Fearless Dining: Mandating Universal Allergen Disclosures on Restaurant Menus

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Nearly twenty percent of consumers self-identify as suffering from a food allergy or sensitivity, and over 30 million people in the United States have medically proven food allergies. Food allergies cause over 200,000 emergency room visits annually in the United States alone. Among these severe allergen-related food incidents, nearly three-quarters arise at restaurants. In spite of this, there is not a single federal or state law regulating written allergen disclosures in restaurants.

Food safety laws have come a long way in the past century. The Federal Food, Drug, and Cosmetic Act (FDCA) established food safety standards in 1938, the Nutrition Labeling and Education Act (NLEA) created nutrition labeling on packaged foods in 1990, and the Food Allergen Labeling and Consumer Protection Act (FALCPA) established allergen labeling on packaged foods in 2004. The Affordable Care Act (ACA) expanded the NLEA to include nutrition labeling in chain restaurants in 2010. However, the FALCPA has not extended allergen labeling to include restaurants.

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This Note proposes universal allergen labeling on restaurant menus as a solution to the lack of allergen labeling. The proposal includes all nine of the major food allergens. This proposal covers all restaurants, great and small. Restaurants would be required to label their menus through negative disclosures using "does not contain" or "free from" language, and would use categorical disclosures that all foods within a given category on the menu do not contain a certain allergen. The Note analyzes the political feasibility of the proposal, the legal feasibility of employing this policy through federal or state laws, and the First Amendment constitutionality of mandatory allergen disclosures in restaurants.

INTRODUCTION

Every three minutes, a food allergy reaction sends someone to the emergency room.[1] Thirty-two million people in the United States have medically proven food allergies.[2] On average, one in thirteen children, or two children in every classroom, have food allergies.[3] Each year in the United States, 200,000 people require emergency medical care for allergic reactions to food,[4] and 600 people die from food anaphylaxis.[5] Children compose approximately two-thirds of those deaths.[6] Pediatric hospitalizations for food allergies tripled between the late 1990s and mid-2000s.[7] Medical procedures to treat anaphylaxis caused by food nearly quadrupled between 2007 and 2016.[8] Restaurants are particularly dangerous to people with allergies because nearly three-quarters of allergen-related food incidents arise at restaurants.[9] Lack of information causes the frequent reactions in restaurants because either the staff is not familiar with which foods contain allergens or the consumers do not notify the staff of allergies.[10] The danger of restaurants to people with allergies, coupled with the lack of allergen information, makes restaurants prime candidates for decreasing the prevalence of allergic reactions by labeling major allergens on menus.

Allergen labeling is important because there are no approved treatments for food allergies beyond strict avoidance of the allergens.[11] In case of emergencies, EpiPens can be used, but they only temporarily reduce the symptoms and are not a treatment.[12]

Allergic reactions occur when the body's immune system reacts to a given food protein exposure.[13] While the body can hypothetically react to any food, and over 170 foods have been reported to cause reactions,[14] certain foods are likelier to cause allergies than others. Milk, eggs, peanuts, tree nuts, wheat,

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1. *Facts and Statistics*, FOOD ALLERGY RSCH. & EDUC., https://www.foodallergy.org/resources/facts-and-statistics [https://perma.cc/JS46-SD6K].
2. *See id.*
3. *See id.*
4. *Id.*
5. *See* Thisanayagam Umasunthar, Jo Leonardi-Bee, Matthew Hodes, Paul J. Turner, Claudia Gore, Parviz Habibi, John O. Warner & Robert J. Boyle, *Incidence of Fatal Food Anaphylaxis in People with Food Allergy: A Systematic Review and Meta-Analysis*, 43 CLINICAL & EXPERIMENTAL ALLERGY 1333, 1333 (2013) (finding that the fatal food anaphylaxis incidence rate is 1.81 per million person-years on average, with individuals under nineteen years old having an incidence rate of 3.25 per million person-years).
6. *See id.*
7. FOOD ALLERGY RSCH. & EDUC., *supra* note 1.
8. *Id.*
9. *See* A. Bryan Endres, Renata Endres & Marinela Krstinić Nižić, *Restaurant Disclosure of Food Allergens: Analysis and Economic Implications*, 21 TOURISM & HOSP. RSCH. 202, 202 (2021).
10. *See id.* at 203.
11. *See* FOOD ALLERGY RSCH. & EDUC., *supra* note 1.
12. *See id.*; *Food Allergies*, U.S. FOOD & DRUG ADMIN., [hereinafter *Food Allergies*] https://www.fda.gov/food/food-labeling-nutrition/food-allergies [https://perma.cc/4KM3-P25N].
13. *See* FOOD ALLERGY RSCH. & EDUC., *supra* note 1.
14. *See id.*

soybeans, fish, crustacean shellfish, and sesame constitute over ninety percent of food allergies.[15]

Unfortunately, food allergies are on the rise, so the number of people who would benefit from allergen disclosures is increasing. A Centers for Disease Control and Prevention (CDC) report found that between the late 1990s and early 2010s, food allergies among children increased by fifty percent.[16] Childhood peanut or tree nut allergies tripled in the United States during that period.[17] Even worse, children are outgrowing food sensitivities more slowly than in previous decades, with many allergies persisting throughout a child's lifetime.[18] Worldwide rates of food allergies in the general population have risen from less than two percent in the 1950s to nearly eight percent in 2021.[19]

Research suggests the rise in allergies may be caused by how and when foods are introduced to U.S. children and how foods are manufactured.[20] For example, introducing peanuts to children under five years old decreases the risk of a peanut allergy.[21] Furthermore, the U.S. method of dry-roasting peanuts increases allergenicity, a measure of how likely a food is to cause an allergic reaction, compared to boiling or frying peanuts.[22] China has a significantly lower rate of peanut allergies even though boiled peanuts are introduced early and often.[23]

Lack of uniformity nationally in what constitutes an allergy for labeling purposes makes avoiding allergens even more difficult, so a federally standardized allergen threshold must be set. People with trace food allergies may react in cases of cross contamination via shared equipment.[24] However, current labeling requirements only require including ingredients and allergens that were expressly added to food.[25] Additional disclosures suggesting cross contamination through shared equipment or facilities are purely voluntary.[26] Similarly, advisory labeling using "may contain" language is voluntary, and

15. *See Food Allergies*, *supra* note 12.

16. *See* FOOD ALLERGY RSCH. & EDUC., *supra* note 1.

17. *See id.*

18. *See id.* at 50–51.

19. Deni E. Béchard, *Small Doses*, STANFORD MAG., Mar. 2021, at 50, https://stanfordmag.org/contents/small-doses [https://perma.cc/LS9S-LZ2G].

20. *See* Caroline Hadley, *Food Allergies on the Rise? Determining the Prevalence of Food Allergies, and How Quickly It Is Increasing, Is the First Step in Tackling the Problem*, 7 EMBO REPS. 1080, 1082 (2006) (finding that the Western diet could explain increases in worldwide food allergies but food manufacturing may be to blame in the United States, suggesting that allergen rates may have as much to do with how and when the food is introduced as with the food itself).

21. *See* FOOD ALLERGY RSCH. & EDUC., *supra* note 1.

22. *See* Hadley, *supra* note 20, at 1082.

23. *See id.*

24. *See* FOOD ALLERGY RSCH. & EDUC., *supra* note 1.

25. *See* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: QUESTIONS AND ANSWERS REGARDING FOOD ALLERGENS, INCLUDING THE FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT OF 2004 (EDITION 4); FINAL GUIDANCE (2006) [hereinafter GUIDANCE FOR INDUSTRY].

26. *See id.*

foods with such labels vary widely in the amount of allergen they actually contain.[27] For example, one study found sufficient peanut protein to cause a reaction in 7.3 percent of products using "may contain" language that did not explicitly add peanuts.[28]

There are few allergen-based disclosures in restaurants. While certain states require knowledge about allergens and communication with consumers, there are absolutely no requirements for menu item labeling of allergens.[29] Restaurants can, and sometimes do, voluntarily label items as vegetarian, vegan, or gluten-free.[30] The only allergen label defined by the Food and Drug Administration (FDA) is "gluten-free." But gluten-free labeling is only a guideline for restaurants because the FDA's definition only applies to packaged food.[31] Many large restaurant chains' websites contain food allergen information,[32] but smaller restaurants, which make up over half of U.S. restaurants,[33] do not usually mention most major allergens.[34]

Due to the inadequacy of allergen disclosures in restaurants and the higher rates of allergic reactions to restaurant food compared to packaged food, universal allergen labeling on restaurant menus should be legally required. All nine of the major food allergens should be required. This proposal covers all restaurants, great and small. Restaurants would be required to label their menus through negative disclosures using "does not contain" or "free from" language and would use categorical disclosures that all foods within a given category on the menu do not contain a certain allergen. The safest way to implement these disclosures is by amending the Federal Food, Drug, and Cosmetic Act (FDCA) to include restaurant allergen labeling. That way, the FDA can then promulgate additional rules for regulating and further explaining the requirements of allergen

27. *See* FOOD ALLERGY RSCH. & EDUC., *supra* note 1.

28. *See id.*

29. *See* discussion *infra* Part I.B.

30. *See Nutrition Calculator*, MCDONALD'S, https://www.mcdonalds.com/gb/en-gb/good-to-know/nutrition-calculator.html [https://perma.cc/97FR-3QZX]; *Allergens & Special Diet*, CHIPOTLE, https://www.chipotle.com/allergens [https://perma.cc/DRS9-B4AV]; *Food Allergies and Sensitivities*, KFC, https://www.kfc.com/food-allergies-and-sensitivities [https://perma.cc/X65M-9THR]; *Starbucks Nutrition and Allergen Information*, STARBUCKS, https://www.starbucks.co.uk/nutrition [https://perma.cc/B2HU-CD66]; *Nutrition & Allergies*, SUBWAY, https://www.subway.com/en-US/MenuNutrition/Nutrition [https://perma.cc/8QZT-XATW]; *Allergen Info*, TACO BELL, https://www.tacobell.com/allergen-info [https://perma.cc/EB4N-GGY6]; *Special Diets Wizard*, BLAZE PIZZA, https://www.blazepizza.com/allergen-info [https://perma.cc/7TM7-2C42]; *Applebee's Food Allergy Listing*, APPLEBEE'S, https://www.applebees.com/en/nutrition/allergen-info [https://perma.cc/CP86-2YBU].

31. *See* 21 C.F.R. § 101.91 (2021).

32. *See supra* note 30 and accompanying text.

33. *See ICYMI . . . Chain Outlets Make Up a Smaller Share of Restaurants in the Northeast and Pacific Northwest*, U.S. DEP'T OF AGRIC., (Oct. 17, 2019), https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=95156 [https://perma.cc/2SUV-9UED].

34. *See Dining Out*, FOOD ALLERGY RSCH. & EDUC., https://www.foodallergy.org/resources/dining-out [https://perma.cc/P3TY-VBW9] (recommending eating at a chain restaurant when dining out over other types of restaurants).

labels. Allergen labeling is likely to be politically feasible because allergen labeling should increase restaurant patronage rather than decrease income.

The Note is structured as follows: Part I discusses existing federal and state laws; Part II discusses two labeling case studies: the menu labeling campaign and the gluten-free labeling rule; Part III discusses the proposed policy; and Part IV discusses the First Amendment constitutionality of mandatory allergen disclosures in restaurants.

I.
EXISTING LAW PROVIDES INSUFFICIENT REQUIREMENTS FOR RESTAURANT ALLERGEN LABELING

Existing law provides no restaurant allergen labeling requirements.[35] Federal laws have grown but have not bridged the gap between regulating allergen labeling and restaurant disclosures and regulating restaurant allergen labeling.[36] State laws take a different approach by informing restaurant staff about allergens instead of consumers.[37]

A. Federal Law Establishes Precedent for FDA Regulation of Restaurants Through the FDCA

Through successive amendments to the FDCA, federal law now allows the FDA to regulate restaurant disclosures and allergen labels on packaged products.[38] In addition to the original FDCA, three federal amendments sufficiently improved food-related consumer protection to pave the way for allergen labeling on menus.[39] These amendments are the Nutrition Labeling and Education Act (NLEA), the Federal Allergen Labeling and Consumer Protection Act (FALCPA), and the Affordable Care Act (ACA).[40]

1. Federal Food, Drug, and Cosmetic Act of 1938 Established Food Standards

The FDCA of 1938 provides the backdrop for regulating allergens.[41] The FDCA sets out the guidelines for regulating food, drugs, medical devices, and cosmetics by the FDA.[42] One of the main goals was to prohibit abuses of food packaging and quality, which the FDCA accomplished through legally

35. *See* discussion *infra* Parts I.A, I.B.
36. *See* discussion *infra* Part I.A.
37. *See* discussion *infra* Part I.B.
38. *See* discussion *infra* Parts I.A.2, I.A.3, I.A.4.
39. *See id.*
40. *See id.*
41. *See* discussion *infra* Parts I.A.1.
42. *Part II: 1938, Food, Drug, Cosmetic Act*, U.S. FOOD & DRUG ADMIN., (Nov. 27, 2018), https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-ii-1938-food-drug-cosmetic-act [https://perma.cc/HH6M-G28G].

enforceable food standards.[43] Repeated amendments to the FDCA increased the scope of the FDA's authority and established subsequent requirements for food, drugs, and medical devices.[44]

For food, the FDCA establishes prohibited acts, criminal and civil penalties, food-related definitions, and food requirements and practices.[45] The FDCA defines food as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[46] It prohibits "adulterated" food that is poisonous or unsanitary,[47] as well as "misbranded" food that has false or incomplete labels, food that makes unsupported claims, or if the food does not rise to the standard of the particular food.[48] In particular, the FDCA prohibits adulteration or misbranding of food in interstate commerce and prohibits the manufacture of adulterated or misbranded food.[49]

Although the FDCA's original enactment established the legal framework for food regulation, it failed to incorporate nutrition or allergen regulations.[50] Three subsequent laws rectified the initial deficiencies: the NLEA, the FALCPA, and the ACA.[51]

2. Nutrition Labeling and Education Act of 1990 Requires Nutrition Information on Packaged Food Labels

Although the NLEA originally applied primarily to packaged foods and specifically exempted food sold in or to restaurants from labeling requirements,[52] in 2010, the ACA amended it to become the first section of the FDCA to allow the FDA to regulate restaurants.[53] The NLEA preempts states and localities from establishing any requirements on nutrition labeling or nutrition claims on labels that are not identical to the NLEA.[54] The original NLEA amended Section 403 of the FDCA's misbranding requirements.[55] Subsection (q)(1) deems a food

43. *Id.*

44. *See* Wallace F. Janssen, *The Story of the Law Behind the Labels*, FDA CONSUMER (June 1981), at 37–45 (explaining that the FDCA was created to fix shortcomings of the original Wiley Act of 1906, with the FDCA expanding FDA control to cosmetics and therapeutic devices, increasing control of food and drugs, and being amended to grow with changes in medical devices and drugs, which suggests the FDCA was the main law controlling the FDA's power after the original Wiley Act).

45. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 341–350I-1.

46. 21 U.S.C. § 321(f).

47. *Id.* §§ 331 (prohibiting adulterated food), 342 (defining adulterated food).

48. *Id.* §§ 331, (prohibiting misbranded food), 343 (defining misbranded food).

49. *See id.* § 331.

50. *See id.* §§ 343(q) (adding nutritional labeling to the FDCA via the NLEA), 343(w) (adding allergen labeling to the FDCA via the FALCPA), 321(qq) (defining allergens under the FALCPA).

51. *See* discussion *infra* Parts I.A.2, I.A.3, I.A.4.

52. *See* 21 U.S.C. § 343(q).

53. *See* discussion *infra* Part I.A.4.

54. *See id.*; 21 U.S.C. § 343-1.

55. *See* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2352 (1990).

misbranded unless its label contains nutrition information.[56] Subsection (r)(1) regulates allowable nutrition claims made in labels.[57]

3. Food Allergen Labeling and Consumer Protection Act of 2004 Established Allergen Labeling for Packaged Foods

The next relevant FDCA amendment, the FALCPA, regulates allergen labeling.[58] However, the FALCPA only applies to packaged food, not restaurant food.[59] The FALCPA amended Section 403 of the FDCA by setting out food-related definitions and adding to the section on misbranding.[60] The FALCPA also created 21 U.S.C. § 374a, which established allergen inspection requirements.[61]

Subsection (qq) defines major food allergens as milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame, as well as any food ingredient that contains protein derived from those nine foods.[62]

Subsection (w) sets the format for allergen labeling by requiring products that contain a major food allergen to have the word "contains," followed by the food from which the allergen is derived immediately after or adjacent to the ingredient list.[63] Furthermore, any person can petition the Secretary of Health and Human Services under subsection (w) to exempt a food ingredient from the allergen labeling requirements, but the burden falls on the petitioner to provide scientific evidence that the ingredient does not cause an allergic response.[64] This suggests that the FDCA may give responsibility to "any person" to prove something about the ingredients in their foods.[65]

21 U.S.C. § 374a creates allergen inspection requirements.[66] It requires inspections of any facility that manufactures, processes, packages, or holds foods. The purpose is to ensure compliance with practices minimizing cross-contact of foods with major allergens that are not "intentional ingredients" and ensures that major allergens are properly labeled.[67] However, it is uncertain if restaurants are included in this regime, as prior inspection requirements

56. *See* 21 U.S.C. § 343(q)(1).
57. *See id.* § 343(r)(1).
58. *See* GUIDANCE FOR INDUSTRY, *supra* note 25.
59. *See id.*
60. *See* Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, 118 Stat. 905 (2004) (codified at 21 U.S.C. §§ 343, 374a) [hereinafter FALCPA].
61. *See id.*
62. Sesame was added to the list of major food allergens in the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2021. *See* Food Allergy Safety, Treatment, Education, and Research Act of 2021, Pub. L. No. 117-11, 135 Stat. 262 (2021) (codified as amended at 21 U.S.C. § 321(qq)(1)).
63. 21 U.S.C. § 343(w)(1)(A).
64. *See id.* § 343(w)(6).
65. *See id.*
66. *Id.* § 374(a).
67. *See id.*

specifically excluded restaurants in certain aspects of inspection, including record inspection.[68]

The FALCPA also addressed cross contamination in two other ways.[69] First, the FALCPA ordered the Secretary of Health and Human Services to pursue revision of the Food Code[70] to offer guidelines for preparing "allergen-free foods in food establishments," including restaurants.[71] Second, the FALCPA required a report within eighteen months of enactment analyzing unintentional cross contamination of foods with major allergens; describing various types of "advisory labeling," including usage of "may contain" by food producers; and summarizing the results of facility inspections for cross contamination.[72]

However, the FALCPA falls short of successfully regulating allergen labeling in three ways.[73] First, it does not define or address the use of advisory labels, with the exception of stating that "may contain" language must be truthful and not misleading.[74] The report mentioned in the preceding paragraph did not establish any guidelines for such labels.[75] Second, the FALCPA did not establish thresholds for any food allergens.[76] Third, the FALCPA labeling requirements do not apply to allergens added as a result of cross contamination through shared facilities and equipment.[77] The FALCPA established the basic guidelines for allergen labeling but requires further development to better regulate allergens.

4. Affordable Care Act of 2010 Expanded the FDCA to Include Restaurants

The FDCA first regulated restaurant food when the ACA amended the NLEA.[78] The ACA, in relevant part, amended 21 C.F.R. § 101.9 by adding

68. *See id.* § 374(a)(1) (excluding farms and restaurants from inspection of records).

69. *See* FALCPA §§ 204, 209.

70. The Food Code is a "model that assists food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry (restaurants and grocery stores and institutions such as nursing homes)." It is a recommendation, not a law or a requirement. *See FDA Food Code*, U.S. FOOD & DRUG ADMIN. (Dec. 28, 2022), https://www.fda.gov/food/retail-food-protection/fda-food-code [https://perma.cc/N7PR-ZFQ5].

71. FALCPA § 209.

72. *Id.* § 204.

73. *See* Sarah Besnoff, *May Contain: Allergen Labeling Regulations*, 162 U. PA. L. REV 1465, 1476–86 (2014) (outlining lack of thresholds, regulation for advisory labels, and instruction on minimizing cross-contact of foods).

74. *See id.* at 1480–83; GUIDANCE FOR INDUSTRY, *supra* note 25.

75. *See* GUIDANCE FOR INDUSTRY, *supra* note 25.

76. *See id.*; Besnoff, *supra* note 73, at 1476–78 (stating that the FALCPA did not establish allergen thresholds).

77. *See* GUIDANCE FOR INDUSTRY, *supra* note 25; Besnoff, *supra* note 73, at 1470, 1476 (contending that under the FALCPA "some food products do not contain advisory labels about cross-contact with major allergens, despite having a high probability of contamination.").

78. *See* U.S. FOOD & DRUG ADMIN., FACT SHEET: FDA'S IMPLEMENTATION OF MENU LABELING MOVING FORWARD (Aug. 2019) [hereinafter MENU LABELING MOVING FORWARD]; Food

restaurant food to the definition of food products for the purpose of nutrition labeling and 21 C.F.R. § 101.10 by providing that nutrition information required by 21 C.F.R. § 101.11 would meet the requirement of nutrition content or health claims of 21 C.F.R. § 101.10.[79] The ACA also amended 21 U.S.C. § 343-1 of the NLEA by including preemption of restaurant nutrition claims.[80] The updated NLEA regulates, but does not preempt, nutrition information labeling on restaurant foods.[81] However, the NLEA regulates and preempts nutrition content claims on restaurant foods.[82]

More importantly, the ACA added restaurant food to the misbranding section, opening the door for the FDA to regulate restaurant menus just as it regulates packaged-food labels.[83] The ACA amended the NLEA misbranding section, 21 U.S.C. § 343(q)(5)(A), to include restaurants.[84] The ACA also added 21 U.S.C. § 343(q)(5)(H), which requires chain retail food establishments with twenty or more locations to provide calorie information for standard menu items, including food on display and self-service food. It also requires qualifying restaurants to provide, upon consumer request, additional written nutrition information for standard menu items.[85] Chain restaurants are restaurants operating under the same name and selling substantially the same menu items.[86]

To augment the inclusion of restaurants in the misbranding section, the ACA also created 21 C.F.R. § 101.11, which defines the terms in 21 U.S.C. § 343(q)(5)(H).[87] This section defines menu or menu board as the "primary writing of the covered establishment from which a customer makes an order."[88] This section also expands the definition of restaurant to include retail establishments that offer "restaurant-type food," including food that is eaten on the premises, taken to go, or processed and prepared primarily in the establishment for sale to consumers.[89] Restaurant-type food also includes self-service food, such as buffets and cafeterias.[90]

In short, by adding restaurant nutrition labeling requirements to the FDCA section on misbranding, the ACA gave the FDA control over restaurants, expanded the FDCA to include restaurants, and opened the door to restaurant-

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Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71156, 71156–62 (Dec. 1, 2014) [hereinafter Nutrition Labeling].

79. *See* Nutrition Labeling, 79 Fed. Reg. at 71162.

80. *See id.* at 71159.

81. *See* N.Y. State Restaurant Ass'n v. N.Y. City Bd. of Health (NYSRA), 556 F.3d 114, 120 (2d Cir. 2009) (finding that restaurant nutrition labeling must conform to Section 343(r), and that the NLEA does not preempt state nutrition labeling laws but does preempt state nutrient claims laws).

82. *See id.*

83. *See* Nutrition Labeling, 79 Fed. Reg. at 71162; 21 U.S.C. § 343(q)(5)(A).

84. *See* Nutrition Labeling, 79 Fed. Reg. at 71162; 21 U.S.C. § 343(q)(5)(A).

85. *See* Nutrition Labeling, 79 Fed. Reg. at 71162.

86. *See id.*; 21 U.S.C. § 343(q)(5)(H).

87. *See* Nutrition Labeling, 79 Fed. Reg. at 71159; 21 C.F.R. § 101.11(a) (2021).

88. 21 C.F.R. § 101.11(a) (2021).

89. *See id.*

90. *See id.*

related preemption laws, inspections, menu requirements, and enforcement. This was a huge step forward and set the groundwork for this Note's proposal.

B. State Laws Recognize the Importance of Allergen Training in Restaurants but Do Not Implement Allergen Menu Labeling

In addition to the federal laws above, seven states have food allergy laws centered on educating restaurant staff in the absence of restaurant food allergen labeling laws. There are also numerous laws about EpiPen usage in the case of anaphylactic shock that attempt to minimize the harm whenever a lack of allergen labeling results in consumption of allergens.[91] These state laws demonstrate the drive for allergen laws: easily preventable child deaths and the constant threat of allergic reaction that children with allergies, and their families, face.[92] Restaurant staff education and EpiPen usage together avoid allergic reactions and aid those experiencing a reaction.

States' varied approaches show why restaurant allergen labeling should be instituted as federal law. State allergen laws lack uniformity, focus, and intensity. Even when the goal is the same, the state law patchwork circulates allergen information in different ways: staffroom posters versus widely applied training courses versus training courses only for certain individuals. There is a lack of focus because different states tackle different aspects of allergen laws: from informing restaurant staff to training them, and from increasing availability of epinephrine to decreasing liability for epinephrine injections.[93] Perhaps the only constant is that all the state laws lack depth and intensity because state policymakers have tried to balance minimizing pressure on restaurants with protecting people with allergies. A federal law is needed to improve state laws' uniformity, to focus state laws on specific aspects of allergen labeling, and to strengthen state laws by showing what level of restaurant allergen requirements are acceptable.

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91. *See 25 Food Allergy Laws*, SPOKIN, https://www.spokin.com/food-allergy-laws [https://perma.cc/K494-JNLS] (listing state EpiPen laws in Minnesota, Virginia, Michigan, New York, Illinois, and Ohio).

92. *See id.* (explaining that Amarria's Law in Virginia was inspired by the death of a seven-year-old after eating a peanut at school; that New York Bill 56005A was inspired by the death of a student on a school bus due to an allergic reaction; that Annie LeGere's Law in Illinois was inspired by the death of a teenager who went into anaphylactic shock and the police were unable to save her because they did not have epinephrine; that Elijah's Law in New York was inspired by the death of a three-year-old with a known lactose allergy who was fed grilled cheese at daycare; that Gio's Law in New York was inspired by the death of teenager due to accidental exposure to peanuts; and that the Allison Rose Suhy Act in Ohio was inspired by the death of a teenager after an anaphylactic reaction to a doughnut with peanuts).

93. *See id.* (describing state laws increasing the availability of epinephrine across ambulances, schools, buses, nurses, police, first responders, and daycare workers and state laws protecting school employees and medical professionals from liability for injecting others with EpiPens).

1. Massachusetts Food Allergy Awareness Act (2009)

The first state bill on food allergies in restaurants was Massachusetts's Food Allergy Awareness Act (FAAA).[94] The FAAA was inspired by a chef and restaurant owner who is the father of a child with multiple food allergies.[95]

The FAAA requires restaurants to display a state-approved food allergy awareness poster in the staff area, to write a notice on menus for consumers with food allergies, and to conduct additional food allergy training for certified food protection managers.[96] The notice on menus must state: "Before placing your order, please inform your server if a person in your party has a food allergy."[97] This regulation applies to all food establishments that "cook, prepare, or serve food intended for immediate consumption either on or off the premises."[98] Grocery stores that have small seating areas also fall under this regulation if they cook, prepare, or serve food.[99] Local health boards enforce the FAAA with fines and other enforcement actions to achieve compliance.[100]

The FAAA also takes a step toward restaurant allergen labeling through required disclosure of all ingredients used by restaurants that wish to be designated as "Food Allergy Friendly" (FAF).[101] FAF is voluntary but the displays and training are not.[102] A FAF designation requires creating a publicly available master list of all the ingredients used in the preparation of each menu item and strictly adhering to procedures that prevent cross contamination.[103] The FAAA also requires the FAF program to list restaurants with its designation on the Department of Public Health's website.[104] Although the FAAA is the first of seven similar state laws, it is the most comprehensive because it includes consumer information and restaurant staff training, applies to many food vendors, and provides a type of consumer allergen disclosure.

94. *See Statewide Restaurant Legislation*, FOOD ALLERGY & ANAPHYLAXIS COLLECTION TEAM, https://www.foodallergyawareness.org/government-relations/statewide-restaurant-legislation/ [https://perma.cc/E76R-G8UR]; *Food Allergies and Restaurants*, FOOD ALLERGY RSCH. & EDUC., [hereinafter *Food Allergies and Restaurants*] https://www.foodallergy.org/resources/food-allergies-and-restaurants [https://perma.cc/AWD5-936V].

95. *See* SPOKIN, *supra* note 91.

96. *See Q & A for MDPH Allergen Awareness Regulation*, MASS. DEP'T OF PUB. HEALTH, (Aug. 19, 2010), [hereinafter *MDPH Q&A*] https://www.woburnma.gov/wp-content/uploads/2017/05/Q-A-Allergen-Awareness-Regulation.pdf [https://perma.cc/E3S5-XPW8].

97. 105 MASS. CODE REGS. 590.011(C)(2) (2018).

98. *Id.* 590.011(C).

99. *See MDPH Q&A*, *supra* note 96.

100. *See id.*

101. *See id.*

102. *See id.*

103. *See id.*

104. *See id.*

2. Rhode Island Food Allergy Awareness in Restaurants Act (2012)

Three years after Massachusetts passed its law in 2009, Rhode Island spread the wave of allergen education in restaurants by enacting a nearly identical act to the FAAA, called the Food Allergy Awareness in Restaurants Act (FAARA).[105] The FAARA was inspired by a teenager who contacted a state senator, wanting to protect people with food allergies, such as her sister.[106]

Like the FAAA, the FAARA requires an allergen poster in the staff area, a notice on menus for consumers with food allergies, and additional food allergy training for restaurant managers.[107] It also created a "Food Allergy Friendly" designation with similar requirements to the Massachusetts FAF.[108] Due to its similarities with the Massachusetts act, this is also one of the more comprehensive state laws.

3. Michigan Senate Bill 0730 (2014)

Another state law was Michigan Senate Bill 0730, signed in 2014 and enacted in 2015, which required certified food safety managers in most restaurants to take training courses with an allergen awareness component every five years.[109] An allergen poster in the staff room was also required, but only until December 31, 2020.[110] This approach provides significantly fewer regulations of allergen education than the prior two laws.

4. Maryland Code, Health-General § 21-330.2 (2014)

Maryland instituted a similarly superficial approach to allergen education in 2014, only requiring food establishments to prominently display food allergy awareness posters in staff areas.[111]

5. Virginia House Bill 2090 (2015)

The following year, Virginia House Bill 2090 was signed into law. This Act was inspired by a teenager with food allergies motivated by the Rhode Island law and a desire to protect herself, her siblings with allergies, and others with food allergies in restaurants.[112] This law requires the state Board of Health to include training standards for food safety and allergy awareness in its restaurant regulations.[113] The law also requires the Commissioner of Health to provide materials on food safety and allergy awareness to train restaurant personnel on

105. 23 R.I. GEN. LAWS § 20.12-1 (2012).
106. *See* SPOKIN, *supra* note 91.
107. *See id.*
108. *See id.*
109. *See* 2014 Mich. Pub. Acts 516.
110. MICH. COMP. LAWS § 289.6152(1) (2015).
111. *See* MD. CODE ANN., HEALTH - GEN. § 21-330.2 (2013).
112. *See* SPOKIN, *supra* note 91.
113. *See* VA. CODE ANN. §§ 35.1-14, 35.1-15 (2022).

minimizing cross contamination.[114] While not as comprehensive as the Massachusetts or Rhode Island laws, this law signaled an improvement from prior laws containing few regulations.

6. Illinois House Bills 2510, 2123, 3018 (2017, 2019, 2019)

Illinois passed three relevant House Bills within three years.

First, House Bill 2510, passed in 2017, amends the Food Handling Regulation Enforcement Act (FHREA) and requires all food service establishments to have at least one certified food service sanitation manager on the premises at all times. Certified service sanitation mangers would have to undergo training that follows nationally recognized industry standards for allergen safety and awareness.[115]

Second, House Bill 2123, passed in 2019, requires any packaged food sold in Illinois to list sesame on labels.[116] This was inspired by a state representative who has a daughter with multiple food allergies, including sesame.[117]

Third, House Bill 3018, passed in 2019, requires all Illinois restaurants to post signage in clear view of customers, reminding them to alert staff to their food allergies.[118] The employee notified of allergies must alert their supervisor or the certified food protection manager on duty of the customer's allergy.[119] The inspiration for this bill was a state senator with food allergies.[120]

The first and third laws are important for awareness and careful handling of allergens in restaurants, but they are not as comprehensive as the Massachusetts and Rhode Island laws in disclosure, widespread training, or consumer information. The "sesame law" demonstrates how a state can implement allergen regulations faster than the federal government, as the sesame law came two years before the federal FASTER Act of 2021.[121]

7. California's Natalie Giorgi Sunshine Act (2019)

Lastly, California Assembly Bill 1532, also known as the Natalie Giorgi Sunshine Act,[122] was passed in 2019. The law was inspired by a death of a

114. *See id.*
115. 410 ILL. COMP. STAT. 625 / 3 (2017).
116. *Id.* 620 / 11 (2019).
117. *See* SPOKIN, *supra* note 91.
118. 410 ILL. COMP. STAT. 625 / 3.08 (2019).
119. *See id.*
120. *See* SPOKIN, *supra* note 91.
121. Although a state can act faster in the hopes of sparking a national trend, the FALCPA preempts state laws, so it is uncertain if the Illinois sesame law would withstand judicial scrutiny. Nonetheless, the addition of an allergen into labeling requirements can draw attention to allergen disclosure issues. *See* Riëtte van Laack, *Illinois Law Requiring Sesame Labeling to Spark a National Trend?*, FDA L. BLOG (Aug. 12, 2019), https://www.thefdalawblog.com/2019/08/illinois-law-requiring-sesame-labeling-to-spark-a-national-trend/ [https://perma.cc/TJV6-XD2D].
122. *See id.*

teenager from anaphylaxis after an allergic reaction to peanuts.[123] This act requires all food handlers to have certification in handling major food allergens and preventing cross contamination.[124] While a step in the correct direction, this act is a narrower regulation compared to some of the preceding regulations, as it does not consider disclosure or consumer information.

All of these laws point to one idea: protection against food-related allergic reactions matters. While some states have existing laws that educate restaurant staff, allergen labeling on restaurant menus serves multiple functions: first, it would act as an allergen reminder, similar to the notice on menus in Massachusetts and Rhode Island; second, it would force restaurant staff to be more aware of what allergens are in the food, as opposed to providing rare training sessions or only training certain staff members; and third, it would serve a disclosure role to consumers about what is safe to eat.

Furthermore, the smorgasbord of different focuses in the above statutes demonstrates the lack of uniformity when allergen regulation is left to states as opposed to the federal government. With the exception of Rhode Island, states are neither considering the laws implemented by sister states nor building on them.[125] The above laws demonstrate the progress in allergen regulation in restaurants over a decade—little to none. In fact, although Illinois's series of laws showed a commitment to allergen regulation, the California, Virginia, Maryland, and Michigan laws had significantly fewer regulations and allergen protections that the Massachusetts and Rhode Island laws that came earlier.[126] States have already failed to develop allergen regulation that improves upon prior laws, so a federal law is necessary.

II.
CASE STUDIES INFORMING CREATION OF AN FDCA AMENDMENT AND EFFECTS OF ALLERGEN LABELING RULES

In addition to existing federal and state laws, there are two case studies that can inform allergen labeling advocates about strategies to create an FDCA amendment and effects of allergen labeling rules. These case studies are the menu labeling campaign for the ACA amendment and the FDA's gluten-free labeling rule. The menu labeling campaign guides information dissemination and political strategies, and the gluten-free labeling rule demonstrates the success of prior allergen labeling attempts and their impacts on consumers.[127]

123. *See* SPOKIN, *supra* note 91.
124. CAL. HEALTH & SAFETY CODE § 113948 (2020).
125. *See* discussion *supra* Part I.B.
126. *See id.*
127. *See* discussion *infra* Parts II.A, II.B.

A. The Fight for an FDCA Amendment: Looking Back at the Menu Labeling Campaign for Calories

The menu labeling campaign, spearheaded by the Center for Science in the Public Interest (CSPI),[128] was the first push to include restaurants under the FDA's jurisdiction by amending the FDCA to require restaurant chains to make nutrition information available to consumers.[129] It is important to consider the roadblocks that the menu labeling campaign encountered because allergen labeling campaigns are likely to meet the same hurdles.

The broad timeline of getting menu labeling codified into federal law started with extensive publications, progressed through local and state law, and culminated in a congressional amendment. Beginning in 1993, CSPI published a series of investigative reports on nutrition content in sit-down restaurants and fast food chains that generated newspaper headlines.[130] These were supported by numerous unaffiliated studies that began as early as 1951 but which increased in frequency and breadth in the 1990s.[131] In 2002, CSPI launched a menu labeling campaign to require calorie labeling on menus at chain restaurants.[132] After initial federal efforts were unsuccessful,[133] advocates turned to states and localities as laboratories of democracy that were willing to try laws that the federal government was hesitant about. In 2006, the New York City Board of Health adopted the nation's first menu labeling policy requiring calorie labeling on menus at chain restaurants.[134] From 2006 to 2010, advocates and public health groups across the country succeeded in passing menu labeling policies in over twenty states and localities, including a few where state law preempted the policies.[135] California became the first state to pass a menu labeling law in 2008.[136] In 2010, Congress passed a national law for calorie labeling on restaurant menus by amending the FDCA via the ACA.[137]

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128. *See Menu Labeling Campaign Timeline*, CTR. FOR SCI. IN THE PUB. INT., [hereinafter *Menu Labeling Campaign Timeline*] https://cspinet.org/sites/default/files/menu-timeline-2.pdf [https://perma.cc/GY8W-T5ZF].

129. MENU LABELING MOVING FORWARD, *supra* note 78.

130. *Menu Labeling Campaign Timeline*, *supra* note 128.

131. *See Restaurant Nutrition Search*, PUBMED, https://pubmed.ncbi.nlm.nih.gov/?term=restaurant+nutrition [https://perma.cc/QE2U-ZE66]; Cheryl L. Albright, June A. Flora & Stephen P. Fortmann, *Restaurant Menu Labeling: Impact of Nutrition Information on Entrée Sales and Patron Attitudes*, 17 HEALTH EDUC. Q. 157, 157 (1990) (finding that environmental strategies may be an effective way to encourage dietary changes but consumer gender and age many influence receptivity); Joni A. Mayer, Patricia M. Dubbert, and John P. Elder, *Promoting Nutrition at the Point of Choice: A Review*, 16 HEALTH EDUC. Q. 31, 31 (1989) (discussing that point of choice dietary interventions have the potential for reaching a large number of individuals at minimal cost, but there may be limitations to such interventions).

132. *Menu Labeling Campaign Timeline*, *supra* note 128.

133. *Id.*

134. *Id.*

135. *Id.*

136. *Id.*

137. *Menu Labeling Campaign Timeline*, *supra* note 128.

However, passing the national law was far from the end of the story due to extensive opposition that postponed implementation for eight years. From 2010 to 2018, the budding law faced significant pushback from industries lobbying the FDA, Congress, and the president to exempt movie theaters, convenience stores, supermarkets, and alcohol sales in restaurants.[138] Nonetheless, all of these industries ended up being covered in the final rule.[139] From 2011 to 2014, CSPI and other organizations provided background research and mobilization of the public to implement strong menu labeling regulations, which the FDA finalized in 2014.[140] The FDA postponed the implementation date multiple times, so the CSPI and the National Consumers League sued the FDA in 2017 for abandoning an earlier enforcement deadline only one day before enforcement was due to begin.[141] In exchange for halting the suit, the FDA nationally implemented menu labeling in 2018.[142]

Even after implementing menu labeling, the FDA performed extensive education and outreach for chains to understand the labeling requirements without actual enforcement.[143] The FDA balanced consumer needs for nutrition information with flexibility of compliance for restaurant chains by providing support for the industries, assessing implementation progress to adjust educational strategies, and engaging with state and local regulatory agencies to ensure uniform, consistent implementation.[144] As of yet, the FDA has not made menu labeling subject to the criminal and civil penalties that are otherwise prescribed in the FDCA.[145]

B. The First Allergen-Free Labeling Rule: Voluntary Gluten-Free Labeling

The second case study focuses on the gluten-free labeling rule, which defines "gluten" and is the first rule to set an allergen threshold that includes any cross contamination.[146] However, this rule is voluntary in the sense that it only

138. *Id.*

139. *Id.*

140. *Id.*

141. *See FDA Agrees to Enforce Menu Labeling Rule in May 2018*, CENT. FOR SCI. IN THE PUB. INT. (Sept. 27, 2017), https://cspinet.org/news/fda-agrees-enforce-menu-labeling-rule-may-2018-20170927 [https://perma.cc/82VQ-U92N].

142. *Id.*

143. MENU LABELING MOVING FORWARD, *supra* note 78.

144. *Id.*

145. *See id.*; 21 U.S.C. § 333(a) (ordering that any person who violates section 331 be imprisoned for up to one year, pay a fine of up to $1,000, or both, and any person who commits a secondary violation, or a violation with intent to mislead, will be imprisoned for up to three years, pay a fine of up to $10,000, or both).

146. *See Gluten and Food Labeling*, U.S. FOOD & DRUG ADMIN. (July 16, 2018), [hereinafter *Gluten and Food Labeling*] https://www.fda.gov/food/nutrition-education-resources-materials/gluten-and-food-labeling [https://perma.cc/7CN6-YF7T]; *Food Allergen Labeling and Consumer Protection Act of 2004 Questions and Answers*, U.S. FOOD & DRUG ADMIN. (July 16, 2018), [hereinafter *FALCPA Q&A*] https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-

applies when companies voluntarily label products "gluten-free."[147] Furthermore, the rule only applies to packaged foods and leaves restaurants' gluten-free menu labels unenforceable. In response to celiac disease patient groups calling for action,[148] the FDA issued a final rule defining "gluten-free" for food labeling in 2013.[149] This rule covers a voluntary claim that can be used by food manufacturers on packaged foods.[150] In 2020, the FDA similarly issued a final rule on gluten-free labeling in fermented and hydrolyzed foods, such as yogurt, alcohol, cheese, and pickles.[151]

These rules were critical for those with gluten allergies because it turned a minefield of food with unknown amounts of a severe allergen into a clearly laid path of acceptable foods to eat. Both rules are codified in 21 C.F.R § 101.91, which includes the definition of gluten, the requirements of gluten-free labeled products to not be misbranded, compliance methods, and a preemption clause. The rule defines gluten as wheat, rye, or barley derivatives, and limits gluten in a food item to 20 parts per million (ppm) to be considered gluten-free, including any cross contamination.[152] Any food labeled gluten-free that does not meet the definition is deemed misbranded under 21 U.S.C. § 343(w).[153] To set the basis for potential future liability for violating the gluten-free labeling rule, the FDA explained that if the amount of gluten in a food is questioned, it will use a "scientifically valid method that can reliably detect and quantify the presence of 20 ppm gluten."[154] Furthermore, the rule preempts a state or locality from implementing any rule that differs from the definition or use of the claim "gluten-free" and similar claims such as "no gluten," "without gluten," and "free of gluten."[155] The rule does not prohibit inclusion of an advisory label, such as "made in a facility that also processes wheat," and even allows such a label in conjunction with a gluten-free label if the total gluten content remains under 20 ppm.[156]

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information/food-allergen-labeling-and-consumer-protection-act-2004-falcpa [https://perma.cc/9XHU-HBSC] (singling out gluten labeling as the only allergen having a separate rule).

147. *Gluten and Food Labeling*, *supra* note 146.

148. Celiac disease is a very similar disease to allergies where one allergen, gluten, causes the immune system to attack the small intestine. *See Gluten-Free Labeling of Foods*, U.S. FOOD & DRUG ADMIN. (Mar. 7, 2022) [hereinafter *Gluten-Free Labeling*] https://www.fda.gov/food/food-labeling-nutrition/gluten-free-labeling-foods [https://perma.cc/CYC4-BFSF].

149. *Id.*; *Three Years Later, What Is the Impact of the Gluten-Free Labeling Standard?*, U.S. FOOD & DRUG ADMIN. (Oct. 4, 2017), [hereinafter *Impact of Gluten-Free Labeling*] https://www.fda.gov/food/conversations-experts-food-topics/three-years-later-what-impact-gluten-free-labeling-standard [https://perma.cc/F8JU-DMGJ].

150. *Gluten-Free Labeling*, *supra* note 148.

151. *Id.*

152. 21 C.F.R. § 101.91 (2021).

153. *Id.*

154. *Id.* § 101.91(c)(1).

155. *Id.*

156. *Questions and Answers on the Gluten-Free Food Labeling Final Rule*, U.S. FOOD & DRUG ADMIN. (June 30, 2022), [hereinafter *Q&A on Gluten-Free Food Labeling*]

While manufacturers are not required to ever personally test the gluten content, manufacturers are "responsible" for ensuring that food with a gluten-free label complies with the gluten-free labeling rule, so manufacturers may use a third party to test the gluten content.[157] Third parties include a third-party laboratory that would analyze in-house gluten content, request certificates of gluten analysis from ingredient suppliers, or participate in a third-party gluten-free certification program.[158] The gluten-free labeling rule does not prohibit third-party certification of gluten-free that uses a more stringent gluten-free threshold.[159] Furthermore, the FDA monitors these foods by sampling, inspecting manufacturing facilities, and doing gluten analyses in the case of consumer complaints.[160] If a label violates requirements, the FDA contacts the company and allows them to make the necessary corrections while recalling mislabeled products.[161]

In contrast, the FDA highly recommends, but does not require, restaurant labeling of "gluten-free" to be consistent with this rule for packaged foods.[162] This means that a gluten-free label on a restaurant menu is not enforceable.

Before the gluten-free labeling rule, "it was pretty much impossible" to determine whether a food was actually gluten-free.[163] One consumer recounted the difficulty of grocery shopping for a child diagnosed with celiac disease before the implementation of this rule: "I spent three hours in the supermarket and I only got two things. And I was crying."[164]

The gluten-free labels have helped both consumers and manufacturers. After implementation of the rule, consumers felt "much more confident" in food shopping.[165] Finding gluten-free products is now "a breeze."[166] In particular, the standardized definition of gluten-free is "a game changer" for celiac individuals and those with gluten allergies in choosing foods.[167] Establishing clear guidelines for "gluten-free" also helped manufacturers by leveling the playing field, thus leading to the increased manufacturing of gluten-free foods.[168] However, cross contamination is still an issue outside the home,[169] such as at restaurants, limiting celiac individuals' willingness to eat out.

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https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-gluten-free-food-labeling-final-rule [https://perma.cc/DS3W-4GUG].

157. *Id.*
158. *Id.*
159. *Id.*
160. *Id.*
161. *Impact of Gluten-Free Labeling*, *supra* note 149.
162. *Q&A on Gluten-Free Food Labeling*, *supra* note 156.
163. *Impact of Gluten-Free Labeling*, *supra* note 149.
164. *Id.*
165. *Id.*
166. *Id.*
167. *Id.*
168. *Id.*
169. *See id.*

These two case studies set the basis for the method and the execution of the proposal. The steps taken and setbacks encountered in the menu labeling campaign should inform the strategies of the allergen labeling campaign to efficiently amend the FDCA. The gluten-free labeling rule demonstrates the importance of allergen labeling to consumers and informs individuals of allergen thresholds, definitions, and optimal allergen phrasing on products.

III.
PROPOSAL: MANDATING UNIVERSAL ALLERGEN DISCLOSURES ON RESTAURANT MENUS

Existing state laws and the gluten-free labeling rule demonstrate the necessity of allergen education and standardized allergen definitions, while existing federal law regulates allergen labeling on packaged food and nutrition labeling on restaurant menus. The menu labeling campaign suggests a path to amending the FDCA for the standardization and regulation of allergen labeling on restaurant menus to significantly reduce the three-quarters of allergic reactions that occur in restaurants.[170]

This proposal will begin by outlining the requirements and allergen language of the proposed amendment to the FDCA. The proposal will list the allergens covered, discuss which types of menus the amendment would apply to, and discuss proposed styles of menu labeling along with a justification for the chosen style. Then, the proposal will discuss which types of restaurants the amendment would apply to, and how the requirements would be adapted to different types of restaurants. Next, the proposal will analyze whether this amendment is best applied at the local, state, or federal level. The proposal will explain why the proposed menu labeling would be effective and how it would be enforced based on existing laws. Lastly, there will be a comparison of current progress of allergen labeling to the menu labeling campaign, along with an analysis of the political feasibility of passing the proposed amendment.

The FDCA should be amended to mandate universal allergen disclosures on all restaurant menus by labeling allergens below each menu item. This proposal covers four key areas: (1) allergens subject to disclosure, (2) types of menus subject to this proposal, (3) disclosure locations, and (4) types of disclosure.

(1) Allergens Subject to Disclosure

Menus must label all nine federally recognized allergens: milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, sesame, and soybean.[171] Furthermore, a

170. *See* Endres et al., *supra* note 9, at 202 (finding that three-quarters of allergen-related food incidents arise at restaurants).

171. 21 U.S.C. § 321(qq)(1).

"common or usual name" of an ingredient is an acceptable variation,[172] so restaurants can choose between synonyms such as dairy and milk and soybeans and soy.[173]

One important distinction from the current FALCPA requirements is that restaurants will be required to disclose "gluten," not wheat. Gluten and wheat are not the same, but wheat is a type of gluten.[174] It is not necessarily safe for a person with a gluten allergy to eat something that does not have wheat.[175] On the other hand, those with wheat allergies may have undiagnosed gluten allergies.[176] It is safer for all consumers for restaurants to disclose gluten instead of wheat. The likelihood of overlap between these two terms also means that it would be unnecessary to burden restaurants with a tenth disclosure when gluten can cover wheat disclosures. Thus, restaurants will be required to disclose gluten as defined under the gluten-free labeling rule.[177]

(2) Types of Menus Subject to This Proposal

As with nutrition labeling laws, foods not appearing on a written menu, such as verbally listed daily specials and condiments, are not covered by this policy.[178] Written daily specials would be covered because written specials are usually written on a menu board. This policy focuses on written menus to employ many existing regulations in the FDCA because menus or menu boards fall within the definition of "label" for restaurants.[179] While any food can have dangerous allergens, including daily specials that are not written out, writing daily specials that were previously orally distributed may create an additional burden on smaller restaurants. Therefore, foods not appearing on written menus are not covered at this time.

(3) Disclosure Locations

Under this amendment, restaurants would be required to apply two types of negative allergen disclosures to their menus. As in the gluten-free labeling rule, there is some flexibility in the sentence structure for these negative disclosures,

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172. *Id.* § 343(w)(1).

173. *See* GUIDANCE FOR INDUSTRY, *supra* note 25.

174. *See* 21 C.F.R. § 101.91 (2021).

175. *Wheat Allergy Diet*, JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/health/wellness-and-prevention/wheat-allergy-diet [https://perma.cc/Q2N8-EBGK].

176. *See Celiac Disease, Non-Celiac Gluten Sensitivity or Wheat Allergy: What Is the Difference?*, GLUTEN INTOLERANCE GRP. (July 2021), https://gluten.org/2019/10/15/celiac-disease-non-celiac-gluten-sensitivity-or-wheat-allergy-what-is-the-difference/ [https://perma.cc/9HNZ-9ALG].

177. *See* 21 C.F.R. § 101.91 (2021).

178. *See Menu Labeling Rule Key Facts for Industry: General Information*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/116000/download [https://perma.cc/36VH-TCGV].

179. *NYSRA*, 556 F.3d at 131.

including "free from" or "does not contain" language.[180] Restaurants can choose which sentence structure they prefer, so long as it is consistent across the menu. Both methods require restaurants to spell out allergens, as opposed to using pictograms or abbreviated versions of the allergen.

The first method is a negative categorical disclosure that states that a menu category is free from a certain allergen. For example, "all appetizers are free from gluten" can be disclosed at the top of the appetizer section of the menu. These disclosures would be at the top of a category, directly under the category label.[181] However, this method may not always be applicable. If a category is not free from any allergen, then there would be no categorical disclosure for that section of the menu, even if other sections have the disclosure.[182] Furthermore, categorical disclosures will not apply to restaurants that don't have menus with categories, such as buffets where each item is individually listed.

The second method is a negative disclosure that a given menu item is free from certain allergens.[183] This method is always applicable to every written menu item. This allergen label must be directly below the menu item.[184] If a categorical disclosure states that the category is free from a given allergen, the individual menu item disclosure does not need to repeat that allergen's disclosure in the same category.

(4) Types of Disclosure

There are four general types of disclosure: written labels, pictogram labels, positive disclosures that state what an item contains, and negative disclosures that state what an item does not contain.

Restaurants would be required to add these allergens as words, not pictograms. While studies have shown that consumers prefer pictograms over words, pictograms would not work in restaurant menu labeling. One study was conducted using only two pictograms, dairy and gluten,[185] but restaurants would be required to list up to nine pictograms, with many allergen pictograms looking very similar, such as soy, sesame, tree nuts, and peanuts. While the effectiveness of pictograms would not be limited to English speakers, it would be difficult for consumers to differentiate nine pictograms. Knowing exactly which allergen is contained in a menu item is central to allergen disclosures, so pictograms alone would not work. Another study showed that consumers have a strong preference

180. *See* 21 C.F.R. § 101.91 (2021) (listing "no gluten," "free of gluten," or "without gluten" as a synonymous claim to "gluten-free").

181. *See infra* Appendix.

182. *See id.*

183. *See id.*

184. *See id.*

185. *See* W. Marty Blom, Liselotte M. van Dijk, Anouska Michelsen-Huisman, Geert F. Houben, André C. Knulst, Yvette F.M. Linders, Kitty C.M. Verhoeckx, Bregje C. Holleman & Leo R. Lentz, *Allergen Labeling: Current Practice and Improvement from a Communication Perspective*, 51 CLINICAL & EXPERIMENTAL ALLERGY 574, 582–83 (2021).

for pictograms in combination with written text.[186] While this would eliminate consumer confusion, it would also add an unnecessary burden on restaurants because there would be additional disclosures, and the disclosures would take up more space than is necessary. Furthermore, neither EU regulations nor the FALCPA regulations use pictograms,[187] so pictograms would introduce a new layer of complexity. Therefore, written text is a better option for menu labeling.

There are three main types of possible written allergen disclosures: negative abbreviations (such as "gf" for gluten-free), positive "contains" disclosures, and negative "free from" disclosures. As with pictograms, abbreviations would introduce confusion because soy, sesame, and shellfish would be abbreviated as variations of "sf." The decision to choose between positive and negative written disclosures is more difficult. The FALCPA uses "contains" language,[188] while the gluten-free labeling rule uses "free from" language.[189] Negative disclosures would likely take up more space on menus than positive disclosures, and thus be more burdensome for restaurants. Because menu items usually contain no more than three or four allergens, over half of the allergens would need to be listed in the "free from" language. On the other hand, positive disclosures alone are not ideal, because the priority for those with severe allergies is their allergen. It does not matter to them what other allergens the food may contain—it matters whether the food is safe for someone with their allergy to eat. Positive disclosures alone do not necessarily convey this information. If someone allergic to gluten sees a menu item that "contains peanuts," the next question is, "What about gluten?" Under the FALCPA, positive disclosures do not have this issue because the "contains" language follows the list of ingredients, thus acting as an allergen summary.[190] The consumer does not need to ask if the food is free from a certain allergen because they can see all the ingredients listed. This is not the case with restaurant menu items, so negative disclosures are a more informative option.

By requiring negative disclosures for each menu item and category, this policy combats the issues above. Categorical disclosures would require fewer individual menu item disclosures, thus decreasing restaurants' burden to disclose. For example, if all salads are free from shellfish, the restaurant would only need to list that once in the categorical disclosure instead of repeating it for each salad menu item. Both negative disclosures fix the follow-up question of positive disclosures because consumers will see individualized as well as categorical information on which allergen each menu item is free from. Therefore, combined negative disclosures are the best method for labeling allergens on restaurant menus.

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186. *See* Carlo A. Marra, Stephanie Harvard, Maja Grubisic, Jessica Galo, Ann Clarke, Susan Elliott & Larry D. Lynd, *Consumer Preferences for Food Allergen Labeling*, 13 ALLERGY, ASTHMA & CLINICAL IMMUNOLOGY 1, 7 (2017).

187. *See* Blom et al., *supra* note 185, at 583; 21 U.S.C. § 343(w).

188. 21 U.S.C. § 343(w).

189. *See* 21 C.F.R. § 101.91 (2021).

190. *See* 21 U.S.C. § 343(w).

A. Allergen Menu Labeling Will Apply to Restaurants Great and Small

These disclosure requirements would apply to all "restaurants or other establishments in which food is served."[191] As with nutrition labeling, similar retail food establishments include movie theaters, amusement parks, and grocery stores when food is ordered from a menu or self-served from a buffet.[192] However, allergen labeling will go beyond nutrition labeling because it will not be limited to restaurant chains and will include food trucks as defined under "restaurant" by the FDA.[193]

Even in the age of DoorDash, many small restaurants do not have official websites, so only restaurants that have websites displaying their menu will be required to label allergens online in addition to the physical menu. For small restaurants that do not have websites, consumers usually have access to pictures of the menus posted by the restaurant or its diners on websites such as Yelp, TripAdvisor, and Facebook, so enforcing menu labeling on physical menus will also distribute allergen labels of those menus online. Of course, just because the policy would require allergen labels on menus does not prohibit listing allergens in an additional way on a website, such as an interactive page that allows consumers to choose an allergen and see the foods that are free from that allergen.[194] Similarly, the proposal does not restrict restaurants from offering additional information on their menus, such as whether an item is vegetarian or vegan, or whether a menu item with an allergen can be modified to be made without the allergen.

Allergen disclosures on certain specialty menus may look different, so long as they have the required disclosures. For example, some prix-fixe Michelin-starred restaurants do not give diners a menu at the beginning of their visit. However, these restaurants will almost always ask diners if they have allergies, and the restaurant gives the menu at the end of the visit. Allergen disclosures would still be required on the menu at the end of the visit to prevent restaurants from offering menus at the end of a meal as a loophole of the policy. In another example, buffets often do not have menus but instead have labels above every

191. *See* 21 C.F.R. § 1.227 (2021) (finding that entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens, are restaurants); *id.* § 101.11 (2021) (defining "similar retail food establishment" as a retail establishment that offers for sale "restaurant-type food," which is defined as food usually eaten on the premises or taken to go and is prepared or served in the establishment).

192. *Overview of FDA Labeling Requirements for Restaurants, Similar Retail Food Establishments and Vending Machines*, U.S. FOOD & DRUG ADMIN., (Nov. 11, 2017), [hereinafter *Similar Retail Food Establishments*] https://www.fda.gov/food/food-labeling-nutrition/overview-fda-labeling-requirements-restaurants-similar-retail-food-establishments-and-vending [https://perma.cc/4K3S-GM3Z].

193. *See id.*; 21 C.F.R. § 1.227 (2021).

194. *See NYSRA*, 556 F.3d at 134 (holding that the First Amendment does not bar the government from compelling "under-inclusive" factual disclosures); CHIPOTLE, *supra* note 30.

food dish. Buffets would be required to put the allergen labels on these food dish labels.

In contrast to requiring allergen disclosures in all restaurants, recent articles discussing food allergen labeling in restaurants have recommended limiting allergen disclosures to restaurants falling under the ACA amendment for nutrition labels,[195] namely restaurants that are part of a chain with twenty or more locations doing business under the same name and with most of the same items.[196] However, this is an unnecessary, inefficient, and insufficient focus. Most large chains, including McDonald's, KFC, Starbucks, Subway, Taco Bell, Chipotle, Blaze Pizza, and Applebee's, already have detailed, easy-to-access allergen information on their websites, even if allergen information is not written on physical menus. Thus, focusing on chains for allergen disclosures is unnecessary.[197] While not everyone can or will access the online allergen information, this information is available. In contrast, most small restaurants do not have this level of disclosure. Focusing on restaurant chains is also inefficient because it diverts resources that could be used to get universal allergen disclosures on all restaurant menus and insufficient because chains make up less than half of U.S. restaurants.[198] In the Northeast and Pacific Northwest, fast food chains make up only around twenty percent of restaurants.[199] Lack of allergen labeling may cause anaphylactic shock, so the stakes are higher with allergen labeling than nutrition labeling. Thus, only labeling twenty to fifty percent of restaurant menus is insufficient. Therefore, universal restaurant allergen disclosure requirements are necessary.

B. Enforcing Allergen Labeling on Restaurant Menus

Allergen disclosures are crucial, so this policy would have multiple rounds of enforcement with increasing severity. As with the nutrition labeling laws,[200] the first year will consist of education and outreach to make sure restaurants understand the new regulations and how to be compliant. Thus far, because of COVID-19 and the first-year policy,[201] the FDA has not begun serious

195. *See* Marie Boyd, *Serving Up Allergy Labeling: Mitigating Food Allergen Risks in Restaurants*, 97 OR. L. REV. 109, 154 (2018) ("[L]ike the menu labeling requirements, as an initial matter, a food allergen requirement should cover any 'restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name . . . and offering for sale substantially the same menu items'").

196. *See* 21 U.S.C. § 343(q)(5)(H)(i).

197. *See supra* note 30 and accompanying text.

198. U.S. DEP'T OF AGRIC., *supra* note 33.

199. *Id.*

200. MENU LABELING MOVING FORWARD, *supra* note 78.

201. *See FDA Provides Flexibility Regarding Menu Labeling Requirements for Chains Restaurants and Similar Retail Food Establishments During the COVID-19 Pandemic*, U.S. FOOD & DRUG ADMIN., (Apr. 1, 2020), https://www.fda.gov/food/cfsan-constituent-updates/fda-provides-flexibility-regarding-menu-labeling-requirements-chain-restaurants-and-similar-retail [https://perma.cc/ESR3-UXC9].

enforcement of nutrition labeling laws, so the following rounds of enforcement are based on enforcement of gluten-free labeling.[202] After the first year, there will be two ways that the government could learn about restaurants not in compliance: inspections, such as through the FDA's district offices, and consumer complaints.[203] Once the government is aware of the infraction, the first step would be to contact the restaurant and give them the opportunity to make appropriate corrections.[204] If the restaurant remains noncompliant with the policy, stage three of enforcement is penalties as dictated by the FDCA.[205] A violation of the policy would result in short-term imprisonment, a monetary fine, or both, if there are repeated violations. Intentional mislabeling would be subject to harsher penalties.[206]

A restaurant violates this policy by not labeling allergens on the menu or by incorrectly labeling allergens. If an enforcement action progresses to court, the court will define "incorrect" labeling as labeling stating a menu item does not have an allergen when it surpasses a threshold ppm of the allergen. There are many commercially available methods and devices that could be used in a court proceeding for testing the ppm of proteins from major food allergens.[207] Furthermore, the FDCA suggests a level of responsibility attributed to any person to prove the ingredients used in their products do not cause allergic reactions.[208] However, setting a threshold ppm is more difficult because different allergens have different thresholds.[209] A higher threshold would be easier for restaurants to adhere to but would be dangerous for those with a higher degree of allergen sensitivity. A lower threshold would be difficult for restaurants to comply with for some allergens that are prevalent in foods whose labels declare

202. *See Impact of Gluten-Free Labeling*, *supra* note 149.

203. *See id.*

204. *See id.*

205. While at this point the FDCA is simply a blueprint for this stage of enforcement, if the policy is passed into federal law, it will likely be added to the FDCA. *See* discussion *infra* Part III.E.

206. *See* 21 U.S.C. § 333(a) (ordering that any person who violates section 331 be imprisoned for up to one year or pay a fine of up to $1,000, or both, and any person who commits a secondary violation, or a violation with intent to mislead, be imprisoned for up to three years or pay a fine of up to $10,000, or both); *id.* § 331(b) (ordering that misbranding of any food is prohibited); *id.* § 343(w) (listing major food allergen labeling requirements as a type of misbranding).

207. *See* U.S. FOOD & DRUG ADMIN., APPROACHES TO ESTABLISH THRESHOLDS FOR MAJOR FOOD ALLERGENS AND FOR GLUTEN IN FOOD 87–88 (2006) [hereinafter APPROACHES TO ESTABLISH THRESHOLDS].

208. *See* 21 U.S.C. § 343(w)(6).

209. *See* P. Collin, L. Thorell, K. Kaukinen & M. Mäki, *The Safe Threshold for Gluten Contamination in Gluten-Free Products. Can Trace Amounts Be Accepted in the Treatment of Coeliac Disease?*, 19 ALIMENTARY PHARMACOLOGY & THERAPEUTICS 1277, 1277 (2004) (finding that gluten-free products contain 20-200 ppm of gluten and recommending a threshold ppm of 100 ppm as safe for celiac individuals); M. Morisset, D. A. Moneret-Vautrin, G. Kanny, L. Guenard, E. Beaudouin, J. Flabbee & R. Hatahet, *Thresholds of Clinical Reactivity to Milk, Egg, Peanut and Sesame in Immunoglobulin E-Dependent Allergies: Evaluation by Double-Blind or Single-Blind Placebo-Controlled Oral Challenges*, 33 CLINICAL & EXPERIMENTAL ALLERGY 1046, 1046 (2003) (finding that detection tests should ensure 10 ppm sensitivity for egg, 24 ppm for peanut, and 30 ppm for milk to guarantee ninety-five percent safety for patients).

them free from that allergen.[210] This policy will employ the FDA's 20 ppm threshold for gluten.[211] However, the FDA has yet to declare threshold levels for the other the FALCPA allergens,[212] so this Note will not prescribe threshold levels for the other allergen disclosures on restaurant menus.

C. Restaurant Allergen Labeling Should Be Done on the Federal Level

Allergen labeling should be implemented at the federal level. However, until federal allergen labeling requirements become a reality, state labeling requirements are an option to begin mandating allergen disclosures on menus. Similar to the federal amendment discussed below, states would introduce restaurant allergen labeling laws by amending any misbranding laws in states where they exist.[213] Uniformity is the main concern when deciding which level of government should implement allergen labeling. It is important to have the same definitions of allergens and allergen thresholds so that consumers crossing state lines know that if they don't have allergic reactions under one state's allergen threshold, they will not have an allergic reaction under a sister state's threshold. When lives are at stake, there is little room to allow states to be "laboratories of democracy." However, given the path that menu nutrition labeling took through building up state laws before arriving at a federal amendment,[214] state labeling requirements may be a temporary necessary evil.

Nonetheless, the end goal should be implementing allergen labeling at the federal level through an amendment to the FDCA. The simplest amendment would add restaurants to the scope of the FALCPA, as codified in the misbranding section of 21 U.S.C § 343(w).[215] Such an amendment would specify that the section (w) subsections apply to both packaged foods and restaurant foods, with the menu or menu board acting as the label, and would set the methods of labeling. Alternatively, as with the ACA amendment of the FDCA, there can be a new subsection of misbranding aimed at restaurants and retail food establishments that specifies the mandatory allergen disclosure methods for restaurants.[216]

Whatever form the provision for allergen labeling ultimately takes, the FDA can then add detail by specifying allergen thresholds, preemption of alternate state restaurant allergen labels, and methods of compliance and

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210. *See* Collin, *supra* note 209, at 1277 (finding that even gluten-free products contain 20-200 ppm of gluten).

211. 21 C.F.R. § 101.91(a)(3) (2021) (defining gluten free as food containing less than 20 ppm).

212. *See* APPROACHES TO ESTABLISH THRESHOLDS, *supra* note 207 (suggesting that, as of 2018, thresholds have not been decided for allergens).

213. *See, e.g.*, CAL. HEALTH & SAFETY CODE §§ 110660–110805 (1995) (listing types of misbranded food).

214. *See* discussion *infra* Part III.E; discussion *supra* Part II.A.

215. *See* 21 U.S.C. § 343(w) (defining major food allergen labeling requirements for packaged foods).

216. *See* 21 U.S.C. § 343(q)(5)(H).

enforcement, similar to the gluten-free labeling provision.[217] As with the NLEA, the FALCPA, and the gluten-free labeling provision, [218] the new law should preempt state and local allergen laws that differ from the FDA's federal laws to promote uniformity of allergen thresholds and definitions of allergen-free food.[219] All three of these recent laws have been strong at the federal level, so there should not be issues with the strength of the allergen labeling provisions.

State allergen labeling is inferior to federal allergen labeling but superior to local allergen labeling. While state allergen labeling does not offer the uniformity that a federal law would, it allows for significantly more uniformity than local laws.

1. Restaurant Allergen Labeling as Local Law Is Not Recommended

In contrast to state policies, local policies are a dangerous and inefficient way of implementing allergen requirements, so this policy should not be carried out at the local level. Local policies are dangerous for allergen labeling because allergen labeling requires setting an acceptable allergen threshold for enforcement purposes and minimizing cross contamination. However, if two nearby counties have their own allergen labeling laws, consumers with allergies would not know that it is safe to eat in one county but not the other until they experience an allergic reaction. In this sense, uniformity is crucial for the effectiveness of allergen labeling. On an average day, a commuter can easily cross three counties on the way to and from work or recreational activities.[220] This means that they would potentially be eating in restaurants with three different allergen labeling laws. In contrast, on an average day, the vast majority of people stay in the same state,[221] so there is less chance of falling prey to varied allergen thresholds across state borders.

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217. *See* 21 C.F.R. § 101.91 (2021).

218. *See* 21 U.S.C. § 343-1 (preempting food labeling that is not identical to the misbranding laws set out in 21 U.S.C. § 343, including nutrition and allergen labeling for packaged foods and nutrition labeling for restaurant foods); 21 C.F.R. § 101.91(d) (2021) (preempting different definitions or thresholds of gluten-free in labeling).

219. This proposal is focused on the first step: getting a uniform law. Once that is in place, states could potentially implement stricter allergen thresholds that don't match the federal one or impose additional allergen restrictions such as requiring labeling of an additional allergen. These variations would be stricter than the federal law, which would denote a safe baseline, so variety across states would be less of an issue at that time. *See* RONALD D. ROTUNDA & JOHN E. NOWAK, TREATISE ON CONSTITUTIONAL LAW SUBSTANCE AND PROCEDURE § 12.3 (5th ed. 2012) (allowing stricter state requirements even when there is a federal statute preempting variation so long as the state law is not an "obstacle" to the purpose of Congress); discussion *supra* Part I.B.6 (referencing the existence of a state sesame allergen labeling law even though the FALCPA preempted state allergen labeling that differed from the FALCPA.)

220. *See County to County Commute Patterns*, STATE OF CAL. EMP. DEV. DEP'T, https://labormarketinfo.edd.ca.gov/data/county-to-county-commute-patterns.html [https://perma.cc/98WN-L5NK] (showing that thirty-six percent of people commuting to San Mateo County drive through at least three counties).

221. *See* Brian McKenzie, *Out-of-State and Long Commutes: 2011*, U.S. CENSUS BUREAU (Feb. 2013), https://www.census.gov/library/publications/2013/acs/acs-20.html [https://perma.cc/2NV6-

Furthermore, the lack of focus in patchwork local policies is also a danger to consumers. Even with a common goal of restaurant allergen labeling, each locality could enforce a different method of allergen labeling. On the state level, this isn't an issue because the average consumer would generally encounter the labeling method in the state they live in, but on the local level, changing labeling styles is ripe for confusion and allergic reactions. Negative pictograms and positive pictograms look quite similar in a small font, and consumers used to viewing which allergens a menu item is free from may overlook the word "contains" in a different locality, thus accidentally eating allergen-containing food that they thought was free from the allergen. While local governments have the power to regulate restaurants, and various counties have succeeded as laboratories of democracy for nutrition labeling,[222] the danger of experimenting on consumers with allergens outweighs the benefits of experimentation at the local level. With allergic reactions at stake, having one set of scientifically backed thresholds and definitions is key, and the FDA has a history of sponsoring reports and research to set scientifically backed food regulations.[223]

In conclusion, uniform allergen labeling should be implemented on the federal level by amending the FDCA.

D. Allergen Menu Labeling Will Be Effective Because People with Allergies Pay Attention to Allergen Labels

This disclosure will work because consumers are already adjusting their purchasing habits based on allergens. Food allergies have no treatment except abstaining from eating the food a person is allergic to.[224] For those with severe allergies, their choices are either to visit an emergency room or to abstain from foods. It is easier to abstain from allergens in packaged foods after the FALCPA and the gluten-free labeling rule, but over sixty percent of Americans eat at restaurants at least once a week,[225] with one-third of calories eaten outside the home.[226] Nearly three-quarters of food-related allergic reactions occur at restaurants due to lack of restaurant server education and consumer information.[227] As such, restaurant allergen disclosures would make abstaining more feasible.

SP69] (finding that even in the state with the highest rate of out-of-state commuters among its resident workers, nearly seventy-five percent commute to work without crossing state borders).

222. *See* discussion *supra* Part II.A.

223. *See* APPROACHES TO ESTABLISH THRESHOLDS, *supra* note 207, at 2.

224. FOOD ALLERGY RSCH. & EDUC., *supra* note 1.

225. Lydia Saad, *Americans' Dining-Out Frequency Little Changed from 2008*, GALLUP (Jan. 11, 2017), https://news.gallup.com/poll/201710/americans-dining-frequency-little-changed-2008.aspx [https://perma.cc/TQB9-RTL8].

226. *Similar Retail Food Establishments*, *supra* note 192.

227. Endres et al., *supra* note 9, at 202.

Some people argue that disclosures never work because consumers do not read them, but this is not an issue for allergen disclosures.[228] While disclosures in the realms of finances, privacy, and website cookies may not be effective,[229] some food disclosures are effective. According to multiple studies, sugary drink warnings have decreased consumption of sugary drinks.[230] Furthermore, the explosion of the voluntary gluten-free product market, valued at over 5 billion dollars annually in 2020,[231] suggests that it is not just celiac and gluten-allergic individuals buying gluten-free foods. One study found that women with celiac disease and women without celiac disease, but who were on a gluten-free diet by choice, chose foods labeled "gluten-free" with the same frequency.[232] Thus, even if the large gluten-free market developed because it became a popularized diet,[233] people are reading the gluten-free label—even when they do not have to fear an allergic reaction.

Finally, the relief of consumers with celiac disease after the FDA's gluten-free labeling rule demonstrates consumer desire for allergen labels and their effectiveness.[234] That relief was marred by only one thing—restaurants weren't subject to the same requirements. Those allergic to gluten and other allergens will notice that next step.

E. Comparisons to the Menu Labeling Campaign

Even without specific thresholds, the march to allergen labeling has already begun, based on the stages of the menu labeling campaign. Research on allergens and anaphylactic shock has been around for decades,[235] but connecting allergens to restaurants and research on allergen knowledge in restaurants has only been a

228. Carl E. Schneider & Omri Ben-Shahar, *The Failed Reign of Mandated Disclosure*, THE REGUL. REV. (June 15, 2015), https://www.theregreview.org/2015/06/15/ben-shahar-schneider-failed-disclosure/ [https://perma.cc/B3WC-Y7V7].

229. *See id.*

230. *See* Anna H. Grummon & Marissa G. Hall, *Sugary Drink Warnings: A Meta-Analysis of Experimental Studies*, 17 PLOS MEDICINE 1, 2 (2020).

231. Nils-Gerrit Wunsch, *Global Gluten-Free Food Market Value from 2020 to 2025*, STATISTA (Aug. 26, 2022), https://www.statista.com/statistics/248467/global-gluten-free-food-market-size/ [https://perma.cc/J4DY-3P9H].

232. *See* Wioleta Zysk, Dominika Głąbska & Dominika Guzek, *Role of Front-of-Package Gluten-Free Product Labeling in a Pair-Matched Study in Women with and Without Celiac Disease on a Gluten-Free Diet*, 11 NUTRIENTS 398, 398 (2019).

233. *See* Kathleen Doheny, *What's Behind the Gluten-Free Trend?*, EMEDICINEHEALTH (Sept. 16, 2016), https://www.emedicinehealth.com/script/main/art.asp?articlekey=198273 [https://perma.cc/3WAZ-PAFR].

234. *See Impact of Gluten-Free Labeling*, *supra* note 149.

235. *See* Hugh A. Sampson, *Food Allergy: Past, Present, and Future*, 65 ALLERGOLOGY INT'L 363, 363 (2016) (explaining that scientific investigation of allergies began after a 1921 experiment); D. Malish, M. Glovsky, D. R. Hoffman, L. Ghekiere & J. M. Hawkins., *Anaphylaxis After Sesame Seed Ingestion*, 67 J. ALLERGY & CLINICAL IMMUNOLOGY 35, 35 (1981) (discussing molecular weights of sesame seed extract that caused positive responses on allergen tests).

popular field of study for the past decade or so.[236] There have also been individual calls for allergen labeling,[237] and multiple organizations have publicly taken up the campaign mantle, especially Food Allergy Research and Education (FARE).[238] Furthermore, states have begun implementing varied allergen requirements in restaurants[239]—some disclosure-based, many knowledge-based—in large part assisted by FARE.[240]

1. Political Feasibility of Passing Allergen Labeling Compared to Menu Labeling

The menu labeling campaign paved the road for allergen labeling, so allergen labeling will likely face significantly less pushback than menu labeling. First, the menu labeling campaign added restaurant food to the food regulated by the FDA,[241] so there is a basis for requiring restaurants to label allergens.

Second, large restaurant chains that have the most significant political power are already listing allergens on their websites,[242] so they are unlikely to be overly involved in any lobbying efforts. While many restaurant chains already listed nutrition information before menu labeling,[243] they did not account for a large portion of lobbying, with the exception of the pizza industry, so it is unlikely they would lobby hard against allergen labeling.[244]

Third, most of the arguments by lobbyists against nutrition labeling are not applicable to allergen labeling, so there should be less pushback from lobbyists against allergen labeling. Supermarkets and convenience stores argued that menu labeling disproportionately burdened stores compared to restaurants because they, unlike restaurants, would be required to establish menu boards.[245] Those menu boards now exist due to menu labeling,[246] so stores would have the same

236. *See* Taylor J. Radke, Laura G. Brown, Brenda Faw, Nicole Hedeen, Bailey Matis, Priscela Perez, Brendalee Viveiros & Danny Ripley, *Restaurant Food Allergy Practices—Six Selected Sites, United States, 2014*, 66 MORBIDITY & MORTALITY WEEKLY REP. 404, 404 (2017) (discussing restaurant allergen training and recommendations to reduce the risk of allergic reactions among consumers); Samuel Bailey, Richard Albardiaz, Anthony J. Frew & Helen Smith, *Restaurant Staff's Knowledge of Anaphylaxis and Dietary Care of People with Allergies*, 41 CLINICAL & EXPERIMENTAL ALLERGY 713, 713 (2011) (finding that despite a high confidence level, there were significant gaps in restaurant staff's knowledge of allergies).

237. *See* Boyd, *supra* note 195, at 154.

238. *Food Allergies and Restaurants*, *supra* note 94.

239. *See* discussion *supra* Part I.B.

240. *Id.*

241. MENU LABELING MOVING FORWARD, *supra* note 78.

242. *See, e.g.*, MCDONALD'S, *supra* note 30.

243. Peter Lehner, *'Big Pizza' is Lobbying Congress to Put Profit Ahead of Public Health*, EARTHJUSTICE (Mar. 7, 2018), https://earthjustice.org/blog/2018-march/big-pizza-is-lobbying-congress-to-put-profit-ahead-of-public-health [https://perma.cc/JV65-FAZ8].

244. *See Menu Labeling Campaign Timeline*, *supra* note 128.

245. *See* Eric M. VanEpps, Christina A. Roberto, Sara Park, Christina D. Economos & Sara N. Bleich, *Restaurant Menu Labeling Policy: Review of Evidence and Controversies*, 5 CURRENT OBESITY REPS. 72, 76–77 (2016).

246. *See Menu Labeling Campaign Timeline*, *supra* note 128.

burden as restaurants. Pizza chains were concerned about creating physical menu boards when most consumers purchased pizza online or by phone.[247] Again, those menu boards now exist, and allergen labeling will be required for online menus as well, so this concern would be unfounded in the case of allergen labeling. Pizza chains also argued against the daily recommended calorie statement, listing nutrition information for the entire pizza instead of one slice, and the variability of customizable meals.[248] Allergen labeling does not have a generic statement. Unlike nutrition labeling, allergen information applies equally to an entire pizza as to a slice without creating a more unhealthy impression. Allergen information will also be less varied than nutrition information because most pizzas will have gluten, dairy, and eggs. Few toppings contain allergens beyond these, while nutrition information varies with every topping. Finally, a general concern with nutrition labeling was calculating the calorie content, because restaurants are required to have a "reasonable basis" for their nutrition content declarations.[249]

With allergens, menu labeling is significantly easier for multiple reasons. First, all packaged foods list ingredients, so as long as chefs know what food they are putting into the menu items, they will know which allergens are directly present in the items. Second, for small kitchens worried about cross contamination, there are numerous retail testing kits for allergens that restaurants can use, eliminating the need to send foods out for lengthy third-party testing.[250] Therefore, most concerns of anti-labeling lobbyists will not apply to allergen labeling.

Finally, and perhaps most significantly, restaurants feared menu labeling would decrease consumption of restaurant food,[251] but allergen labeling would likely *increase* consumption.[252] Furthermore, studies have shown that consumers are willing to pay more for products with "free from" labels, because consumers find them more informative than other disclosures.[253] This is likely to decrease the chance of lobbying by the industries that lobbied the FDA and Congress against menu labeling.[254] Food-related industries would benefit from the

247. *See id.*

248. *See id.*

249. *See Questions and Answers on the Menu and Vending Machines Nutrition Labeling Requirements*, U.S. FOOD & DRUG ADMIN., (July 11, 2018), https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-menu-and-vending-machines-nutrition-labeling-requirements [https://perma.cc/KCA4-QAVA].

250. *See* APPROACHES TO ESTABLISH THRESHOLDS, *supra* note 207.

251. *See* VanEpps et al., *supra* note 245, at 74 (describing the possibility that menu labeling will result in preference for restaurants with lower-calorie options).

252. *See* Endres et al., *supra* note 9, at 207 (explaining that accommodating diners with food allergies can increase patronage of a restaurant by five to fifteen percent).

253. *See* Christina Hartmann, Sophie Hiekeb, Camille Taperb & Michael Siegrist, *European Consumer Healthiness Evaluation of 'Free-from' Labelled Food Products*, 68 FOOD QUALITY & PREFERENCE 377, 377 (2018).

254. *See Menu Labeling Campaign Timeline*, *supra* note 128.

disclosure, even considering the up-front costs of allergen labeling, such as reprinting menus and organizing kitchens to minimize cross contamination.

While nutrition disclosures may cause consumers to avoid a more expensive menu item or avoid the restaurant altogether in favor of restaurants with lower-calorie options, allergen labeling would allow a consumer to visit restaurants that they had previously avoided due to allergen concerns. By disclosing which dishes have certain allergens, restaurants may be able to increase their consumer base.[255] As an example, gluten-free food as a whole is a huge market, expected to increase from 5.6 billion dollars to 8.3 billion dollars annually between 2020 and 2025.[256] While this may be in large part because nearly one-third of gluten-free consumers eat gluten-free as a lifestyle choice,[257] not due to allergies, it nevertheless demonstrates the profitability of gluten-free labeling. Ultimately, this market sprang up from voluntary allergen disclosures. Therefore, allergen labeling laws are likely to benefit restaurants, so they should have a high degree of political feasibility.

IV.
LEGAL FEASIBILITY OF PASSING ALLERGEN LABELING ON RESTAURANT MENUS

Restaurant allergen labeling is legally feasible.[258] The FDA would likely have the authority to regulate allergen disclosures under a hypothetical federal law.[259] Until a federal law is passed, however, states can legally implement their own restaurant allergen labeling laws because they are not preempted by existing federal laws in the FDCA.[260] Furthermore, governmental regulation of allergen disclosure on restaurant menus is constitutional under the First Amendment because allergen disclosures pass the *Zauderer* test.[261]

A. Restaurant Allergen Labeling as Federal Law Through FDCA Amendment

The FDA likely has the authority to regulate restaurant allergen disclosures. It already regulates restaurant chains disclosures and allergen disclosures.[262] The new question is whether the FDA can regulate smaller restaurants that are not part of chains. The answer is likely yes. The FDA's powers apply only to interstate commerce, but "interstate commerce" is very broadly defined and includes locally finished products made from components that have moved in

255. Chain restaurants' voluntary decision to disclose allergens suggests that they are not worried about those disclosures decreasing consumer traffic. *See* sources cited *supra* note 30.

256. Wunsch, *supra* note 231.

257. *See id.*

258. *See* discussion *infra* Part IV.

259. *See* discussion *infra* Part IV.A.

260. *See* discussion *infra* Part IV.B.

261. *See* discussion *infra* Part IV.C.

262. 21 U.S.C. § 343.

interstate commerce.[263] Congress has defined "food" to include ingredients,[264] and courts have specified that if an ingredient moved in interstate commerce, the FDA can regulate the finished product, whether or not the finished product itself moved in interstate commerce.[265] While small restaurants generally use more locally sourced products than large chains, which use national distributors, there is a very high chance that almost every restaurant uses at least one ingredient that crossed state borders, whether that ingredient be salt, spices, out-of-season fruits and vegetables, or ingredients from other countries. Such restaurants could be regulated under the FDA's power.

The few restaurants whose ingredients are entirely locally sourced would also likely be subject to the FDA's authority. The FDA's power to regulate restaurants' nutrition labels already reflects Congress's conclusion that the restaurant business, broadly, is a class of commercial activity that substantially affects interstate commerce, so the "*de minimis* character of individual instances" is irrelevant.[266] In other words, individual restaurants, even if they do not directly affect commerce, or if their "individual impact on interstate commerce is minimal," can be regulated by Congress because restaurants "substantially affect interstate commerce in the aggregate."[267] The case for regulating restaurants which use entirely local ingredients is strong, because small restaurants *do* participate in commerce—namely the sale of restaurant meals[268]—even if these restaurants do not participate in interstate commerce. Taken together, the total commercial effect of restaurants using only local food nationwide is "far from trivial,"[269] even if there are relatively few of them compared to restaurants using ingredients that traveled through interstate commerce.

Furthermore, Congress's authority over interstate commerce does not require determining whether the activities of small restaurants actually substantially affects interstate commerce in the aggregate, but only whether a

263. *FDA Regulation of Products in Interstate Commerce*, *in* FDA ENFORCEMENT MANUAL ¶ 150 (Dennis Tosh ed., Supp. 2016).

264. *Id.*

265. *See id.*; Baker v. United States, 932 F.2d 813, 816 (9th Cir. 1991) (holding that wholly intrastate manufactures and sales of drugs are within the FDA's regulatory authority as long as an ingredient used in the final product travelled in interstate commerce).

266. *See* Gonzales v. Raich, 545 U.S. 1, 17 (2005).

267. *See* Taylor v. United States, 579 U.S. 301, 306 (2016) ("[E]ven if appellee's activity be local and though it may not be regarded as commerce, it may still, whatever its nature, be reached by Congress if it exerts a substantial economic effect on interstate commerce." (quoting Wickard v. Filburn, 317 U.S. 111, 125 (1942)); *Gonzales*, 545 U.S. at 18 ("Congress can regulate purely intrastate activity that is not itself 'commercial,' in that it is not produced for sale, if it concludes that failure to regulate that class of activity would undercut the regulation of the interstate market in that commodity.").

268. *See NYSRA*, 556 F.3d at 131 (finding that disclosure of nutrient information is "in connection with a proposed commercial transaction—the sale of a restaurant meal").

269. *See Wickard*, 317 U.S. at 127–28 (finding that although the appellee's own contribution to the demand for wheat is trivial, this is not enough to remove him from the scope of federal regulation when his contribution, taken together with that of many others similarly situated, is far from trivial).

"rational basis" exists for this determination.[270] Given the enforcement difficulties in distinguishing restaurants using only local products from restaurants using ingredients that traveled through interstate commerce, Congress would have a rational basis for believing that a failure to regulate intrastate restaurants would leave a hole in restaurant allergen labeling regulation.[271] Therefore, the FDA can likely regulate allergen labeling in all restaurants, regardless of size.

B. Restaurant Allergen Labeling as State Law Through Amending State Misbranding Laws

Until federal allergen labeling requirements become a reality, state labeling requirements may be a necessary evil to begin mandating allergen disclosures on menus. Unlike federal laws, which are largely given free rein so long as they do not infringe on constitutional rights, state laws are more limited. Whenever there is a chance that state laws may infringe upon interstate commerce, which is the domain of federal law, state laws face multiple hurdles. Two constitutional provisions are potential impediments to states establishing allergen menu labeling laws: the Supremacy Clause and the Dormant Commerce Clause.

1. There Are No Current Federal Laws That Would Preempt a State Restaurant Allergen Labeling Law

The Supremacy Clause provides the basis for Congress's power to preempt state law when it is impossible to comply with both federal and state law or when state laws could obstruct the "purposes and objectives" of federal law.[272] Preemption does not bar state or local laws that are identical to the FDCA. In particular, preemption in the food label context has an exemption for state law claims which "coincide with the federal regulatory scheme, which ensures that these claims will not conflict with or impair the FDA's regulatory power."[273] In contrast, state laws that have more stringent requirements than the FDCA are murkier, as some cases allow more stringent requirements while other cases do not allow states to include additional information on a federally approved

270. *See Gonzales*, 545 U.S. at 22.

271. *See id.* ("Given the enforcement difficulties that attend distinguishing between marijuana cultivated locally and marijuana grown elsewhere . . . we have no difficulty concluding that Congress had a rational basis for believing that failure to regulate the intrastate manufacture and possession of marijuana would leave a gaping hole in the CSA.").

272. *See* CHARLES S. ZIMMERMAN, PHARMACEUTICAL AND MEDICAL DEVICE LITIGATION § 15A:4 (2022); JAMES T. O'REILLY & KATHARINE A. VAN TASSEL, FOOD AND DRUG ADMINISTRATION § 26:72 (4th ed. 2022).

273. O'REILLY & VAN TASSEL, *supra* note 272, § 26:74.

label.[274] Generally, "express preemption in food labeling is the exception, not the norm."[275]

Furthermore, in areas of traditional state regulation, there is an assumption that a federal statute does not preempt state law unless explicitly stated by Congress.[276] Health and safety issues, especially food labeling, are traditionally an area of state regulation, so there is a strong presumption against preemption.[277] The presumption may be overcome by demonstrating that Congress or the regulatory authority intended the preemption, but this is a high bar.[278] In the area of food labeling under the FDCA, the presumption against preemption is still effective because the FDA does not intend to use its authority to preempt state laws unless there is a "genuine need to stop the proliferation of inconsistent requirements between the FDA and the States."[279]

State implementation of restaurant allergen disclosure requirements is not preempted by existing law, because there is no express statement that allergen labeling in restaurants is preempted, no applicable federal statute, and no conflict with state law. The FALCPA and the gluten-free labeling rule preempt nonidentical state laws for packaged foods,[280] but not for restaurant menu items. As it applies to restaurants, the amended NLEA only preempts nutrition content claims on restaurant foods—it does not preempt any allergen labels or claims.[281] Furthermore, there is a strong presumption against preemption from any other FDCA provisions that are more distant from allergen labeling because restaurant allergen disclosures fall within the category of food labels.[282]

Therefore, a state law on restaurant allergen disclosures is not preempted.

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274. *See* ROTUNDA & NOWAK, *supra* note 219, § 12.3 (discussing that where "there is neither such actual conflict between the two schemes of regulation that both cannot stand in the same area, nor evidence of a congressional design to preempt the field," a state may constitutionally reject avocados that a federal authority certified as marketable, because the state law is not an obstacle to the accomplishment and execution of the full purposes and objectives of Congress). *But see* Kanter v. Warner-Lambert Co., 122 Cal. Rptr. 2d 72, 84–85 (Ct. App. 2002) ("[W]hen a state law claim, however couched, would effectively require a manufacturer to include additional or different information on a federally approved label, it is preempted."); Peviani v. Hostess Brands, Inc., 750 F. Supp. 2d 1111, 1119–20 (C.D. Cal. 2010) (finding preemption because otherwise, plaintiff would impose a state law for trans-fat disclosure that is not required by federal law); Chacanaca v. Quaker Oats Co., 752 F. Supp. 2d 1111, 1121–23 (N.D. Cal. 2010) (explaining state laws that tried to impose labeling requirements that were not identical to FDA regulations regarding use of the terms "0 grams trans fat" and "good source" of calcium and fiber were expressly preempted).

275. O'REILLY & VAN TASSEL, *supra* note 272, § 26:88.

276. *Id.*

277. Plumley v. Massachusetts, 155 U.S. 461, 472 (1894) ("[I]f there be any subject over which it would seem the states ought to have plenary control . . . it is the protection of the people . . . in the sale of food products.").

278. ZIMMERMAN, *supra* note 272, §§ 15A:5, 15A:6.

279. O'REILLY & VAN TASSEL, *supra* note 272, § 26:88.

280. *See* GUIDANCE FOR INDUSTRY, *supra* note 25; *Gluten-Free Labeling*, *supra* note 148.

281. *See NYSRA*, 556 F.3d at 120.

282. *See* O'REILLY & VAN TASSEL, *supra* note 272, § 26:88.

2. State Restaurant Allergen Labeling Laws Do Not Violate the Dormant Commerce Clause

State restaurant allergen labeling laws do not violate the second potential hurdle, the Dormant Commerce Clause, which protects out-of-state competitors and out-of-state consumers by requiring congressional approval for any state discriminating against interstate transportation or trade.[283] This is meant to support the goal of establishing a unified national economy.[284]

The threshold question for a Dormant Commerce Clause analysis is whether a state law affects interstate commerce.[285] State labeling of foods and ingredients sold across state lines meets that threshold.[286]

The first prong of the Dormant Commerce Clause analysis considers whether a state law discriminates against interstate commerce because of its interstate nature, in which case the state law is a *per se* violation of the Dormant Commerce Clause.[287] There are two types of regulations that discriminate against interstate commerce: regulations that facially discriminate against out-of-state interests and regulations that have the effect of favoring in-state commerce at the expense of interstate commerce.[288]

Restaurant allergen labeling does not fall in either of these categories, so it passes the first prong of the Dormant Commerce Clause analysis. There is no benefit to restaurants in using ingredients that traveled through interstate commerce versus intrastate commerce, as restaurants need to disclose all major allergens, regardless of whether the food is locally or nationally sourced, and packaged food labeling requirements are uniform across the nation due to the FDCA. As such, restaurant allergen labeling does not facially discriminate against out-of-state interests, nor does it favor intrastate commerce at the expense of interstate commerce.

When there is no discrimination against interstate commerce, the second prong requires a balancing test comparing the burden imposed on interstate commerce against the local benefits.[289] This is determined on a case-by-case analysis,[290] but there is a presumption of constitutionality once the law is found nondiscriminatory.[291] This is such a strong presumption that the party

283. *See* ROTUNDA & NOWAK, *supra* note 219, §§ 11.1, 11.11.

284. *Id.* § 11.1.

285. *See* Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 578–79 (1986).

286. *See* Grocery Mfrs. of Am., Inc. v. Gerace, 755 F.2d 993, 997 (2d Cir. 1985), *aff'd*, 474 U.S. 801 (1985) (analyzing state labeling law "for foods shipped in interstate commerce").

287. ROTUNDA & NOWAK, *supra* note 219, § 11.8; Laura Murphy, Jillian Bernstein & Adam Fryska, *More than Curiosity: The Constitutionality of State Labeling Requirements for Genetically Engineered Foods*, 38 VT. L. REV. 477, 539 (2013).

288. *See Brown-Forman Distillers*, 476 U.S. at 579.

289. Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970).

290. *See id.* ("[T]he extent of the burden that will be tolerated will of course depend on the nature of the local interest involved").

291. *See* Murphy et al., *supra* note 287, at 548.

challenging the statute has the burden to prove it is unconstitutional by pointing to a particular section of the Constitution that would prohibit the statute and must demonstrate "clearly and convincingly" that it was the "constitutional aim" of that provision to deny the state legislature the power to enact the statute.[292] Nonetheless, recognized burdens on interstate commerce include withdrawal of a business from an in-state market and financial effects such as increased business costs, compliance costs, or lost profits.[293]

These burdens would likely be negligible because allergen labeling requirements would increase profits without significant increased costs,[294] as existing state laws that do not violate the Dormant Commerce Clause suggest.[295] Even if some restaurants choose to withdraw from an in-state market, this would affect intrastate end users much more so than interstate suppliers, and as such would not substantially impact interstate commerce. Interstate suppliers may be affected by allergen labeling, but labeling on grocery stores menus would not carry over to other states and thus would not burden interstate commerce. Therefore, restaurant allergen labeling would at most be an incidental burden on interstate commerce.

Furthermore, public health and safety is a legitimate local interest that justifies incidental burdens on interstate commerce.[296] Labeling laws, in particular an imitation cheese product labeling law, have been justified by the state's interest in health, consumer information, and permitting consumers to clearly discern what type of product they were purchasing.[297] The health interest is compounded in the case of allergen labeling, as allergic reactions send many more consumers to the hospital than imitation cheese.

In short, state allergen labeling laws would likely be upheld under the balancing test, because allergen laws are motivated by strong public health interests that have been upheld as outweighing incidental burdens on interstate commerce.

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292. Smith v. Robinson, 2018-0728, 14 (La. 12/5/18), 265 So. 3d 740, 749.

293. Exxon Corp. v. Governor of Md., 437 U.S. 117, 127 (1978) (holding that there is no impermissible burden on interstate commerce simply because an otherwise-valid regulation caused some business to change interstate suppliers after the withdrawal of petroleum refiners from the Maryland market). *See, e.g.*, Parker v. Brown, 317 U.S. 341, 355, 359 (1943) (discussing the burden imposed on raisin producers by a California statute that required two-thirds of the yearly raisin crop to be sold through a California agency at a fixed price, thereby limiting producers' ability to compete and limiting their potential for profits).

294. *See* Endres et al., *supra* note 9, at 210 (explaining that accommodating diners with food allergies can increase patronage of a restaurant by five to fifteen percent).

295. *See, e.g.*, *MDPH Q&A*, *supra* note 96 (ordering restaurants to display a state-approved food allergy poster, have a menu notice, and hold food allergy training for food protection managers).

296. *See Parker*, 317 U.S. at 362–63 (finding that the "safety, health and wellbeing of local communicates" is an appropriate interest).

297. *See Grocery Mfrs. of Am.*, 755 F.2d 1003–04 (holding that New York's interests in health, consumer information, preventing deception, and allowing consumers to discern what type of product they were purchasing were legitimate interests served by a regulation prohibiting the misleading labeling of imitation cheese products).

Therefore, restaurant allergen labeling laws at the state level would be constitutional under the Dormant Commerce Clause because they do not discriminate against any commerce for its interstate nature or impose an undue burden on interstate commerce balanced against the many local benefits the laws provide.

C. Mandating Restaurant Allergen Labeling is Constitutional Under Zauderer

Although implementing allergen labeling on the federal level is the best approach, mandating allergen labeling is constitutional under the First Amendment at the federal, state, or local level. In the case of compelled commercial disclosures, such as mandating restaurant businesses to disclose information about their products, *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio* sets out an applicable test.

Zauderer was a disciplinary proceeding for an attorney who published advertisements in local newspapers to attract clients.[298] The Ohio Office of Disciplinary Counsel believed that the ads violated a disciplinary rule that attorneys should not put ads in newspapers, and that the explanation of fees and costs in the ads was misleading.[299] The Ohio Supreme Court held that the attorney violated the disciplinary rule and deserved public reprimand, and the attorney appealed.[300]

The U.S. Supreme Court focused on the attorney's First Amendment rights and rationalized that an advertiser's rights are sufficiently protected so long as disclosure requirements are "reasonably related" to the government's interest in preventing deception of consumers.[301] Therefore, the government can compel speech that is "purely factual and uncontroversial" with the goal of eliminating consumer deception, so long as the compelled speech is not "unduly burdensome" on the speaker.[302] The attorney's advertisements were factual, but the statement of fees was misleading.[303] As such, the Court held that there should not be discipline for advertising geared to specific legal problems. The state's interest in banning in-person solicitation could not carry over to discipline for newspaper advertisement, and attorneys could not be disciplined for truthful and nondeceptive printed ads. However, the state could require an attorney advertising his availability on contingent-fee basis to disclose that clients will have to pay costs even if their lawsuits are unsuccessful when ads do not distinguish between "legal fees" and "costs."[304]

298. *See* Zauderer v. Off. of Disciplinary Couns. of Sup. Ct. of Ohio, 471 U.S. 626, 629 (1985).
299. *See id.* at 630.
300. *See id.* at 636.
301. *See id.* at 651.
302. *See id.*
303. *See id.* at 651–53.
304. *See id.* at 655–56.

In *Zauderer*, the Supreme Court established the rational basis test to decide whether a given compelled commercial disclosure violates free speech rights under the First Amendment.[305] In other words, "commercial actors," such as businesses, disclosing "commercial information" required by law are subject to *Zauderer*.[306] Restaurant menu labeling comports with the First Amendment under this test because the compelled allergen disclosures are factual and uncontroversial, reasonably related to a legitimate government interest, and not unduly burdensome or unjustified.[307]

1. Mandating Menu Labeling is Compelled Commercial Disclosure, so Zauderer *Applies*

Zauderer is the appropriate test for determining First Amendment constitutionality of allergen labeling on menus because menu labeling is a compelled commercial disclosure. It is compelled because allergen labels would be required by law to disclose information to the public regarding allergens in food. While there is no all-purpose test to distinguish commercial speech from noncommercial speech under the First Amendment,[308] the U.S. Supreme Court has described commercial speech as "expression related solely to the economic interests of the speaker and its audience."[309] In particular, this is speech that proposes a commercial transaction, so allergen labeling on restaurant menus is likely commercial speech by law because requiring disclosure of allergen information is "in connection with a proposed commercial transaction—the sale of a restaurant meal."[310] There are limited-purpose tests for commercial speech, but they are aimed at false advertising and consumer deception,[311] which are not the issues with allergen disclosures. Thus, allergen labeling on restaurant menus falls within the scope of *Zauderer*'s test for compelled commercial disclosures.

2. Allergen Disclosures Are Purely Factual and Uncontroversial

Once a disclosure falls within the scope of the *Zauderer* test, the threshold analysis is whether the disclosure is purely factual and uncontroversial. Allergen disclosures are directly informative of the "intrinsic characteristics" of the menu items that restaurants sell, so they are factual.[312] Disclosures that are based on a

305. *See id.* at 650–51; *NYSRA*, 556 F.3d at 132.

306. *See NYSRA*, 556 F.3d at 132.

307. *See Zauderer*, 471 U.S. at 651.

308. *See* Kasky v. Nike, Inc., 45 P.3d 243, 256 (Cal. 2002).

309. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 561 (1980). *See also* ROTUNDA & NOWAK, *supra* note 219, § 20.29(b).

310. *See NYSRA*, 556 F.3d at 131 (finding that a regulation requiring disclosure of California information in connection with the sale of a restaurant meal is commercial speech).

311. *See Kasky*, 45 P.3d at 256.

312. *See* Am. Meat Inst. v. USDA, 760 F.3d 18, 27 (D.C. Cir. 2014) (holding that country-of-origin labeling qualifies as factual, and the facts are directly informative of intrinsic characteristics of the product for sale).

government "opinion"[313] or disclosures that are intended to evoke an emotional response to shock the viewer are not factual,[314] but neither of these are the case with allergen listing. Instead, disclosing allergens promotes the First Amendment goal of the "discovery of truth,"[315] because consumers are made aware of the allergens in the meals they eat.

Allergen disclosures are also uncontroversial. While there is no legal test for what is considered uncontroversial, the D.C. Circuit has defined controversial as communicating a message that is "controversial for some reason other than [a] dispute about simple factual accuracy."[316] In that instance, the court decided that labeling food with an intrinsic characteristic was uncontroversial,[317] suggesting that labeling the allergens in foods would also be uncontroversial. The U.S. Supreme Court once interpreted controversial to mean extremely politically controversial, such as abortion measures.[318] However, food labeling does not rise to this level: the Second Circuit upheld mandatory disclosure of calorie information in spite of controversy in which calorie content was prioritized over other nutrition information.[319] Therefore, allergen labeling is uncontroversial, so it passes the first prong and threshold question of the *Zauderer* test.

3. Allergen Labeling on Restaurant Menus Is Reasonably Related to the Legitimate Government Interest in Preventing Dangerous Allergic Reactions

As required by the next prong, allergen labeling on menus is reasonably related to the government public health interest of preventing allergic reactions. While the government interest that *Zauderer* acknowledged is preventing deception,[320] multiple federal Courts of Appeal have unanimously allowed government interests other than consumer deception.[321] Among these other interests are food-related public health interests and increasing consumer awareness about potentially dangerous elements of the products they

313. *See* Discount Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 561 (6th Cir. 2012).

314. *See* R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1216 (D.C. Cir. 2012), *overruled by* Am. Meat Inst. v. USDA, 760 F.3d 18 (D.C. Cir. 2014) (holding that graphic warnings primarily intended to evoke an emotional response are not "purely" factual).

315. *See NYSRA*, 556 F.3d at 132 (finding that commercial disclosure requirements are treated more leniently because they further the discovery of truth).

316. *See Am. Meat Inst.*, 760 F.3d at 27, 34.

317. *Id.* at 27 (holding that country-of-origin labeling was not controversial because it communicated a message controversial for some reason other than dispute about factual accuracy).

318. *See* Nat'l Inst. of Fam. & Life Advocs. v. Becerra (NIFLA), 585 U.S. ___, slip op. at 9 (2018).

319. *See NYSRA*, 556 F.3d at 132.

320. *See Zauderer*, 471 U.S. at 651.

321. *See* Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 310 n.8 (1st Cir. 2005) (finding that there is no precedent limiting *Zauderer* to the government interest of preventing consumer deception); *NYSRA*, 556 F.3d at 133.

purchase.[322] The D.C. Circuit previously barred alternate government interests in the application of *Zauderer*, but that decision was later overturned.[323] Therefore, it is likely that alternate government interests are acceptable. Thus, the government's food-related public health interest and interest in increasing consumer awareness about elements of products that may threaten them are both legitimate interests driving allergen labeling.

Proving that a government interest is "reasonably related" to the required disclosure generally requires evidentiary proof. However, the evidentiary burden is not a high bar. When it is self-evident that the government interest relates to the issue, there is no need for a survey or official study, and evidence demonstrating a pattern is adequate to establish the connection.[324] In this instance, the prevalence of laws inspired by the deaths of children who consumed undisclosed allergens,[325] as well as the reality that the majority of fatal food allergy reactions are triggered by food eaten outside the home,[326] is likely sufficient to prove that the harms are real and that disclosure will alleviate them to a significant degree.[327] Therefore, allergen labeling on restaurant menus is reasonably related to the legitimate government interest of public health and informing consumers of dangers in products.

4. Listing Allergens on Menus Is Neither Unduly Burdensome nor Unjustified

Allergen disclosures pass the last prong of the *Zauderer* test because these disclosures are neither unduly burdensome nor unjustified as they take up little space on a menu and are used to alleviate real harms. Allergen disclosures must be balanced against their likely burden on protected speech by considering how

322. *See NYSRA*, 556 F.3d at 134 (applying *Zauderer* to the government interest of informed consumer decision making to reduce obesity); Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001) (holding that a goal of increasing consumer awareness of the presence of mercury in products was consistent with the policies underlying First Amendment protection of commercial speech).

323. *See* Am. Meat Inst., 760 F.3d at 20 ("We now hold that *Zauderer* in fact does reach beyond problems of deception.").

324. *See* Milavetz, Gallop & Milavetz, P.A. v. United States, 559 U.S. 229, 251 (2010) (finding that evidence demonstrating a pattern is adequate to establish that the likelihood of deception is not speculative).

325. *See supra* note 92.

326. *See* S. Allan Bock, Anne Muñoz-Furlong & Hugh A. Sampson, *Further Fatalities Caused by Anaphylactic Reactions to Food, 2001–2006*, 119 J. ALLERGY & CLINICAL IMMUNOLOGY 1016, 1016–18 (2007); S. Allan Bock, Anne Muñoz-Furlong & Hugh A. Sampson, *Fatalities Due to Anaphylactic Reactions to Foods*, 107 J. ALLERGY & CLINICAL IMMUNOLOGY 191, 191–93 (2001); Hugh A. Sampson, Louis Mendelson & James P. Rosen, *Fatal and Near-Fatal Anaphylactic Reactions to Food in Children and Adolescents*, 327 NEW ENG. J. MED. 380, 380–83 (1992).

327. *See* Fla. Bar v. Went for It, Inc., 515 U.S. 618, 626 (1995).

much of the menu the disclosures cover and if they drown out restaurants' messages about their food.[328]

There is no threshold amount for how much of a document a disclosure can cover without infringing on free speech rights, but a required allergen disclosure would be burdensome and unjustified if a smaller warning would accomplish the government's goals.[329] Allergen labeling cannot be condensed more than it already is, as negative disclosures are the best way to accomplish the public health goal. Using a mix of categorical and individualized allergen labels decreases the space that the disclosures take up by minimizing repetition. The labels could potentially use a smaller font size, but the space saved would be negligible unless the disclosures became difficult to read, at which point the small size would decrease effectiveness. Therefore, smaller warnings would not accomplish the government's public health goals as successfully. Additionally, the allergen disclosures would not drown out restaurants' messages about their food options and choice ingredients, but would rather enhance those messages by informing consumers which products are safe for them.

For the compelled disclosures to not be unjustified, the government must prove that they remedy a harm from allergens that is "potentially real, not purely hypothetical."[330] Based on the studies of fatal anaphylactic shock occurring from consumption outside the home,[331] allergens are a very real harm.

Proving that the allergen disclosure is not "unduly burdensome" requires the government to demonstrate that the labels do not impose a "government-scripted, speaker-based disclosure requirement that is wholly disconnected" from the government's public health and informational interests.[332] Restaurants are only required to disclose allergen information about the menu items they set for themselves, so allergen labeling does not impose a script.[333] Furthermore, allergen labels are required for all restaurants, not certain types of restaurants, and the labels are directly connected to the government interest in ensuring allergen information for consumers.[334] Therefore, allergen labeling on restaurant menus is neither unduly burdensome nor unjustified.

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328. *See NIFLA*, 585 U.S. ___, slip op. at 19 (holding that a required warning that covers twenty percent of product labels drowns out the plaintiff's messages, so is unduly burdensome and unjustified when balanced against the burden on speech).

329. *See* Am. Beverage Ass'n v. City & Cnty. of S.F., 916 F.3d 749, 757 (9th Cir. 2019) (clarifying that a warning that covers ten percent of product labels is not necessarily valid or invalid but depends on an evidentiary showing that a smaller warning would accomplish the government's goals).

330. *See* Ibanez v. Fla. Dep't of Bus. & Pro. Regul., Bd. of Acct., 512 U.S. 136, 146 (1994).

331. *See* sources cited *supra* notes 5, 325.

332. *See NIFLA*, 585 U.S. ___, slip op. at 18.

333. *See* Chong Yim v. City of Seattle, 451 P.3d 675, 693 (Wash. 2019) (finding that landlords must disclose the rental criteria they set for themselves, so the rule does not impose any type of script).

334. Sorrell v. IMS Health, Inc., 564 U.S. 552, 571–72 (2011) (holding that speaker-based restrictions require heightened judicial scrutiny in the context of the *Central Hudson* test for restricting commercial speech). *See generally* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557 (1980) (showing that *Sorrell* is not yet required in the *Zauderer* analysis).

As such, allergen labeling passes the *Zauderer* test, so allergen labeling on restaurant menus is in accordance with the First Amendment.

CONCLUSION

Reactions to food allergies cause hospitalizations in the United States every few minutes, and there is no treatment other than to avoid allergens.[335] There are nine major allergens: milk, egg, peanut, tree nuts, wheat, soy, fish, crustacean shellfish, and sesame.[336] Federal law requires allergen labels on packaged foods,[337] and some state laws require allergen training for restaurant staff.[338] However, there is no single law requiring allergen labels for restaurant menu items, even though over half of the U.S. population goes to a restaurant at least once a week.[339] This policy will fill that gap.

Allergen labeling advocates should strive to include universal restaurant menu allergen labeling in the FDCA via an amendment which allows the FDA to enforce labeling under the misbranding provisions. Under this law, restaurants would be required to use categorical and individualized negative disclosures to list what each menu category and menu item does not contain. Allergen labeling of restaurant menus is unlikely to encounter significant pushback, and thus will be politically feasible, because most of the arguments against nutrition labeling are irrelevant to allergen labeling,[340] and menu labeling is likely to increase the number of consumers who visit a given restaurant, thus decreasing the chance of lobbying by powerful industries.[341] Allergen labeling in restaurants also does not violate the Supremacy Clause, the Dormant Commerce Clause, or the First Amendment right to free speech. In short, introducing allergen labeling of restaurant foods on restaurant menus would help protect and inform consumers with food allergies while remaining a politically feasible, constitutionally sound solution that does not overly burden restaurants.

Now is the best time to push for adopting universal allergen menu labeling in restaurants and to leverage the recent success of the nutrition menu labeling campaign and the FDA's voluntary gluten-free labeling rule for packaged foods. The menu labeling campaign made it possible for the FDCA to allow the FDA to regulate restaurant menus. [342] The voluntary gluten-free labeling rule proved that people read such labels, that there is a large, profitable market for allergen-free products,[343] and that allergen labeling can be standardized to a certain

335. FOOD ALLERGY RSCH. & EDUC., *supra* note 1.
336. *Food Allergies*, *supra* note 12.
337. *See* FALCPA § 203.
338. *See, e.g.*, *MDPH Q&A*, *supra* note 96.
339. Saad, *supra* note 225.
340. *See* discussion *supra* Part III.E.
341. *See* Endres et al., *supra* note 9, at 210 (explaining that accommodating diners with food allergies can increase patronage of a restaurant by five to fifteen percent).
342. *Menu Labeling Campaign Timeline*, *supra* note 128.
343. *See* Wunsch, *supra* note 231.

threshold of containing a given allergen.[344] Before the momentum disappears, restaurant allergen disclosures should be implemented to build on these recent laws to improve the quality of life of the millions of Americans suffering from allergies.

APPENDIX. EXAMPLE OF MENU LABELING

Sample Menu

Starters

All starters are free from fish, shellfish, tree nuts, and peanuts.

[Starter Item Name 1]
[Item description]
Free from gluten, dairy

[Starter Item Name 2]
[Item description]
Free from egg, sesame, soy

Main Course

[Main Course Item Name 1]
[Item description]
Free from gluten, fish, shellfish, egg

[Main Course Item Name 2]
[Item description]
Free from tree nuts, sesame, soy, peanuts, dairy

344. *See* 21 C.F.R. § 101.91 (2021).