phrase can still be misleading. Lavie v. Procter & Gamble Co., 129 Cal. Rptr. 2d 486, 489 (Cal. Ct. App. 2003) (noting that even though a phrase—such as "Aleve is gentler to the stomach lining than aspirin"—is technically true it can still be misleading).

329. The Ninth Circuit has held that context is important. *See* Moore v. Trader Joe's Co., 4 F.4th 874, 883–84 (9th Cir. 2021) (holding that the surrounding context is important because a reasonable consumer would not conclude that "100% New Zealand Manuka Honey" means that the product consists of only honey "derived exclusively from a single floral source" given the impossibility of controlling bee migration, the product's inexpensive cost, and the presence of a good rating).

330. *See supra* Part I.B (outlining the ideal use of PALs).

331. *See supra* Part I.B (discussing the strong deterrent effect of PALs despite their tendency to be overcautious).

because the consumer presumes egg is in fact in the product—like an ingredient.[332] If there is no risk that egg could be introduced into the product, then a consumer who avoids a product due to an egg-PAL is doing so because of a food manufacturer's false representation about an "ingredient" in the product. Admittedly, it is unclear how prominent this sort of flagrant misusage of PALs is—or even how a plaintiff could find this information out—but if they could, both these false representation and ingredient arguments should make PALs actionable under the CLRA.[333]

Not only do these consumer protection statutes give potential litigants the best route to success, but they also have a better chance to overcome the potential defenses of assumption of the risk and preemption that thwart a common law failure to warn claim. First, there is no issue with an assumption of the risk because the lawsuit involves a challenge to the misleading nature of the label, not the label itself. Said another way, the warning is at issue, and therefore a manufacturer cannot defend by arguing that they issued a warning.[334]

Second, preemption is arguably not applicable here because the FDA's failure to regulate the use of PALs allows courts to inquire into their misleading nature. Drawing again on "natural" claims, these lawsuits have mostly avoided preemption because there is no current binding FDA definition of the term.[335] Potential PAL plaintiffs should make a similar argument because the

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332. *Id*.

333. This information would be incredibly difficult to obtain pre-suit and even in discovery. *See supra* Part I.B (noting the complex nature of food manufacturing processes).

334. In this sense, it would be comparable to a defendant arguing that their warning frees them from liability regardless of the adequacy of the warning, something California courts have flatly rejected. *See, e.g.*, Jackson v. Deft, Inc., 273 Cal. Rptr. 214, 223–24 (Cal. Ct. App. 1990) (holding that triable issues of fact exist about the adequacy of a warning even though a warning was present).

335. *See, e.g.*, Holk v. Snapple Beverage Corp., 575 F.3d 329, 341–42 (3d Cir. 2009) (concluding that the plaintiff's state law claims regarding the term "natural" were not preempted because of inaction by the FDA). In addition, primary jurisdiction, a defense that has thwarted many "natural" claims, is arguably not applicable here either because the FDA has not indicated it will act and standardize PALs soon, which appears to be a significant factor for the invocation of the doctrine. *See A "Natural" Stand Off*, *supra* note 244, at 302 (noting that stays of litigation increased after the comment period opened for a "natural" definition and subsequently decreased when the comment period failed to produce any binding definition).

FDA has yet to standardize the language of PALs.[336] While this same argument would also apply to preemption in the state common law cases, the lack of regulation becomes even more important in the consumer protection context.

As opposed to state common law theories that require a court to directly confront whether the product's label was sufficient, the consumer protection context involves a separate inquiry apart from the label itself. The former cause of action asks about the sufficiency of the label, and the FDCA—through its permission of PALs—easily answers this question affirmatively.[337] The latter, which asks whether a reasonable consumer is misled by the statement, cannot be answered as easily and instead requires the court's fact-finding determination.[338] While compliance with sufficiency requirements may be good evidence for a food manufacturer, it is not enough to preempt a case involving misled consumers because the label—though compliant—could still be misleading.[339] Admittedly, a food manufacturer could still argue that the remedy from any such lawsuit would necessarily impose a duty beyond what the FDCA requires, but this same consideration is present in the "natural" context, and courts have nonetheless chosen to adjudicate the claims.[340]

The goal of any lawsuit challenging PALs is to reduce their use and promote better and more accurate food labels. As demonstrated by "natural" caselaw, litigation can cause change. PAL lawsuits should follow the approach pioneered by "natural" litigants and utilize California's unique and expansive consumer protection statutes. Because of the novelty of any PAL lawsuit,

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336. *E.g.*, *This Blog Post May Contain*, *supra* note 100 (highlighting that PALs are voluntary and not regulated).

337. *See supra* Part I.B (discussing the effects of the FALCPA on PALs).

338. *See, e.g.*, Brazil v. Dole Food Co., 935 F. Supp. 2d 947, 960 (N.D. Cal. 2013) ("Brazil's case is 'far less about science than it is about whether a label is misleading.' . . . Furthermore, 'every day courts decide whether conduct is misleading,' and the 'reasonable-consumer determination and other issues involved in Plaintiff's lawsuit are within the expertise of the courts to resolve.'" (quoting Jones v. ConAgra Foods, Inc., 912 F. Supp. 2d 889, 898–99 (N.D. Cal. 2012))).

339. *See generally* Spano *ex rel.* C.S. v. Whole Foods, Inc., 65 F.4th 260, 265 (5th Cir. 2023) (discussing compliance and violations of FDA regulations as evidence and nothing more).

340. *E.g.*, Bohac v. Gen. Mills, Inc., No. 12-CV-05280, 2013 WL 5587924, at *3 (N.D. Cal. Oct. 10, 2013) (ruling that a Court could decide the definition of the term "natural" without usurping FDA authority because it had yet to act).

the UCL's broad applicability and relatively undefined tests make it the best route to pursue a challenge, but the CLRA's broad standing requirements and clearly defined actionable behavior also help potential plaintiffs. Furthermore, consumer protection statutes provide litigants a better way to circumvent the same defenses that thwarted a common law claim. While this litigation approach does raise some of the same concerns seen in other contexts, namely how one food manufacturer may be subject to different standards than others, this imperfectness highlights that the best solution is for the FDA to act. And perhaps these lawsuits could serve as an impetus for the FDA to act.[341] But as it stands now, the current state of PAL use and the FDA's unwillingness to act leaves consumers no choice but to pursue legal action under these California statutes.

CONCLUSION

When Paul Jakobson or any other individual with food allergies reads a food label, the FALCPA was intended to make their choices easy. A product either contained an allergen or not, and Paul could decide quickly if he could eat it. The lack of regulation of PALs thwarts this very purpose. With food allergies on the rise, and no established cure other than avoidance, the FALCPA and its central promise of clarity for those with allergies is needed now more than ever. Sadly, current food labels possess little to no clarity, as Congress's decision to omit PAL regulation from the FALCPA allows manufacturers to apply PALs inconsistently and pervasively to the detriment of those with food allergies. Because of the seriousness of this situation, a solution is needed, but the FDA seems unlikely to give one.

Therefore, consumers must take action to reduce the use of PALs and promote better use. At first glance, the courts seem to offer few avenues of relief. Federal law provides no private right of action suitable for challenging PAL use, and PALs defy liability from traditional state law theories. California's consumer protection statutes, however, offer one potential solution. Using

341. Though, this seems unlikely because the FDA has still not defined the term "natural," even after all these lawsuits. *See Auburn Food Historian Explains New FDA Guidelines for 'Healthy' Food Labels*, AUBURN UNIV.: EXPERT ANSWERS (Oct. 3, 2022), https://ocm.auburn.edu/experts/2022/10/031511-fda-healthy-label-changes.php [https://perma.cc/CQ6Y-2LTX] ("'[N]atural' continues to be used by food companies today without any clear meaning or consistency.").

"natural" lawsuits as signposts, a lawsuit challenging the use of PALs as an unfair or deceptive business practice could potentially succeed. And it must because, although it may surprise the parents in Paul Jakobson's class or Americans more broadly, those with food allergies are suffering at the hands of food manufacturers, and the situation only seems to be getting worse. Thus, the answer to the question, "Is it really that important?," is indeed quite simple, even if it may not be the one most expect. To those with food allergies, those who care for them, and hopefully, one day, all of society more broadly: *Yes, this really is that important.*