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Serving Up Allergy Labeling: Mitigating Food Allergen Risks in Restaurants

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MARIE BOYD*

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Allergens in restaurant food cause many allergic reactions and deaths. Yet no federal, state, or local law adequately protects people from these harms. Although federal law requires the labeling of “major food allergens” in packaged food, there are no allergen labeling requirements for restaurant-type food. In addition, existing food safety requirements for restaurants are inadequate to prevent allergen cross contact.

The existing legal scholarship on food allergens in restaurants is limited. Much of the legal scholarship on labeling in restaurants focuses on menu labeling—the provision of calorie and other nutrition information to combat obesity. The requirements of Section 4205 of the Patient Protection and Affordable Care Act exemplify this type of labeling. Although the literature describes the problem of food

allergens in restaurants, it has not fully explored potential regulatory solutions. This Article explores how, as a first step, menu labeling regulation can inform the development of food allergen regulation to reduce the risks that allergens pose in restaurants and similar retail establishments. It also discusses how menu labeling can help anticipate and respond to potential opposition and challenges to allergen requirements.

Using menu labeling as a guide, this Article argues that certain chain restaurants and similar retail establishments should be required to furnish “major food allergen” labeling upon consumer request in order to advance public health. Labeling changes alone, however, are insufficient to protect people with food allergies. Restaurants should also be required to employ science-based practices to prevent allergen cross contact and ensure their workers are trained on food allergen management. Although state and local governments may play an important role addressing food allergen management in restaurants and advancing public health, ultimately federal action is needed.

INTRODUCTION

Exposure to a food allergen can be deadly.¹ For the estimated nearly 5% of adults and 8% of children with food allergies, eating out may entail significant risk.² One study found that “[n]early half of reported fatal food allergy reactions over a 13-year period were caused by food from a restaurant or other food establishment.”³ In another study, nearly 14% of people in a registry of people with peanut and tree nut allergies reported that an allergic reaction had occurred in a restaurant or other food establishment.⁴ A follow-up study found that in most of the cases examined, someone in the establishment knew that

¹ Joshua A. Boyce et al., *Guidelines for the Diagnosis and Management of Food Allergy in the United States: Summary of the NIAID-Sponsored Expert Panel Report*, 31 NUTRITION RES. 61, 63 (2011).

² Scott H. Sicherer & Hugh A. Sampson, *Food Allergy: Epidemiology, Pathogenesis, Diagnosis, and Treatment*, 133 J. ALLERGY & CLINICAL IMMUNOLOGY 291, 291 (2014); see also *infra* Section I.A (discussing prevalence of food allergies and the variations in and limitations of existing data).

³ Taylor J. Radke et al., *Restaurant Food Allergy Practices—Six Selected Sites, United States, 2014*, 66 MORBIDITY & MORTALITY WKLY. REP. 404, 404 (2017); see also Christopher Weiss & Anne Muñoz-Furlong, *Fatal Food Allergy Reactions in Restaurants and Food-Service Establishments: Strategies for Prevention*, 28 FOOD PROTECTION TRENDS 657, 658 (2008).

⁴ See Terence J. Furlong et al., *Peanut and Tree Nut Allergic Reactions in Restaurants and Other Food Establishments*, 108 J. ALLERGY & CLINICAL IMMUNOLOGY 867, 867 (2001).

the food causing the reaction contained peanut or tree nut and that in the remaining cases contamination was reported.⁵ In half of the cases where someone in the establishment knew that the food contained peanut or tree nut, the allergen was “hidden,” preventing its visual identification.⁶ These harms are avoidable. Yet many restaurants lack a comprehensive allergen management system.

There are no federal labeling requirements for common allergens in restaurant-type food.⁷ Federal guidance on preventing allergen cross contact is inadequate.⁸ And even recently enacted state laws intended to make restaurant-type food safer for people with food allergies fall short. They are generally focused on increasing allergen awareness and training for certain restaurant workers rather than requiring more comprehensive plans and procedures to provide information about the presence of common food allergens and prevent cross contact.⁹

Much of the legal scholarship on labeling in restaurants is focused not on the provision of food allergen information but on the provision of calorie and other nutrition information to consumers as a means to address public health concerns related to obesity.¹⁰ The calorie and nutritional labeling provisions are commonly referred to as “menu labeling” because the information is provided on menus and menu boards.¹¹ Although the existing literature has described the problems

⁵ *Id.* at 868.

⁶ *Id.*

⁷ *See infra* Section I.B.

⁸ *See infra* Section I.C.1. Cross contact is when “a residue or other trace amount of an allergenic food is unintentionally incorporated into another food.” *Food Allergies: Reducing the Risks*, FDA: CONSUMER UPDATES, <https://www.fda.gov/forconsumers/consumerupdates/ucm089307.htm> (last updated Dec. 18, 2017); *see also Avoiding Cross Contact*, FOOD ALLERGY RES. & EDUC., <https://www.foodallergy.org/life-with-food-allergies/living-well-everyday/avoiding-cross-contact> (last visited Aug. 11, 2018) (noting that cross contact is “not universally used in the food service industry” and that “[t]he commonly used term is cross-contamination”).

⁹ *See infra* Section I.C.2. As this Article was going to press, the Township of Edison, New Jersey approved an ordinance that provides that as of April 1, 2019, restaurants “must identify on a menu all food items that contain or are prepared with” any of the following: “milk, eggs, peanuts, tree nuts, fish, shellfish, soy and wheat,” or “monosodium glutamate (‘MSG’) and commercial sulfites used as a food preservative or additive.” Edison Township, N.J., Ordinance O.2015-2018 (Aug. 22, 2018). The ordinance also provides that by that same date restaurants “must indicate on their public display menu sign . . . that such menus are available.” *Id.* Of note, the ordinance does not address the prevention of cross contact. *Id.*

¹⁰ *See* Laura E. Derr, *When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004*, 61 *FOOD & DRUG L. J.* 65, 156–57 (2006).

¹¹ Menu labeling generally refers to requirements that certain restaurants provide calorie and other nutrition information to consumers on menus, menu boards, or other labeling. *See*,

posed by the lack of food allergen labeling and management requirements, it has not thoroughly explored possible solutions. This Article explores how menu labeling can and should inform the regulation of allergen labeling and management in restaurants. This examination is timely as the final compliance date for the Food and Drug Administration's (FDA) menu labeling rule was May 7, 2018.¹²

This Article approaches the issue of food allergens in restaurants and similar retail establishments from a public health law perspective.¹³ It considers how law can help to reduce allergic reactions triggered by food allergens in restaurants, while respecting the autonomy of individuals with food allergies. Using lessons drawn from menu labeling, this Article argues that certain chain restaurants that sell standardized menu items should be required to make labeling for "major food allergens" in restaurant-type foods available to consumers upon request.¹⁴

e.g., Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,160 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101).

¹² See Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments, 82 Fed. Reg. 20,825, 20,825 (May 4, 2017).

¹³ Public health law considers "the legal powers and duties of the state, in collaboration with its partners . . . to ensure the conditions for people to be healthy and . . . the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals." PUBLIC HEALTH LAW AND ETHICS: A READER 9 (Lawrence O. Gostin ed., 2d ed. 2010).

¹⁴ These allergens are milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans. Federal Food, Drug, and Cosmetic Act (FDCA) § 201(q), 21 U.S.C. § 321(q) (2012). These eight allergens or groups of allergens account for 90% of food allergies in the United States. FDCA § 403 note, 21 U.S.C. § 343 note. This Article does not address the management of food allergens in schools, prisons, and airplanes due to the unique considerations that they pose. Schools, prisons, and airplanes are also not covered by FDA's interpretation of the menu labeling provisions of the Patient Protection and Affordable Care Act (ACA). See Food Labeling, 79 Fed. Reg. at 71,169, 71,171; FDA, GUIDANCE FOR INDUSTRY: A LABELING GUIDE FOR RESTAURANTS AND RETAIL ESTABLISHMENTS SELLING AWAY-FROM-HOME FOODS – PART II (MENU LABELING REQUIREMENTS IN ACCORDANCE WITH 21 CFR 101.11) (Apr. 2016), <https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm461963.pdf>; see also Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, § 4205, 124 Stat. 119 (2010) (codified at FDCA §§ 403, 403A, 21 U.S.C. §§ 343, 343-1). For a discussion of food allergen management in airplanes and schools see, e.g., John G. Browning, *Keep Your Hands Off My Nuts—Airlines, Peanut Allergies, and the Law*, 77 J. AIR L. & COM. 3, 4 (2012); Michael Borella, *Food Allergies in Public Schools: Toward a Model Code*, 85 CHI.-KENT L. REV. 761 (2010); Heather Martone, *2.2 Million Children Left Behind: Food Allergies in American Schools—A Study of the Food Allergy and Anaphylaxis Management Act*, 18 J.L. & POL'Y 775, 776 (2010). See also 21 U.S.C. § 2205 (Supp. IV 2016); CTRS.

Labeling changes alone, however, are not enough because without other changes, labeling may increase the risks for consumers with food allergies. For example, if food is mislabeled or has an allergen due to cross contact, a person with a food allergy may consume the food thinking that it is safe and have an allergic reaction. Although a full examination of measures to prevent allergen cross contact, train restaurant workers, and educate the public about food allergies is beyond the scope of this Article, such measures are also needed to help prevent allergic reactions triggered by restaurant foods. This Article recognizes that preventing food allergen cross contact and ensuring accurate labeling in restaurants will likely raise difficult and complex questions. Existing processes should be used to begin to address these questions.

This Article also draws from the literature on the regulation of menu labeling to explore how federal, state, and local governments might require food allergen labeling and management. As in the menu labeling context, the enactment of comprehensive food allergen requirements at the local and state levels may serve as the catalyst for federal reform. Ultimately, this Article argues that changes to federal law are needed to address the labeling and management of food allergens in restaurant-type food.

This Article proceeds in several parts: Part I provides an introduction to food allergies and the risks that food allergens in restaurants may pose to consumers who have allergies. It then describes the federal allergen labeling requirements for prepackaged food and the corresponding gap in the regulation of allergen labeling for restaurant-type food. It also discusses other laws bearing on food allergens in restaurants and their limitations. Part II provides an overview of efforts to regulate menu labeling, including New York City's menu labeling rules, Section 4205 of the Patient Protection and Affordable Care Act, and FDA's menu labeling regulations.¹⁵ Part III draws on this examination to argue for allergen labeling requirements for restaurants and accompanying management requirements, and to address counterarguments, including that food allergen requirements would be too difficult or costly for restaurants. Part IV then draws on the earlier examination of menu labeling to explore how federal, state, and local

FOR DISEASE CONTROL & PREVENTION, VOLUNTARY GUIDELINES FOR MANAGING FOOD ALLERGIES IN SCHOOLS AND EARLY CARE AND EDUCATION PROGRAMS (2013).

¹⁵ FDCA §§ 403, 403A, 21 U.S.C. §§ 343, 343-1 (codifying portions of section 4205 of the ACA); Food Labeling, 79 Fed. Reg. at 71,156; N.Y.C., N.Y., HEALTH CODE § 81.50 (2006), *invalidated by* New York State Rest. Ass'n v. N.Y.C. Bd. of Health, 509 F. Supp. 2d 351, 352 (S.D.N.Y. 2007); N.Y.C., N.Y., HEALTH CODE § 81.50 (2008).

governments could enact these changes and the potential benefits of federal action.

I

RESTAURANTS, FOOD ALLERGIES, AND THE LIMITATIONS OF EXISTING LAW

A. Food Allergies and Restaurants

A food allergy is an adverse immune response to food.¹⁶ Food allergy management necessarily depends heavily on avoidance of the allergen.¹⁷ Food allergens are the “specific components of food or ingredients within food . . . that are recognized by allergen-specific immune cells and elicit specific immunologic reactions, resulting in characteristic symptoms.”¹⁸ In 2011, an expert panel sponsored by the National Institute of Allergy and Infectious Diseases concluded that there are “no medications . . . recommended . . . to prevent . . . food-induced allergic reactions from occurring in an individual with [an] existing [food allergy].”¹⁹ Accordingly, the first line of treatment is allergen avoidance.²⁰ For allergic individuals, failure to avoid food allergens can result in a reaction, including anaphylaxis, “a serious allergic reaction that is rapid in onset and may cause death.”²¹

Determining the prevalence of food allergies in the United States is difficult and estimates vary.²² A 2010 review and analysis of the available evidence regarding the prevalence of allergies found that they “affect more than 1% or 2% but less than 10% of the US population.”²³

¹⁶ Boyce et al., *supra* note 1, at 64 (defining food allergy as “an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food”). Food allergies are distinct from food intolerances. *Id.* at 65.

¹⁷ *Id.* at 69–73 (treatment guidelines); A. Wesley Burks et al., *ICON: Food Allergy*, 129 *J. ALLERGY & CLINICAL IMMUNOLOGY* 906, 915 (2012).

¹⁸ Boyce et al., *supra* note 1, at 64.

¹⁹ *Id.* at 69 (emphasis omitted).

²⁰ *Id.*

²¹ *Id.* at 66 tbl.1 (noting various symptoms of food-induced allergic reactions).

²² See, e.g., NAT’L ACADS. SCIS., ENG’G, & MED., *FINDING A PATH TO SAFETY IN FOOD ALLERGY: ASSESSMENT OF THE GLOBAL BURDEN, CAUSES, PREVENTION, MANAGEMENT, AND PUBLIC POLICY* (Virginia A. Stallings & Maria P. Oria eds. 2017); see also Scott H. Sicherer, *Epidemiology of Food Allergy*, 127 *J. ALLERGY & CLINICAL IMMUNOLOGY* 594, 594, 597–98 (2011) (discussing study limitations).

²³ Jennifer J. Schneider Chafen et al., *Diagnosing and Managing Common Food Allergies: A Systematic Review*, 303 *JAMA* 1848, 1849, 1853 (2010) (focusing on allergies to “cow’s milk, hen’s egg, peanut, tree nut, fish, and shellfish”); see also KRISTEN D. JACKSON ET AL., NCHS DATA BRIEF NO. 121, *TRENDS IN ALLERGIC CONDITIONS AMONG*

More recent estimates indicate that food allergies likely affect almost 5% of adults and 8% of children,²⁴ although one recent study estimated the prevalence of food allergies and intolerances to be about 4%.²⁵ The prevalence of food allergies is thought to be increasing.²⁶ Despite the fact that “more than 170 foods have been identified as being potentially allergenic,”²⁷ only a few foods account for the majority of food allergic reactions.²⁸

Unanticipated exposure to food allergens is not uncommon. Each year there are approximately 203,000 emergency room visits for food-related acute allergic reactions in the United States, which translates to one visit every three minutes.²⁹ Anaphylaxis to food leads to an estimated 30,000 emergency room visits and an estimated 150 deaths each year in the United States.³⁰ Most anaphylactic reactions take place outside of the home, with 25% taking place while dining at restaurants.³¹ Even when allergic individuals are actively avoiding the allergen, allergic reactions can occur.³² A number of fatal reactions have occurred at restaurants or in association with restaurant food.³³

CHILDREN: UNITED STATES, 1997–2011 (2013) (reporting on trends in food allergy prevalence for children).

²⁴ Sicherer & Sampson, *supra* note 2, at 292.

²⁵ Warren W. Acker et al., *Prevalence of Food Allergies and Intolerances Documented in Electronic Health Records*, 140 J. ALLERGY & CLINICAL IMMUNOLOGY 1587, 1589 (2017) (estimating the prevalence of food allergies and intolerances to be 3.6%).

²⁶ See JACKSON ET AL., *supra* note 23; Sicherer & Sampson, *supra* note 2, at 292. In addition, new foods may pose allergy risks. Diane Thue-Vasquez, *Genetic Engineering and Food Labeling: A Continuing Controversy*, 10 SAN JOAQUIN AGRIC. L. REV. 77, 93 (2000).

²⁷ Burks et al., *supra* note 17, at 906.

²⁸ *Id.* at 906–07; Hugh A. Sampson, *Update on Food Allergy*, 113 J. ALLERGY & CLINICAL IMMUNOLOGY 805, 807 (2004) (stating that “[m]ilk, egg, and peanut account for the vast majority of food-induced allergic reactions in American children” and “peanut, tree nuts, fish, and shellfish account for most of the food-induced allergic reactions in American adults”).

²⁹ Sunday Clark et al., Letter to the Editor, *Frequency of US Emergency Department Visits for Food-Related Acute Allergic Reactions*, 127 J. ALLERGY & CLINICAL IMMUNOLOGY 682, 682 (2011); *Facts and Statistics*, FOOD ALLERGY RES. & EDUC., <https://www.foodallergy.org/life-food-allergies/food-allergy-101/facts-and-statistics> (last visited Feb. 13, 2018). Anaphylaxis is an acute allergic reaction. *Id.*

³⁰ FDA, FOOD FACTS, FOOD ALLERGIES: WHAT YOU NEED TO KNOW (2017). And anaphylaxis may be underreported. See F. Estelle R. Simons, *Anaphylaxis*, 125 J. ALLERGY & CLINICAL IMMUNOLOGY S161, S161 (2010).

³¹ J. Leftwich et al., *The Challenges for Nut-Allergic Consumers of Eating Out*, 41 CLINICAL & EXPERIMENTAL ALLERGY 243, 247 (2010).

³² Furlong et al., *supra* note 4, at 868.

³³ See Weiss & Muñoz-Furlong, *supra* note 3, at 658–59; see also Roxanne Dupuis et al., *Food Allergy Management Among Restaurant Workers in a Large U.S. City*, 63 FOOD CONTROL 147 (2016); Furlong et al., *supra* note 4, at 869; Hugh A. Sampson, *Peanut Allergy*, 346 NEW ENG. J. MED. 1294 (2002); S. Allan Bock et al., Letter to the Editor,

At the same time, Americans are increasingly turning to restaurants and other retail food establishments for food away from home,³⁴ and the growth in demand for food away from home is expected to continue over the remainder of the decade.³⁵ From 1960 to 2000, “spending on away-from-home foods as a percentage of total food expenditure . . . steadily [rose] by approximately 5–6% per decade.”³⁶ More Americans ate out in 1999–2000 than in 1987, and they did so with a greater frequency.³⁷ In 2002, the National Restaurant Association (NRA) reported that Americans over the age of seven, on average, eat 218 restaurant meals a year.³⁸ Another report found that on average those aged 16–34 eat out 3.8 times a week, compared to 2.8 times a week for those aged 35–74.³⁹ The share of caloric intake from food prepared away from home has also increased.⁴⁰ And in 2014, for the first time on record, the monthly sales at restaurants surpassed those at

Further Fatalities Caused by Anaphylactic Reactions to Food, 2001–2006, 119 J. ALLERGY & CLINICAL IMMUNOLOGY 1016 (2007).

³⁴ HAYDEN STEWART ET AL., U.S. DEP’T OF AGRIC., AGRIC. ECON. REP. NO. 829, THE DEMAND FOR FOOD AWAY FROM HOME: FULL-SERVICE OR FAST FOOD? (2004) [hereinafter STEWART ET AL., FOOD AWAY FROM HOME]; HAYDEN STEWART ET AL., U.S. DEP’T OF AGRIC., ECON. INFO. BULL. NO. 19, LET’S EAT OUT: AMERICANS WEIGH TASTE, CONVENIENCE, AND NUTRITION (2006) [hereinafter STEWART ET AL., LET’S EAT OUT].

³⁵ STEWART ET AL., FOOD AWAY FROM HOME, *supra* note 34, at 2.

³⁶ Ashima K. Kant & Barry I. Graubard, *Eating Out In America, 1987–2000: Trends and Nutritional Correlates*, 38 PREVENTIVE MED. 243, 243 (2004). *But see Table 10—Food Away from Home as a Share of Food Expenditures*, U.S. DEP’T OF AGRIC. ECON. RES. SERV.: FOOD EXPENDITURES (Jan. 26, 2016), <https://www.ers.usda.gov/data-products/food-expenditure-series/food-expenditure-series/#Food> [https://web.archive.org/web/20170223202214/https://www.ers.usda.gov/webdocs/DataFiles/Food_Expenditures__17981/FoodExpenditures_table10.xls] (showing that overall, from 1929 to 2014, food away from home as a share of food expenditures increased, but there were years that it decreased); BIING-HWAN LIN & JOANNE GUTHRIE, U.S. DEP’T OF AGRIC., ECON. INFO. BULL. NO. 105, NUTRITIONAL QUALITY OF FOOD PREPARED AT HOME AND AWAY FROM HOME, 1977–2008 (2012) (noting a decline from 2006–2007 to 2010). Although away from home food estimates include schools, as noted earlier, this Article does not address allergen labeling and management in schools. *See supra* note 14.

³⁷ Kant & Graubard, *supra* note 36, at 247.

³⁸ *See* CTR. FOR SCI. IN THE PUB. INTEREST, ANYONE’S GUESS: THE NEED FOR NUTRITION LABELING AT FAST-FOOD AND OTHER CHAIN RESTAURANTS (2003).

³⁹ CHRISTINE BARTON ET AL., BOS. CONSULTING GRP., MILLENNIALS PASSIONS: FOOD, FASHION, AND FRIENDS (2012).

⁴⁰ LIN & GUTHRIE, *supra* note 36, at iii. Changes in survey methodology may have contributed to the reported increase. *Id.* at 3–4; *see also* Ji Hee Choi & Lakshman Rajagopal, *Food Allergy Knowledge, Attitudes, Practices, and Training of Foodservice Workers at a University Foodservice Operation in the Midwestern United States*, 31 FOOD CONTROL 474, 474 (2013) (discussing the foodservice industry in the United States).

grocery stores.⁴¹

Although restaurants obviously provide food, they “are about more than what you get on the plate.”⁴² Among other things, they can provide leisure and social enjoyment,⁴³ serve as loci for the conduct of business,⁴⁴ and help facilitate travel.⁴⁵ Indeed, the broader significance of restaurants in the United States is reflected in the centrality of restaurant accessibility to the civil and disability rights movements.⁴⁶

⁴¹ *Restaurant Sales Surpass Grocery Store Sales*, NAT’L RESTAURANT ASS’N: NEWS & RES. (May 13, 2015), <https://www.restaurant.org/News-Research/News/Restaurant-sales-surpass-grocery-store-sales-for-t> [<https://web.archive.org/web/20150515012802/https://www.restaurant.org/News-Research/News/Restaurant-sales-surpass-grocery-store-sales-for-t>].

⁴² *Four Critics, One Restaurant’s Food, Sound, Design, Fashion*, WASH. POST: MAG. (Mar. 27, 2014), https://www.washingtonpost.com/lifestyle/magazine/four-critics-one-restaurants-food-sound-design-fashion/2014/03/27/292d6732-9a6d-11e3-b931-0204122c514b_story.html?noredirect=on&utm_term=.4547fae86f1c; Inga-Britt Gustafsson, *Culinary Arts and Meal Science—A New Scientific Research Discipline*, 4 FOOD SERV. TECH. 9 (2004); see also NAT’L REST. ASS’N, 2017 RESTAURANT INDUSTRY POCKET FACTBOOK (2017) [hereinafter 2017 FACTBOOK].

⁴³ See, e.g., 2017 FACTBOOK, *supra* note 42; see also ALAN WARDE & LYDIA MARTENS, *EATING OUT: SOCIAL DIFFERENTIATION, CONSUMPTION AND PLEASURE* 18 (2000). For example, one sociological study of food consumption outside the home in England in the 1990s, found that diners claim a “great sense of pleasure and satisfaction . . . from eating out” and that “[e]ating out is a major . . . conduit for sociable interaction.” WARDE & MARTENS, *supra*, at 215–27.

⁴⁴ See, e.g., Anna Nicholson Bass, *From Business Dining to Public Speaking: Tips for Acquiring Professional Presence and Its Role in the Business Curricula*, 3 AM. J. BUS. EDUC. 57, 60–61 (2010) (discussing dining etiquette and noting that “[y]our manners at business meals can affect your success in being hired and promoted and in conducting business with clients”); Wendy Gerzog Shaller, *Reforming the Business Meal Deduction: Matching Statutory Limitations with General Tax Policy*, 24 DUQ. L. REV. 1129 (1986). For example, one survey found that “49 percent of chief financial officers said their most successful business meetings, outside the office, were conducted at a restaurant.” JACQUELINE WHITMORE, *BUSINESS CLASS: ETIQUETTE ESSENTIALS FOR SUCCESS AT WORK* 81 (2005) (referencing a survey).

⁴⁵ See, e.g., *Katzenbach v. McClung*, 379 U.S. 294, 304 (1964) (holding that Congress “had a rational basis for finding that racial discrimination in restaurants had a direct and adverse effect on the free flow of interstate commerce”). In *Katzenbach*, the Supreme Court noted that during the Congressional Hearings on the Civil Rights Act,

there was an impressive array of testimony that discrimination in restaurants had a direct and highly restrictive effect upon interstate travel by Negroes. This resulted, it was said, because discriminatory practices prevent Negroes from buying prepared food served on the premises while on a trip, except in isolated and unkempt restaurants and under most unsatisfactory and often unpleasant conditions. This obviously discourages travel and obstructs interstate commerce for one can hardly travel without eating.

Id. at 300.

⁴⁶ See, e.g., *id.* at 294; Press Release, U.S. Dep’t of Justice, U.S. Attorney’s Office, E. Dist. of Pa., U.S. Attorney Launches Review of 25 Restaurants for Compliance with Americans with Disabilities Act (Mar. 11, 2015), <https://www.justice.gov/usao-edpa/pr/us-attorney-launches-review-25-restaurants-compliance-americans-disabilities-act>; HARRIS

Both the Civil Rights Act of 1964 and the Americans with Disabilities Act contain provisions regarding restaurants.⁴⁷ As one civil rights activist remarked in 1960, the “sit-ins and other demonstrations are concerned with something much bigger than a hamburger or even a giant-sized Coke.”⁴⁸ Access to restaurants is a part of full first-class citizenship,⁴⁹ and restaurants are an important component of culture in the United States.⁵⁰

But the act of eating out, which many may take for granted, may pose significant risks for individuals with a food allergy, and they may seek to avoid these risks by not eating out or only eating at certain restaurants.⁵¹ This is consistent with research suggesting that “food allergic patients may . . . perceive that they . . . are more physically restricted (for example, in terms of travel, occupational opportunities, or attending social events) compared to non-food allergic people.”⁵² Several studies suggest that food allergies can negatively affect quality

INTERACTIVE, THE ADA, 20 YEARS LATER, KESSLER FOUNDATION/NOD SURVEY OF AMERICANS WITH DISABILITIES 8, 31 (2010), <http://www.2010disabilitysurveys.org/pdfs/surveyresults.pdf> [https://web.archive.org/web/20101105124512/http://www.2010disabilitysurveys.org/pdfs/surveyresults.pdf] (reporting results of survey of Americans with disabilities and identifying “going to restaurants” as one of “13 very important indicators of the quality of life and standard of living of Americans with disabilities”); MILES WOLFF, LUNCH AT THE FIVE AND TEN: THE GREENSBORO SIT-INS: A CONTEMPORARY HISTORY 64–65 (1970); 134 CONG. REC. S5107 (daily ed. Apr. 28, 1988) (statement of Sen. Lowell Weicker).

⁴⁷ See 42 U.S.C. § 2000a(a) (2012) (Title II); 42 U.S.C. § 12182 (2012). For a discussion of food allergy as a potential disability under the Americans with Disabilities Act, see Section I.C.4.

⁴⁸ LET NOBODY TURN US AROUND: VOICES OF RESISTANCE, REFORM, AND RENEWAL 393 (Manning Marable & Leith Mullings eds., 2d ed. 2009) (quoting Ella Baker, *Bigger than a Hamburger*, S. PATRIOT, June 1960, at 18).

⁴⁹ *Id.*

⁵⁰ See THE RESTAURANTS BOOK: ETHNOGRAPHIES OF WHERE WE EAT (David Beriss & David Sutton eds., 2007).

⁵¹ Furlong et al., *supra* note 4, at 868–69 (reporting that 19% of families that reported a reaction in a restaurant or other food establishment indicated “that they would reduce their frequency of eating out” and that, after reactions in restaurants, “families altered their approach to restaurants and other food establishments”); Natalie J. Avery et al., *Assessment of Quality of Life in Children with Peanut Allergy*, 14 PEDIATRIC ALLERGY & IMMUNOLOGY 378, 380 (2003) (stating that “[u]nexpectedly, 60% of [Peanut Allergy (PA)] subjects made mostly positive comments about restaurants,” although “[t]he majority did clarify . . . that they always go to the same restaurant because they cater for people with PA”); see also Ryan Ahuja & Scott H. Sicherer, *Food-Allergy Management from the Perspective of Restaurant and Food Establishment Personnel*, 98 ANNALS ALLERGY, ASTHMA & IMMUNOLOGY 344, 346 (2007).

⁵² Jantine Voordouw et al., *Subjective Welfare, Well-Being, and Self-Reported Food Hypersensitivity in Four European Countries: Implications for European Policy*, 107 SOC. INDICATORS RES. 465, 467 (2012).

of life.⁵³ One parent of a child with a food allergy described “every potential outing/trip/travel [as] a puzzle as to how to make it somewhat safe and find out what and where to eat.”⁵⁴ Food allergies can affect the quality of life of those with food allergies as well as their families and caregivers due to “[t]he constant threat of exposure, need for vigilance and expectation of outcome.”⁵⁵

The significant gaps in some food service workers’ training, knowledge of food allergies, and proper food allergen management,⁵⁶ may increase the risk eating out poses to individuals with food allergies. For example, one study of food allergy practices in six cities found that only 44.4% of surveyed managers, 40.8% of food workers, and 33.3% of servers “reported receiving food allergy training while working at their respective restaurants.”⁵⁷ Another survey of food service workers in limited-service Philadelphia restaurants found that there were “fundamental knowledge gaps regarding how to reduce the risk of and respond to food allergy adverse events.”⁵⁸ That survey found that “no single respondent could identify all seven steps necessary for safe food preparation” that the researchers gleaned from the ServSafe Allergens online course and Food Allergy Research & Education materials.⁵⁹ Furthermore, the survey found “that the majority of participating food service workers could identify . . . zero

⁵³ See, e.g., Darío Antolín-Amérigo et al., *Quality of Life in Patients with Food Allergy*, 14 CLINICAL & MOLECULAR ALLERGY 1 (2016); Voordouw et al., *supra* note 52.

⁵⁴ Derr, *supra* note 10, at 75.

⁵⁵ See Antolín-Amérigo et al., *supra* note 53, at 2; see also Voordouw et al., *supra* note 52; B.M.J. de Blok et al., *A Framework for Measuring the Social Impact of Food Allergy Across Europe: A EuroPrevall State of the Art Paper*, 62 ALLERGY 733 (2007).

⁵⁶ See, e.g., Dupuis et al., *supra* note 33; Ahuja & Sicherer, *supra* note 51. The failures may not solely be a result of restaurants, however, as consumers with food allergens may take risks. See, e.g., Matthew J. Greenhawt et al., *Food Allergy and Food Allergy Attitudes Among College Students*, 124 J. ALLERGY & CLINICAL IMMUNOLOGY 323 (2009); Margaret A. Sampson et al., *Risk-Taking and Coping Strategies of Adolescents and Young Adults with Food Allergy*, 117 J. ALLERGY & CLINICAL IMMUNOLOGY 1440 (2006). Of course, some restaurants may do better in accommodating guests with food allergies. See, e.g., Paul Antico, *2018 Top 10 Most Allergy-Friendly Restaurant Chains*, ALLERGY EATS (Mar. 7, 2018), <https://www.allergyeats.com/2018-top-10-most-allergy-friendly-restaurant-chains/>.

⁵⁷ Radke et al., *supra* note 3, at 404.

⁵⁸ Dupuis et al., *supra* note 33, at 152.

⁵⁹ *Id.* at 152–53. The ServSafe Allergens Course is an allergen training course from the National Restaurant Association Educational Foundation. Nat’l Rest. Ass’n Educ. Found., *ServSafe Allergens*, SERVS SAFE, <https://www.servsafe.com/ServSafe-Allergens> (last visited Feb. 13, 2018). Food Allergy Research & Education (FARE) is an organization that works on behalf of people with food allergies. *History of Fare*, FOOD ALLERGY RES. & EDUC., <https://www.foodallergy.org/about-fare/history> (last visited Feb. 13, 2018).

or one of those seven necessary steps.”⁶⁰ Despite this, respondents expressed “confidence” and an “inflated sense of their own self-efficacy for safe food allergy management.”⁶¹ Similarly, a survey of restaurant and food establishment personnel in New York City and Long Island found that the respondents’ “comfort level in managing food allergy exceeded [their] knowledge base” and that “there was no correlation of knowledge about [managing food allergy] with comfort level in meal provision” for allergic consumers.⁶² This overconfidence is troubling because, in addition to potentially putting customers with food allergies at risk, it may prevent food service workers from taking steps to improve their management of food allergens absent regulation and oversight.⁶³

B. The Gap in Federal Law

Federal food labeling law does not address the problem of food allergens in nonpackaged food, such as food often served at restaurants and similar food establishments.⁶⁴ Instead, it focuses on labeling

⁶⁰ Dupuis et al., *supra* note 33, at 153.

⁶¹ *Id.*

⁶² Ahuja & Sicherer, *supra* note 51, at 345.

⁶³ See, e.g., Anthony T. Robinson & Louis D. Marino, *Overconfidence and Risk Perceptions: Do They Really Matter for Venture Creation Decisions?*, 11 INT’L ENTREPRENEURSHIP MGMT. J. 149, 162 (2015) (discussing overconfidence in the context of venture creation decisions and finding that “the more overconfident tend to perceive fewer risks”).

⁶⁴ See Federal Food, Drug, and Cosmetic Act (FDCA) § 403(w), 21 U.S.C. § 343(w) (2012); *Food Allergen Labeling and Consumer Protection Act of 2004 Questions and Answers*, FDA (July 18, 2006), <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106890.htm> [hereinafter *FDA Questions and Answers*]. A number of commentators have noted this gap. See, e.g., Derr, *supra* note 10, at 92 (“No mandatory system comparable to packaged food labeling exists for the disclosure of food ingredients to food establishment patrons.”); Neal D. Fortin, *The Food Allergen Labeling and Consumer Protection Act: The Requirements Enacted, Challenges Presented, and Strategies Fathomed*, 10 MICH. ST. U. J. MED. & L. 125, 135 (2006) (“Although not strictly speaking an exemption, the Food Allergen Act only applies to food labeled under the authority of the [FDCA]. Thus, products not regulated under the [FDCA], such as meat and poultry, and foods not requiring labeling are also free from the Food Allergen Act’s requirements. An important example of the latter is restaurant food, which generally does not require labeling.”); Jonathan B. Roses, *Food Allergen Law and the Food Allergen Labeling and Consumer Protection Act of 2004: Falling Short of True Protection for Food Allergy Sufferers*, 66 FOOD & DRUG L.J. 225, 225 (2011) (“FALCPA also falls short because it only regulates packaged food, and fails to regulate allergen labeling in restaurants.”); Sydney Knell Leavitt, *Death by Chicken: The Changing Face of Allergy Awareness in Restaurants and What to Do When Food Bites Back*, 42 U. TOL. L. REV. 963, 965 (2011) (“Historically, restaurants have not been required to disclose either the ingredients of the food they serve or the presence of allergens.”); Gideon Martin,

certain food allergens in packaged foods.⁶⁵

The Food Allergen Labeling and Consumer Protection Act (FALCPA) requires food that is or contains a “major food allergen” to have the required food allergen information on the label.⁶⁶ FALCPA covers eight “major food allergens”—milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans—as well as food ingredients that contain a protein derived from one of the specified foods.⁶⁷ As noted earlier, these eight allergens or groups of allergens account for 90% of food allergies in the United States.⁶⁸ The required allergen information can be provided in one of two ways: The label may have “the word ‘Contains’, followed by the name of the food source from which the major food allergen is derived . . . printed immediately after or . . . adjacent to the list of ingredients.”⁶⁹ Alternatively, the label may have “the name of the food source from which the major food allergen is derived” in parentheses following “the common or usual name of the major food allergen in the list of the

Comment, *Allergic to Equality: The Legislative Path to Safer Restaurants*, 13 APPALACHIAN J.L. 79, 84 (2013) (“[F]ederal law protects allergy sufferers only when it comes to packaged foods.”).

⁶⁵ FDCA § 403(w), 21 U.S.C. § 343(w).

⁶⁶ Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, § 203, 118 Stat. 891 (2004) (codified in scattered sections of 21 U.S.C. (FDCA)). A “label” is “a display of written, printed, or graphic matter upon the immediate container of any article.” FDCA § 201(k), 21 U.S.C. § 321(k). “[L]abeling” is “all labels and other written, printed, or graphic matter (1) upon an article or any of its containers or wrappers, or (2) accompanying such article.” FDCA § 201(m), 21 U.S.C. § 321(m).

The information may appear on other labeling if the Secretary finds that it “is sufficient to protect the public health” and publishes a notice of that finding in the Federal Register. FDCA § 403(w)(3), 21 U.S.C. § 343(w)(3). FDA has stated that the “requirements apply to all packaged foods sold in the U.S. that are regulated under the [FDCA].” FDA, GUIDANCE FOR INDUSTRY: QUESTIONS AND ANSWERS REGARDING FOOD ALLERGENS, INCLUDING THE FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT OF 2004 (EDITION 4); FINAL GUIDANCE (Oct. 2006) [hereinafter FDA FINAL GUIDANCE], available at <https://www.fda.gov/Food/GuidanceRegulation/ucm059116.htm>. Raw agricultural commodities, “foods in [their] raw or natural state,” do not require allergen labeling. FDCA §§ 201(r), 403(w), 21 U.S.C. §§ 321(r), 343(w).

⁶⁷ FDCA §§ 201(qq), 403(w), 21 U.S.C. §§ 321(qq), 343(w). It excludes highly refined oils derived from one of the eight foods as well as ingredients derived from these highly refined oils. *Id.* In addition, it establishes procedures by which a food may be exempted from the allergen labeling requirements. *Id.* FALCPA also directed the Secretary of Health and Human services to issue a proposed rule within two years of its enactment, and then a final rule within four, “to define, and permit use of, the term ‘gluten-free’ on the labeling of foods.” FDCA § 403 note, 21 U.S.C. § 343 note.

⁶⁸ FDCA § 403 note, 21 U.S.C. § 343 note.

⁶⁹ FDCA § 403(w)(1), 21 U.S.C. § 343(w)(1).

ingredients.”⁷⁰ The “major food allergen” provisions are self-executing⁷¹ and apply to food labeled on or after January 1, 2006.⁷² A food that is not in compliance with FALCPA’s labeling requirements is deemed to be misbranded in violation of the Food, Drug, and Cosmetic Act (FDCA).⁷³ FALCPA also expressly preempts nonidentical state and local allergen labeling requirements.⁷⁴

FDA has indicated that FALCPA’s labeling requirements “do not apply to foods provided by a retail food establishment that are placed in a wrapper or container in response to a consumer’s order—such as the paper or box used to convey a sandwich that has been prepared in response to a consumer’s order.”⁷⁵ FALCPA, however, is not silent on allergy management issues in restaurants. It directs the Secretary of Health and Human Services to “pursue revision of the Food Code,” a model code “to provide guidelines for preparing allergen-free foods in food establishments, including in restaurants, grocery store delicatessens and bakeries.”⁷⁶

In addition, the 2011 Food Safety Modernization Act (FSMA) Hazard Analysis and Risk-Based Preventive Controls (HARPC) provisions for food facility operators created a framework for a “prevention-based food safety system” that explicitly addresses allergens as hazards.⁷⁷ With respect to food allergens, FSMA requires hazard analysis, preventive controls, monitoring, corrective actions, verification, record keeping, a written plan and documentation, and a

⁷⁰ *Id.* FALCPA does not require the name of the food source in parentheses in certain limited circumstances where the name of the food source from which the food allergen is derived appears elsewhere in the ingredient list. *Id.*

⁷¹ S. REP. NO. 108-226, at 3 (2004).

⁷² FALCPA was effective January 1, 2006. FDCA § 201 note, 21 U.S.C. § 321 note.

⁷³ See FDCA § 301, 21 U.S.C. § 331 (prohibiting misbranding or causing misbranding of food provided that certain interstate commerce connection requirements are met); FDCA § 403(w), 21 U.S.C. § 343(w).

⁷⁴ FDCA § 403A(a)(2), 21 U.S.C. § 343-1(a)(2); see also *infra* Section IV.B.3.a.

⁷⁵ FDA FINAL GUIDANCE, *supra* note 66. They do however apply to foods that are packaged, labeled, and offered as food for human consumption. FDA *Questions and Answers*, *supra* note 64. Simply extending FALCPA to restaurant-type food would leave many unanswered questions. Accordingly, this Article argues that menu labeling for restaurant-type food should be used to inform allergen labeling. See *infra* Parts III & IV.

⁷⁶ 42 U.S.C. § 243 note. The Act specified that the Secretary must “consider guidelines and recommendations developed by public and private entities for public and private food establishments” *Id.*

⁷⁷ Sarah Besnoff, Comment, *May Contain: Allergen Labeling Regulations*, 162 U. PA. L. REV. 1465, 1475 (2014); see also FDA Food Safety and Modernization Act (FSMA), Pub. L. No. 111-353, § 103, 124 Stat. 3885 (2011) (codified in scattered sections of 21 U.S.C. and 42 U.S.C.); FDCA § 418, 21 U.S.C. § 350g.

reanalysis of hazards.⁷⁸ Restaurants and other retail food establishments, however, are excluded from the definition of facility and thus these requirements.⁷⁹

C. Other Limitations of the Law

1. The Food Code

The Food Code, which is published by the Public Health Service and FDA, predates FALCPA, but since FALCPA was enacted, consistent with that Act,⁸⁰ the Food Code has been revised to address food allergen management.⁸¹ Despite these revisions, the Food Code continues to have several significant limitations when it comes to protecting people with food allergies.

Prior to FALCPA, the Food Code did not explicitly mention allergens in its text, although it discussed allergen management in explanations in its annexes.⁸² The 2005 Food Code, which was published the year after FALCPA, addresses food allergen management in more detail than previous versions of the code.⁸³ It refers to allergens in the text and discusses FALCPA's labeling requirements.⁸⁴ The 2005 code provides that the person in charge of a

⁷⁸ FDCA § 418, 21 U.S.C. § 350g. FDA has promulgated regulations implementing these allergen provisions and making "FDA's long-standing position that the CGMPs address allergen cross-contact . . . explicit in the regulatory text." 80 Fed. Reg. 55,908, 55,913 (Sep. 17, 2015) (codified at scattered sections of 21 C.F.R.); 21 C.F.R. § 117 (2017); *see also Frequently Asked Questions About Food Allergies*, FDA: ALLERGENS, <https://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAllergens/ucm530854.htm> (last visited Aug. 12, 2018).

⁷⁹ FDCA § 415(c)(1), 21 U.S.C. § 350d(c)(1).

⁸⁰ *See* 42 U.S.C. § 243 note.

⁸¹ *Compare* FOOD CODE (FDA 2005), FOOD CODE (FDA 2009), FOOD CODE (FDA 2013), *and* FOOD CODE (FDA 2017), *with* FOOD CODE (FDA 1993), FOOD CODE (FDA 1995), FOOD CODE (FDA 1997), FOOD CODE (FDA 1999), *and* FOOD CODE (FDA 2001).

⁸² *See, e.g.*, FOOD CODE annex 3 (FDA 2001); FOOD CODE annex 5 (FDA 2001); FOOD CODE annex 3 (FDA 1997); FOOD CODE annex 3 (FDA 1999). This examination is limited to the Food Code in its current format, beginning with the 1993 Food Code. *FDA Food Code*, FDA, <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm> (last updated Feb. 12, 2018). FDA and the Public Health Service have periodically published proposals and recommendations regarding restaurants and food since 1934. *FDA Food Code 1997 – Previous Editions*, FDA, <https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm054040.htm> [<https://web.archive.org/web/20150609141305/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm054040.htm>].

⁸³ *Compare* FOOD CODE (FDA 2005), *with* FOOD CODE (FDA 1997), FOOD CODE (FDA 1999), *and* FOOD CODE (FDA 2001).

⁸⁴ FOOD CODE (FDA 2005).

food establishment, such as a restaurant,⁸⁵ must be able during inspections and upon request to describe foods that are major food allergens and the symptoms of an allergic reaction that an allergen could cause.⁸⁶ Consistent with FALCPA, the code also notes that food packaged in a food establishment must be properly labeled for major food allergens.⁸⁷ Many foods in restaurants, however, are excluded from this requirement: as noted above, FDA has defined “[p]ackaged” to exclude “a wrapper, carry-out box, or other nondurable container used to containerize food with the purpose of facilitating food protection during service and receipt of the food by the consumer.”⁸⁸

An annex to the 2005 code identifies use of “a rigorous sanitation regime to prevent cross contact between allergenic and non-allergenic ingredients” as a means to control allergen hazards, which are associated with “[f]oods containing or contacted by” a major food allergen.⁸⁹ In addition, the Food Code states that before an effective Hazard Analysis and Critical Control Point (HACCP) system can be implemented, there must be “a strong foundation of procedures that address the basic operational and sanitation conditions within an operation,” which may include allergen management.⁹⁰ In general, although the Food Code encourages the “implementation of food safety management systems based on HACCP principles,” use “of HACCP at the retail level is voluntary.”⁹¹

Subsequent editions of the Food Code have added additional food allergen management requirements.⁹² For example, the person in charge must ensure that “[e]mployees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties.”⁹³ In addition, the cleaning and sanitizing measures for

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.* § 3-602.11.

⁸⁸ *Id.* § 1-201.10(B).

⁸⁹ *Id.* annex 4, tbl.2.

⁹⁰ *Id.* annex 4, at 479. HACCP “is a systematic approach to identifying, evaluating, and controlling food safety hazards” that “is designed to ensure that hazards are prevented, eliminated, or reduced to an acceptable level before a food reaches the consumer.” *Id.* annex 4, at 478; *see also infra* Section III.A.3 (proposing that HACCP be used for the management of food allergens in restaurants).

⁹¹ FOOD CODE annex 4, at 478 (FDA 2005).

⁹² *See* FOOD CODE (FDA 2009); FOOD CODE (FDA 2013).

⁹³ FOOD CODE § 2-103.11 (FDA 2009); *Id.* annex 3, at 327 (identifying food allergies as “an increasing food safety and public health issue” and explaining the revision of the person in charge’s duties to include allergy awareness in the food safety training of employees).

equipment used to prepare raw foods that are major food allergens were strengthened.⁹⁴

Although the Food Code has given more attention to the management of food allergens since the enactment of FALCPA, it has several limitations. As a model code, it lacks the independent force of law.⁹⁵ The adoption of the code and its provisions depend on voluntary action by local, state, and federal regulators and legislators.⁹⁶ Although FDA “encourages . . . adopt[ion of] the latest version of the Food Code,”⁹⁷ jurisdictions may be slow or fail to adopt updated editions of the Code.⁹⁸ For example, a 2016 report indicates that at least one agency in each of the fifty states and the District of Columbia had adopted the FDA Food Code; however, in eleven states at least one agency had adopted a version of the Food Code that predates FALCPA.⁹⁹ Jurisdictions may fail to adopt the most recent edition of the Food Code because doing so may be time intensive and burdensome. FDA generally publishes a new edition of the code every four years and may also publish supplements.¹⁰⁰ Further adding to the variation, some states have adopted the standards set forth in the Food

The findings of one study, however, “indicate that employee training might not be occurring according to recommendations.” Radke et al., *supra* note 3, at 405.

⁹⁴ *FDA Releases 2013 Food Code: Updated Code is a Model for State, City, County, Tribal, Territorial Agencies and Industry*, FDA (NOV. 14, 2013), <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm374979.htm> [<https://web.archive.org/web/20160328075637/https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm374979.htm>] [hereinafter *FDA Releases 2013 Food Code*]; FOOD CODE § 4-602.11 (FDA 2013).

⁹⁵ FOOD CODE preface iii (FDA 2017).

⁹⁶ *Id.*

⁹⁷ *2017 Food Code*, FDA, <https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm595139.htm> (last updated Mar. 12, 2018). The preface to the Food Code notes that a state legislative body may enact the Code into a statute, an administrative agency with rulemaking authority may promulgate it as a regulation, or a local legislative body with appropriate powers may adopt it as an ordinance. FOOD CODE preface viii (FDA 2017).

⁹⁸ *See* FDA, ADOPTION OF THE FDA FOOD CODE BY STATE AND TERRITORIAL AGENCIES RESPONSIBLE FOR THE OVERSIGHT OF RESTAURANTS AND RETAIL FOOD STORES (2016).

⁹⁹ *Id.* at 4–6. Some states have more than one agency with regulatory oversight over the retail food industry. *Id.* at 2.

¹⁰⁰ *See* Drew Falkenstein, *A Call for Uniform Model Food Code Application*, FOOD SAFETY NEWS (Jan. 13, 2010), <http://www.foodsafetynews.com/2010/01/a-call-for-uniform-model-food-code-application/#.VZraSGA7b8s> (arguing for a nationwide Food Code as a way to “streamline the often complex process of employee training, particularly for national restaurant chains that currently must account for many different regulatory schemes”). The 2017 edition of the Food Code was released in February of 2018. *See FDA Releases 2017 Food Code*, FDA (Feb. 12, 2018), <https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm595143.htm>; FOOD CODE (FDA 2017).

Code with modifications¹⁰¹ and “local regulatory agencies can be using more updated Food Codes than the state.”¹⁰²

Jurisdictions’ delay or failure to adopt the most recent version of the Food Code is concerning from an allergen management perspective because they may not be benefiting from FDA’s “best” and most recent advice regarding retail food safety,¹⁰³ as older versions of the Food Code generally have less extensive food allergen provisions. In addition, the jurisdictional variations that result from these delays and failures undermine the uniformity that is one of the goals of the model code.¹⁰⁴

The lack of uniformity may also increase the regulatory burdens on restaurants that have locations in jurisdictions that have adopted different editions of the Food Code or modified the Food Code.¹⁰⁵ It may also harm people with food allergies by increasing uncertainty and risk. For example, if a person visits a restaurant with locations in two different states, she may be unaware that the locations may be subject to different requirements regarding the management of allergens even if they are part of the same chain.

But even in the highly unlikely event that the “[m]ore than 3,000 state, local and tribal agencies [that] . . . regulate the retail food and foodservice industries in the United States” were to voluntarily adopt a

¹⁰¹ See EcoSure, *Read Any Good Food Code Lately?*, Ecolab: FOOD SAFETY MONITOR, <http://www.ecolab.com/~media/Ecolab/Ecolab%20Home/Documents/DocumentLibrary/PublishedArticles/FSMonitorNewsletter/March%202014/ReadAnyGoodFoodCodeLatelyMarch2014.ashx> (last visited Feb. 14, 2018) (providing examples of states adopting modified versions of the Food Code); Eva Merian Spahn, *Keep Away from Mouth: How the American System of Food Regulation Is Killing Us*, 65 U. MIAMI L. REV. 669, 713 (2011) (providing additional example of a modified version of the Food Code).

¹⁰² EcoSure, *supra* note 101; see also Nicholas R. Johnson & A. Bryan Endres, *Small Producers, Big Hurdles: Barriers Facing Producers of “Local Foods,”* 33 HAMLIN J. PUB. L. & POL’Y 49, 77–78 (2011) (stating that “[w]hile each state scheme is different, state-level food regulation typically begins with a food sanitation statute (often modeled on the FDA Food Code) that sets forth general parameters, leaves the precise regulatory details to the state department of public health or its equivalent, and places inspection and enforcement powers in the hands of local health inspectors”) (internal citations omitted).

¹⁰³ FOOD CODE preface iii (FDA 2017).

¹⁰⁴ *Id.* preface iv (stating that “[i]ndustry conformance with acceptable procedures and practices is far more likely where regulatory officials ‘speak with one voice’ about what is required to protect the public health, why it is important, and which alternatives for compliance may be accepted”); Falkenstein, *supra* note 100 (arguing that “[i]t is time for a federal mandate making the FDA’s Model Food Code . . . compulsory as a baseline regulatory scheme on all states, territories, and tribal jurisdictions”).

¹⁰⁵ See Falkenstein, *supra* note 100; see also *infra* Section IV.B (discussing benefits and limitations of state and local action).

uniform Food Code,¹⁰⁶ the current Food Code does not provide a comprehensive approach to allergen management in restaurants. Although the Food Code acknowledges the importance of labels and ingredient information for consumers with food allergies,¹⁰⁷ it does not generally address the labeling of nonpackaged food.¹⁰⁸ Instead, it suggests that “[w]hen food is under the direct control of the operator and provided to the consumer upon consumer request, the consumer has an opportunity to ask about . . . allergens.”¹⁰⁹ This suggestion is problematic, however, because the operator may not be equipped to provide sound information.¹¹⁰ Indeed, there have been reports of consumers who died from an allergic reaction to food served by a restaurant—after the restaurant assured the consumer the allergen was not in the food.¹¹¹

The Food Code’s approach to preventing allergen cross contact fails to adequately control major food allergens. For example, in explaining the strengthened cleaning requirements for equipment that has “contacted raw animal foods that are major food allergens,” FDA in the 2013 Food Code explicitly recognized that the change is “limited in scope” and “falls short of comprehensive allergen cross-contact control for all eight (8) major food allergens.”¹¹²

As noted earlier, FALCPA directed the Secretary of Health and Human services to “pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments, including in restaurants, grocery store delicatessens and bakeries.”¹¹³

¹⁰⁶ *Retail Food Protection*, FDA, <https://www.fda.gov/food/guidanceregulation/retailfoodprotection/ucm2006807.htm> (last visited Aug. 12, 2018).

¹⁰⁷ See FOOD CODE annexes 3 & 4, at 476, 560 (FDA 2017) (stating that “[i]ngredient information is needed by consumers who have allergies to certain food or ingredients” and that “[c]onsumers with food allergies rely heavily on information contained on food labels to avoid food allergens”).

¹⁰⁸ See FOOD CODE §§ 3-602.11–.12 (FDA 2017); see also *id.* annex 3, at 476–77.

¹⁰⁹ *Id.* annex 3, at 476.

¹¹⁰ See *supra* notes 56–63 and accompanying text.

¹¹¹ Jonathan Bridges, *Suing for Peanuts*, 75 NOTRE DAME L. REV. 1269, 1277, 1289 n.19 (2000) (summarizing lawsuits).

¹¹² FOOD CODE annex 3, at 509 (FDA 2013); see also FOOD CODE annex 3, at 512 (FDA 2017). In addition, FDA in its Food Code Reference System in response to a question about the potential for allergic reactions when oil used to fry fish is used to fry other foods, noted that although “it is prudent” to prevent cross contact by major food allergens when such contact “can be prevented with little investment in time or resources,” “the 2005 Food Code does not address operational procedures to prevent [such] contact.” *Food Code Reference System*, FDA, <http://www.accessdata.fda.gov/scripts/fcrs/disclaimer.cfm> (last visited Feb. 14, 2018) (search “allergen”) (registration required).

¹¹³ 42 U.S.C. § 243 (2012).

FDA noted in the 2005 Food Code that FALCPA directed it to pursue such revisions.¹¹⁴ But, as one commentator observed, “[t]he FALCPA’s failure to mandate what revisions must be made to the Food Code means that the FALCPA’s Food Code provision may yield few results, depending on FDA’s initiation of further revisions at the agency’s discretion.”¹¹⁵ To date, this appears to have been the case.

2. State and Local Allergen Awareness Laws

In 2009, Massachusetts enacted an Act Relative to Food Allergy Awareness (FAAA),¹¹⁶ becoming the first state to pass a food allergen restaurant awareness law.¹¹⁷ The act requires that “a person licensed as an innholder or common victualler, when serving food” (1) post an approved food allergy awareness poster in the staff work area, (2) include a notice informing customers of their “obligation to inform the server about any food allergies,” and (3) require “[a] person in charge and certified food protection manager” to view a video concerning food allergies as part of a course to obtain certification as an approved food protection manager.¹¹⁸ Except as specifically provided, the FAAA does not create or change a private cause of action or change the duty under any other statute or the common law.¹¹⁹ The FAAA requires that the Massachusetts Department of Public Health develop a program by which restaurants can be designated as “Food Allergy Friendly” and maintain a list of such restaurants.¹²⁰ The act is intended “to minimize the risk of illness and death due to accidental ingestion of food

¹¹⁴ FOOD CODE annex 4, at 483 (FDA 2005).

¹¹⁵ Derr, *supra* note 10, at 135.

¹¹⁶ An Act Relative to Food Allergy Awareness, MASS. GEN. LAWS ch. 140, § 6B (2010) [hereinafter Food Allergy Awareness Act]; MASS. DEP’T OF PUB. HEALTH, Q&AS FOR MDPH ALLERGEN AWARENESS REGULATION (2010) [hereinafter Q&AS FOR MDPH], <http://www.mass.gov/eohhs/docs/dph/environmental/foodsafety/food-allergen-3-reg-faqs.pdf>.

¹¹⁷ *Food Allergies and Restaurants*, FOOD ALLERGY RES. & EDUC., <https://www.foodallergy.org/education-awareness/advocacy-resources/advocacy-priorities/food-allergies-and-restaurants> (last visited Feb. 14, 2018).

¹¹⁸ Food Allergy Awareness Act § 6B(b)(1)–(2), (c). The FAAA also provides that an alternate person in charge must “be knowledgeable with regard to the relevant issues concerning food allergies as they relate to food preparation.” § 6B(c). The Massachusetts Public Health Council has adopted food allergy awareness regulations under the authority of the FAAA. Mass. Pub. Health Council Allergen Regulations, 105 CMR 590.000.

¹¹⁹ Food Allergy Awareness Act § 6B(f).

¹²⁰ § 6B(g).

allergens by increasing restaurant industry and consumer awareness” with respect to food allergens.¹²¹

The FAAA is limited, however, in that it does not require covered establishments to provide ingredient or allergen information for menu items. In addition, although it requires that establishments post a food allergy awareness poster and that a person in charge receive food allergen certification,¹²² it does not mandate that food workers take specific measures to prevent cross contact. The Food Allergy Friendly designation program had not been implemented at the time that this Article was written.¹²³

Several other states have also enacted food allergy awareness laws for restaurants.¹²⁴ Although the particular terms of these laws vary, broadly speaking, these laws share features of the Massachusetts law and are limited in scope. These features include (1) the display of a food allergy awareness poster in the staff area,¹²⁵ (2) a notice to customers of their obligation to inform their server about any food allergies,¹²⁶ and (3) the designation of a manager who must be knowledgeable regarding food allergies as they relate to food preparation and must complete food allergen training,¹²⁷ or the establishment of other training standards.¹²⁸ Like the Massachusetts

¹²¹ Q&AS FOR MDPH, *supra* note 116.

¹²² *See* Food Allergy Awareness Act § 6B.

¹²³ *See* Jessica L. Brewer, Comment, *To Eat or Not to Eat?: How Ohio Can Foster More Confidence Between Restaurants and Food Allergic Individuals*, 41 U. DAYTON L. REV. 303, 321 (2016).

¹²⁴ *See, e.g.*, MICH. COMP. LAWS § 289.6152(1) (2015); MD. CODE ANN., HEALTH-GEN. § 21-330.2 (West 2013); 23 R.I. GEN. LAWS § 23-20.12-2 (2012); H.R. 2510, 100th Gen. Assemb., Reg. Sess. (Ill. 2017).

¹²⁵ MICH. COMP. LAWS § 289.6152(1); MD. CODE ANN., HEALTH-GEN. § 21-330.2; 23 R.I. GEN. LAWS § 23-20.12-2; H.R. 2090, 2015 Gen. Assemb., Reg. Sess. (Va. 2015).

A number of other states have considered food allergy awareness bills. *See, e.g.*, S. 49, 2015 Gen. Assemb., Reg. Sess. (Conn. 2015); S. 1072, 2014 Leg., Reg. Sess. (Fla. 2014); S. 422, 2014 Gen. Assemb., Reg. Sess. (Ga. 2014). In addition, a number of states have considered or adopted resolutions designating food allergy or anaphylaxis awareness weeks. *See, e.g.*, S. Con. Res. 67, 2012 Leg., Reg. Sess. (Cal. 2012); S. Res. 1002, 51st Leg., Reg. Sess. (Ariz. 2013).

¹²⁶ 23 R.I. GEN. LAWS § 23-20.12-2.

¹²⁷ *Id.*; MICH. COMP. LAWS § 289.2129; 410 ILL. COMP. STAT. §§ 625/3.06-07 (2017).

¹²⁸ VA. CODE ANN. § 35.1-14A (West 2015). The Virginia law also requires that the State Health Commissioner provide written materials for the training of restaurant personnel on “food safety and food allergy awareness and safety.” *Id.*

The Michigan law, like the Massachusetts Food Allergy Awareness Act, does not establish or change any private cause of action or change any duty except as it expressly provides. *Compare* Food Allergy Awareness Act, MASS. GEN. LAWS ch. 140, § 6B (2010), *with* MICH. COMP. LAWS § 289.6152.

law, these laws fail to mandate comprehensive food allergen protections.

Furthermore, at least two cities have enacted food allergen measures for restaurants. In 2009, the New York City Council passed and the mayor approved a local law requiring food service establishments to display, “in a conspicuous location accessible to all employees involved in the preparation and the service of food,” a poster containing information on food allergy created by the Department of Health and Mental Hygiene.¹²⁹ Similarly, the City of St. Paul, Minnesota, enacted an ordinance requiring restaurants to display an approved food allergy awareness poster in the staff area.¹³⁰ Both the New York City and St. Paul measures are limited in scope and, like the state laws discussed above, do not require comprehensive food allergen measures. And, as noted earlier, as this Article was going to press, the Township of Edison, New Jersey, approved an ordinance that will require restaurants to “identify on a menu all food items that contain or are prepared with” any of the eight major food allergens, “as well as monosodium glutamate (‘MSG’) and commercial sulfites used as a food preservative or additive” and to “indicate . . . that such menus are available.”¹³¹ The ordinance also establishes requirements for caterers and establishments operating with plenary retail consumption licenses.¹³² It does not, however, address cross contact prevention.¹³³

3. Tort Law

A person injured by an allergic reaction to food from a restaurant may be able to recover under several different theories of liability.¹³⁴ This section focuses on products liability, specifically failure to warn

¹²⁹ N.Y.C., Local Law 17 of 2009, available at https://locallaws.dos.ny.gov/sites/default/files/drop_laws_here/ECMMDIS_appid_DOS20150218075531_44/Content/090213438000981d.pdf; N.Y.C., N.Y., ADMINISTRATIVE CODE 17-195 (2017); see also N.Y.C., N.Y., HEALTH CODE § 81.0(s) (defining food service establishment); N.Y. DEP’T OF HEALTH & MENTAL HYGIENE, RULES OF THE CITY OF N.Y. ch. 27 (Food Allergy Information) (adopting rules defining the scope and applicability of the food allergen poster law).

¹³⁰ ST. PAUL, MINN., CODE OF ORDINANCES ch. 331A.11.

¹³¹ Edison Township, N.J., Ordinance O.2015-2018 (Aug. 22, 2018).

¹³² *Id.*

¹³³ See *id.*

¹³⁴ In addition, a person injured by an allergic reaction to food from a restaurant may have a claim for negligence or breach of warranty. See, e.g., RESTATEMENT (SECOND) OF TORTS § 281 (AM. LAW INST. 1965) (negligence); U.C.C. § 2-313 (AM. LAW INST. & UNIF. LAW COMM’N 2002) (breach of warranty).

and manufacturing defects, to illustrate tort law's limitations in addressing food allergens in restaurants.¹³⁵

Before turning to an examination of the specifics of these claims, however, it is worth noting two points. First, in contrast to the laws discussed in the prior sections, which seek to prevent allergic reactions to food with preventative measures, “a principal function of tort law is to compensate a victim for the wrongdoing or unreasonable conduct of the tortfeasor.”¹³⁶ The possibility of damages, however, may be of no value to a person with a food allergy who has suffered a fatal reaction at a restaurant.¹³⁷ As Professors Eric Posner and Cass Sunstein have succinctly stated a “dead person cannot be compensated—she is dead.”¹³⁸ But even if an allergic reaction does not result in death, tort law may not make the person whole. As Professor Sean Hannon Williams has written, “The make-whole account of tort damages is aspirational only. To truly make someone whole would require undoing the injury. This is rarely possible”¹³⁹ Thus, from the perspective of an individual potential plaintiff, the benefits of tort law may be limited.

Second, a search for case law addressing allergic reactions to food identified only a few cases, which is consistent with what others have observed.¹⁴⁰ The limited case law may create uncertainty for potential plaintiffs. The scientific literature suggests that the lack of lawsuits is not due to a lack of potential plaintiffs because a significant number of people with food allergies have experienced allergic reactions in

¹³⁵ DAN B. DOBBS ET AL., HORNBOOK ON TORTS 810, 825 (2nd ed. 2016); RESTATEMENT (SECOND) OF TORTS § 402A; RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (AM. LAW INST. 1998).

¹³⁶ 74 AM. JUR. 2D *Torts* § 2 (1974).

¹³⁷ Andrew J. McClurg, *It's A Wonderful Life: The Case for Hedonic Damages in Wrongful Death Cases*, 66 NOTRE DAME L. REV. 57, 66 (1990) (“A dead person cannot be compensated for his lost life. A trillion dollars would contribute nothing toward making him whole again.”). *But see* Sean Hannon Williams, *Lost Life and Life Projects*, 87 IND. L.J. 1745, 1763 (2012) (exploring whether a life can be improved by events after its end). Compensation is of course not the only purpose of tort law; tort law may have a deterrent effect by creating an incentive for restaurants to take measures to make foods safer for those with food allergies. *See, e.g.*, Robert L. Rabin, *Poking Holes in the Fabric of Tort: A Comment*, 56 DEPAUL L. REV. 293, 301 (2007) (describing tort law as “an engine of compensation as well as deterrence”).

¹³⁸ Eric A. Posner & Cass R. Sunstein, *Dollars and Death*, 72 U. CHI. L. REV. 537, 558 (2005).

¹³⁹ Williams, *supra* note 137, at 1763.

¹⁴⁰ *See, e.g.*, Bridges, *supra* note 111, at 1275 (noting that lawsuits due to anaphylactic reactions to nuts appear to be uncommon); Brewer, *supra* note 123, at 310 (identifying only one case involving a person who had an allergic reaction from food served by a restaurant in Ohio); Roses, *supra* note 64, at 232.

restaurants and other establishments,¹⁴¹ some of which have been fatal.¹⁴² Therefore, it may be fair to conclude that these cases often settle.¹⁴³ The limited case law, however, may “color[] settlement terms in a way adverse to the would-be plaintiffs” who are injured by an allergic reaction to a food.¹⁴⁴

A person injured by an allergic reaction to an allergen in a restaurant’s food may have a failure to warn claim. Failure to warn, unlike manufacturing defects discussed below, has “gravitated toward a negligence approach.”¹⁴⁵ Under the approach taken by Third Restatement of Torts, the plaintiff would have to prove by a preponderance of the evidence that the restaurant failed to provide a reasonable warning and that failure rendered the food not reasonably safe.¹⁴⁶ There is some uncertainty about when a restaurant has a duty to warn about common food allergens. On the one hand, a warning that a food contained a common allergen could entirely prevent a customer with a known allergy from having an allergic reaction. On the other hand, when the presence of a food allergen and the risks presented by it are widely known, a warning is unnecessary.¹⁴⁷ In addition, when the risk of an allergic reaction is not “reasonably foreseeable at the time of sale,” a warning about the risk is not required.¹⁴⁸ A warning about an allergen “is required when [it] . . . is one to which a substantial number of persons are allergic”; however, this is “not precisely quantifiable.”¹⁴⁹ Proving causation may also present challenges. As one commentator has noted, “In the few cases of litigation on the record, virtually all plaintiffs seeking redress under” failure to warn and

¹⁴¹ See, e.g., Furlong et al., *supra* note 4; see also Weiss & Muñoz-Furlong, *supra* note 3.

¹⁴² See Carol A. Wham & Kanchan M. Sharma, *Knowledge of Café and Restaurant Managers to Provide a Safe Meal to Food Allergic Consumers*, 71 NUTRITION & DIETETICS 265, 265 (2014).

¹⁴³ See Roses, *supra* note 64, at 226 (stating that “the likely reason for the sparse record of litigation is that the vast majority of incidents settle before ever reaching a courtroom”).

¹⁴⁴ *Id.*

¹⁴⁵ DOBBS ET AL., *supra* note 135, at 806, 825.

¹⁴⁶ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY, § 2 (AM. LAW INST. 1998); see also DOBBS ET AL., *supra* note 135, at 82; RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (AM. LAW INST. 1965).

¹⁴⁷ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmts. j, k, m (“The ingredient that causes the allergic reaction must be one whose danger or whose presence in the product is not generally known to customers.”); see also RESTATEMENT (SECOND) OF TORTS § 402A cmt. j.

¹⁴⁸ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmts. k, m.

¹⁴⁹ *Id.* § 2; see also RESTATEMENT (SECOND) OF TORTS § 402A cmt. j.

manufacturing or product defect causes of action “have faced difficulties in proving causation and duty to warn about the risk of allergic reaction.”¹⁵⁰

A person injured by a food allergen may also have a manufacturing defect claim, for example, if the food was not intended to have a food allergen but did due to allergen cross contact during preparation. To prove a manufacturing defect claim, the plaintiff would have to show by a preponderance of the evidence that (1) the food had the manufacturing defect at the time it left the restaurant’s hands, (2) the food was expected to and did reach the consumer without change, and (3) the food caused the allergic reaction.¹⁵¹ A food “has a manufacturing defect when it disappoints consumer expectations by departing from its intended design” even though all possible care was exercised in its preparation and marketing.¹⁵² In other words, there is strict liability for these defects.¹⁵³ Accordingly, manufacturing defect claims may be easier for a potential plaintiff to prove than failure to warn claims; however, proving that the food was defective, that it was defective when it left the restaurant’s hands, and that the defect caused the allergic reaction may still present challenges.¹⁵⁴

Thus, although tort law may provide some relief for persons injured by reactions to allergens in restaurant-type food and may help make restaurants safer for those with food allergies through its deterrent effect, it does not fill the gaps identified earlier.

4. Disability Law

Although “[c]ourts have repeatedly refused to grant disability status to those with severe food allergies,”¹⁵⁵ severe food allergies may

¹⁵⁰ *Roses, supra* note 64, at 232; *see also* *Leavitt, supra* note 64, at 972–73 (noting that in the context of section 402A of the Restatement (Second) of Torts “plaintiffs face great difficulties establishing that restaurants owe a duty to warn of the presence of allergens and that the restaurants somehow caused the plaintiffs’ adverse allergic reactions” and that the *Third Restatement’s* “principles have only been minimally explored in food-allergy cases”).

¹⁵¹ *DOBBS ET AL., supra* note 135, at 810. Restatement (Second) of Torts Section 402A, comment f provides that the section “applies to any person engaged in the business of selling products for use or consumption,” including “to the operator of a restaurant.” *RESTATEMENT (SECOND) OF TORTS* § 402A cmt. f.

¹⁵² *DOBBS ET AL., supra* note 135, at 806, 810; *RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY* § 2.

¹⁵³ *DOBBS ET AL., supra* note 135, at 806, 810; *RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY* § 2.

¹⁵⁴ *See* *Roses, supra* note 64, at 232; *Leavitt, supra* note 64, at 972–73.

¹⁵⁵ Jason Mustard, Comment, *Nothing to Sneeze At: Severe Food Allergy as a Disability under the ADA Amendments Act of 2008*, 45 *GOLDEN GATE U. L. REV.* 173, 174 (2015).

constitute a disability under the Americans with Disabilities Act Amendments Act of 2008 (ADAAA). Due to a lack of case law, however, there is some uncertainty regarding how courts will interpret the ADAAA.

In *Land v. Baptist Medical Center*, a case predating the ADAAA, the mother of a child with a peanut allergy sued Baptist Medical Center under the Americans with Disabilities Act of 1990 (ADA) when it refused to provide day care services for her child after the child had two allergic reactions at the day care.¹⁵⁶ The district court granted summary judgment for Baptist Medical Center on the ADA claim and the United States Court of Appeals for the Eighth Circuit affirmed.¹⁵⁷ The court of appeals stated that “[t]he pivotal question [was] . . . whether [the child’s] allergy substantially limits her ability to eat and breathe” and concluded that it did not.¹⁵⁸ The court explained that “[a]lthough [the child] cannot eat foods containing peanuts or their derivatives, the record does not suggest that [the child] suffers an allergic reaction when she consumes any other kind of food or that her physical ability to eat is in any way restricted.”¹⁵⁹ In addition, the court stated that “the record shows [the child’s] ability to breathe is generally unrestricted, except for the limitations she experienced during her two allergic reactions.”¹⁶⁰ Thus the court concluded that the child’s allergy did “not substantially or materially limit these major life activities within the definition of disability under the ADA.”¹⁶¹

However, several commentators have argued that the ADAAA, which expanded the definition of disability, “provides rules of construction that dismantle the *Land* court’s holding”¹⁶² and may increase the protections for people with food allergies.¹⁶³ Under the ADAAA, disability is defined in part as “a physical . . . impairment that

¹⁵⁶ *Land v. Baptist Med. Ctr.*, 164 F.3d 423 (8th Cir. 1999).

¹⁵⁷ *Id.* at 424.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.* at 425.

¹⁶⁰ *Id.*

¹⁶¹ *Id.*; see also *Bohacek v. City of Stockton*, No. CIV S-04-0939 GGH, 2005 WL 2810536, at *5 (E.D. Cal. Oct. 26, 2005) (holding that a child with a peanut allergy “does not have a disability because there is no substantial limitation on his major life activities”).

¹⁶² See, e.g., Mustard, *supra* note 155, at 188; see also 42 U.S.C. § 12102(4)(D)-(E) (2012).

¹⁶³ See Tess O’Brien-Heinzen, *A Complex Recipe: Food Allergies and the Law*, WIS. LAW., May 2010, at 8, 9; Mustard, *supra* note 155, at 175 (arguing that “courts must classify individuals with severe food allergies as having a disability”); Roses, *supra* note 64, at 226 n.8.

substantially limits one or more major life activities of [an] individual.”¹⁶⁴ “Major life activities” include “eating,” “breathing,” and “the operation of a major bodily function.”¹⁶⁵ In addition, the ADAAA provides that “[a]n impairment that is episodic or in remission is a disability if it would substantially limit a major life activity when active.”¹⁶⁶

Case law on whether a severe food allergy may constitute a disability under the ADAAA is limited, but suggests that it may.¹⁶⁷ In addition, a 2012 agreement between the United States Department of Justice and Lesley University recognized that “[f]ood allergies may constitute a disability under the ADA.”¹⁶⁸ The University’s obligations at issue in the Lesley Agreement do differ from those of restaurants that serve the general public as that agreement involved a complaint involving the University’s mandatory meal plan for students living on campus. In a question and answer document discussing the agreement, however, the United States Justice Department indicated that “[a] restaurant may have to take some reasonable steps to accommodate individuals with disabilities where it does not result in a fundamental alteration of that

¹⁶⁴ 42 U.S.C. § 12102(1).

¹⁶⁵ § 12102(2).

¹⁶⁶ § 12102(4)(D).

¹⁶⁷ See *Hebert v. CEC Entm’t, Inc.*, No. 6:16-CV-00385, 2016 WL 5003952, at *3 (W.D. La. July 6, 2016), *report and recommendation adopted*, No. 16-CV-0385, 2016 WL 5081009 (W.D. La. Sept. 16, 2016) (holding that parents’ allegations that their son’s food allergy is a disability “are sufficient to overcome the defendant’s first challenge to the sufficiency of the complaint”); *Mills v. St. Louis Cty. Gov’t*, No. 4:17CV0257 PLC, 2017 WL 3128916, at *5 (E.D. Mo. July 24, 2017) (stating that *Land* is of “limited assistance” in determining whether a food allergy is a disability because “the *Land* court analyzed the child’s alleged disability pursuant to an approach rejected by the ADAAA” and that plaintiff’s allegation of a shellfish allergy was sufficient to state a claim to survive motion to dismiss); *Knudsen v. Tiger Tots Cmty. Child Care Ctr.*, No. 12-0700, 2013 WL 85798, at *3 (Iowa Ct. App. 2013) (reversing district court’s grant of summary judgment and remanding for consideration of “whether [the child’s] allergy would substantially limit a major life activity ‘when active’”); *Lopez-Cruz v. Instituto de Gastroenterologia de P.R.*, 960 F. Supp. 2d 367, 371 n.8 (D.P.R. 2013) (stating that, although “[a] number of courts conclude that an individual does not suffer a disability when an impairment only manifests itself when the individual is exposed to an allergen at work,” these “cases were decided prior to the ADA being amended by the ADA Amendments Act of 2008,” which “provides that the disability inquiry is to be made without consideration of ‘the ameliorative effects of mitigating measures,’ . . . and that an impairment occurring episodically may be considered a disability if it substantially limits a major life activity when active”); see also *Roses*, *supra* note 64, at 226 n.8.

¹⁶⁸ U.S. DEP’T OF JUSTICE, DJ 202-36-231, SETTLEMENT AGREEMENT BETWEEN THE UNITED STATES OF AMERICA AND LESLEY UNIVERSITY (2012).

restaurant's operations."¹⁶⁹ Thus, the ADAAMA should provide individuals with severe food allergies greater protections than the pre-ADAAMA law, although it remains to be seen how courts will interpret the amendments.

II MENU LABELING

Although current law regarding allergen labeling and management in restaurants is at best limited, there is another context in which restaurant labeling has received substantial attention: menu labeling. This Part discusses New York City's (NYC) 2006 and 2008 menu labeling rules and the legal challenges to these rules. The 2008 rule, and the United States Court of Appeals for the Second Circuit's holding that the rule was not preempted by federal labeling law and did not violate the First Amendment of the United States Constitution, helped pave the way for other cities, counties, states, and, ultimately, the federal government to enact menu labeling requirements. This Part focuses on the aspects of local, state, and federal menu labeling laws, which can be used to inform the regulation of food allergens.

A. Local and State

1. New York City

a. 2006 Menu Labeling Regulation

In September 2006, the NYC Board of Health proposed a menu labeling rule that would have required "some restaurants [to] post calorie information on menus and menu boards."¹⁷⁰ The proposal was

¹⁶⁹ U.S. DEP'T OF JUSTICE, QUESTIONS AND ANSWERS ABOUT THE LESLEY UNIVERSITY AGREEMENT AND POTENTIAL IMPLICATION FOR INDIVIDUALS WITH FOOD ALLERGIES (2013); *see also* 42 U.S.C. § 12188 (2012) (enforcement), § 2000a-3(a) (civil actions for injunctive relief).

¹⁷⁰ Press Release, N.Y.C. Dep't of Health & Mental Hygiene, Health Department Proposes Two Changes to City's Health Code for Public Comment: First, to Phase Out Artificial Trans Fat in All Restaurants; Second, to Require Calorie Labeling in Some Restaurants (Sept. 26, 2006), <https://web.archive.org/web/20060928231402/http://www.nyc.gov/html/doh/html/pr2006/pr093-06.shtml> (accessing Internet Archive from Sept. 28, 2006) [hereinafter Press Release, Changes to City's Health Code]; *see also* Brent Bernell, *The History and Impact of the New York City Menu Labeling Law*, 65 FOOD & DRUG L.J. 839, 845 (2010) (discussing history of NYC's menu labeling law); Michael A. McCann, *Economic Efficiency and Consumer Choice Theory in Nutritional Labeling*, 2004 WIS. L. REV. 1161, 1199 (2004) (discussing earlier efforts to get restaurants in New York, and particularly New York City, to provide nutritional information through voluntary agreements).

driven, at least in part, by the growth in food consumed outside the home, “a leading cause of excess calorie intake.”¹⁷¹ The proposal “was designed to primarily impact large, chain restaurants,”¹⁷² and the NYC Department of Health and Mental Hygiene estimated that the proposal “would affect about one in ten restaurants” in NYC.¹⁷³ The Board of Health hoped that the required calorie information would cause consumers to choose healthier foods and thus decrease calorie consumption and obesity.¹⁷⁴

Less than three months after it proposed the new rule, the Board unanimously voted to amend the City’s Health Code to require food service establishments “that voluntarily disclose[] the nutrition information of” standardized menu items to post calorie information on their menus and menu boards next to each menu item.¹⁷⁵ The Board acted pursuant to its rulemaking authority under the NYC Charter, which gives it “the power to create regulations without any involvement from the City Council or other city or state agencies.”¹⁷⁶

The restaurant industry opposed the rule on both policy and legal grounds.¹⁷⁷ Critics “questioned whether the proposal could achieve the

¹⁷¹ Sheri Kindel, *The Impact of Calorie Disclosure Regulations on the Consumer and Business Sector*, 10 OHIO ST. BUS. L.J. 245, 248 (2016). The Board had to decide “which restaurants would fall under the rule, what information they would be required to post, and how restaurants should have to display that information.” Bernell, *supra* note 170, at 845.

¹⁷² Bernell, *supra* note 170, at 839.

¹⁷³ Press Release, N.Y.C. Dep’t of Health & Mental Hygiene, Board of Health Votes to Require Calorie Labeling in Some New York City Restaurants (Dec. 5, 2006), <https://web.archive.org/web/20061208225608/http://www.nyc.gov:80/html/doh/html/pr2006/pr113-06.shtml> (accessing Internet Archive from Dec. 8, 2006).

¹⁷⁴ Bernell, *supra* note 170, at 843 (discussing the rationale for NYC’s menu labeling law, namely the role of restaurants in excess calorie consumption, the link between excess consumption and the obesity epidemic, the deaths and health problems associated with the obesity epidemic, and the “calorie information gap”).

¹⁷⁵ *Id.* at 839; N.Y.C. DEP’T OF HEALTH & MENTAL HYGIENE BD. OF HEALTH, NOTICE OF ADOPTION OF AN AMENDMENT (§ 81.50) TO ARTICLE 81 OF THE NEW YORK CITY HEALTH CODE (2006), <https://www1.nyc.gov/assets/doh/downloads/pdf/public/notice-adoption-hc-art81-50.pdf>; Press Release, Changes to City’s Health Code, *supra* note 170 (stating that the “proposal would only affect restaurants that make calorie information for standard menu items publicly available on or after March 1, 2007”); *Why the Health Department Proposes that Certain Restaurants List Calorie Content on Menus*, N.Y.C. DEP’T OF HEALTH & MENTAL HYGIENE, https://web.archive.org/web/20061003135901/http://www.nyc.gov/html/doh/html/cdp/cdp_pan-calorie-summary.shtml (accessing Internet Archive from Oct. 3, 2006).

¹⁷⁶ N.Y.C., N.Y., CHARTER §§ 558, 1043 (2004); Thomas J. Lueck, *City May Ask Restaurants to List Calories*, N.Y. TIMES (Oct. 30, 2006), <https://www.nytimes.com/2006/10/30/nyregion/30calories.html>.

¹⁷⁷ See Memorandum from Lynn D. Silver, Assistant Comm’r, Bureau of Chronic Disease Prevention & Control & Candace Young, Dir., Physical Activity & Nutrition, to Thomas R. Frieden, Comm’r 18 (Nov. 27, 2006), <https://web.archive.org/web/2007>

stated [health] benefit,” whether it was feasible, and whether the regulatory strategy it embodied was appropriate.¹⁷⁸ The New York State Restaurant Association (NYSRA) sued the Board of Health and the NYC Department of Health and Mental Hygiene to block the rule.¹⁷⁹ It argued that (1) the rule, which was to take effect on July 1, 2007, was expressly preempted by the Nutritional Labeling and Education Act of 1990 (NLEA) and FDA’s regulations, and (2) the rule violated its members’ First Amendment rights.¹⁸⁰

The United States District Court for the Southern District of New York held that the regulation was preempted by federal law: under the NLEA, if a restaurant makes a voluntary nutrition content claim, the claim must comply with the requirements of FDA’s implementing regulations.¹⁸¹ NYC’s menu labeling requirements differed from what was required under the NLEA and the regulations. Thus, the court held that the NLEA expressly “preempts any state regulation of nutrient content claims, including claims made by restaurants, that ‘[are] not identical to the requirement[s]’” of federal law.¹⁸² The court did not reach the First Amendment claim.¹⁸³

b. 2008 Menu Labeling Regulation

Following the invalidation of the 2006 regulation, the Board of Health proposed a new regulation, which it adopted by resolution on January 22, 2008.¹⁸⁴ The 2008 regulation required covered establishments to clearly and conspicuously post

calorie information . . . on all menu boards and menus, as well as on food item display tags, adjacent or in close proximity, to the menu

0222021652/http://www.nyc.gov:80/html/doh/downloads/pdf/cdp/cdp-pan-calorie-comments-response.pdf (accessing Internet Archive from Feb. 22, 2007) (listing organizations opposing the proposal as including the National Restaurant Association, the New York State Restaurant Association, the National Council of Chain Restaurants, Wendy’s, McDonald’s, and Domino’s, among others).

¹⁷⁸ *Id.* at 3.

¹⁷⁹ Complaint, *N.Y. State Rest. Ass’n v. N.Y.C. Bd. of Health*, 509 F. Supp. 2d 351 (S.D.N.Y. 2007) (No. 07 Civ. 5710), 2007 WL 2778812.

¹⁸⁰ *Id.* at 1–2; *N.Y. State Rest. Ass’n*, 509 F. Supp. 2d at 352.

¹⁸¹ *N.Y. State Rest. Ass’n*, 509 F. Supp. 2d at 352.

¹⁸² *Id.* at 362–63 (invalidating N.Y.C. HEALTH CODE § 81.50 (2006)).

¹⁸³ *Id.*

¹⁸⁴ N.Y.C. DEP’T OF HEALTH & MENTAL HYGIENE BD. OF HEALTH, NOTICE OF ADOPTION OF A RESOLUTION TO REPEAL AND REENACT §81.50 OF THE NEW YORK CITY HEALTH CODE (2008), <https://www1.nyc.gov/assets/doh/downloads/pdf/public/notice-adoption-hc-art81-50-0108.pdf> [hereinafter NOTICE OF ADOPTION].

item, using a font and format that is at least as prominent in size as that used to post either the name or price of the menu item.¹⁸⁵

For menu items offered in different flavors and varieties, a range of calories was permitted to be listed.¹⁸⁶ The rule defined “[c]overed food service establishment” as

a food service establishment within the City of New York that is one of a group of 15 or more food service establishments doing business nationally, offering for sale substantially the same menu items, in servings that are standardized for portion size and content, that operate under common ownership or control, or as franchised outlets of a parent business, or do business under the same name.¹⁸⁷

The Board explained its focus on chain restaurants, noting that “the measure can be readily and accurately implemented [by chain restaurants], which account for a large and disproportionate proportion of meals served, and which serve food whose consumption has been clearly associated with excessive calorie intake and with obesity.”¹⁸⁸

The restaurant industry continued to resist the revised regulation¹⁸⁹ and, as with the earlier regulation, challenged it in court.¹⁹⁰ The NYSRA argued that federal law preempted the 2008 regulation and that the regulation unconstitutionally infringed on its members’ First Amendment rights.¹⁹¹ But whereas the United States District Court for the Southern District of New York invalidated the 2006 regulation,¹⁹² the 2008 regulation withstood review.¹⁹³ The Court of Appeals for the Second Circuit held that “[i]n requiring chain restaurants to post calorie information on their menus, NYC merely stepped into a sphere that Congress intentionally left open to state and local governments” and that “the First Amendment is not violated, where as here, the law in

¹⁸⁵ *Id.* at 11.

¹⁸⁶ *Id.* at 13.

¹⁸⁷ *Id.* at 12.

¹⁸⁸ *Id.*

¹⁸⁹ See LYNN SILVER & CATHY NONAS, SECTION 81.50 CALORIE POSTING RESPONSE TO COMMENTS 7 (2008) (listing “[o]rganizations in [o]pposition” as including the National Restaurant Association, the International Franchise Association, and several restaurants and establishments).

¹⁹⁰ *N.Y. State Rest. Ass’n v. N.Y.C. Bd. of Health*, No. 08 Civ. 1000(RJH), 2008 WL 1752455 (S.D.N.Y. Apr. 16, 2008), *aff’d*, 556 F.3d 114 (2d Cir. 2009).

¹⁹¹ *N.Y. State Rest. Ass’n*, 556 F.3d at 117.

¹⁹² *N.Y. State Rest. Ass’n v. N.Y.C. Bd. of Health*, 509 F. Supp. 2d 351, 352 (S.D.N.Y. 2007).

¹⁹³ *N.Y. State Rest. Ass’n*, 556 F.3d at 117.

question mandates a simple factual disclosure of caloric information and is reasonably related to NYC's goals of combating obesity."¹⁹⁴

2. Others

The NYC menu labeling law—and the favorable decision from the Court of Appeals—helped pave the way for other jurisdictions to consider and enact menu labeling requirements.¹⁹⁵ Although a full examination of these laws is beyond the scope of this Article, there are several features that are worth noting.

First, the scope and requirements of these laws varied. For example, within the state of California, there were different menu labeling requirements for San Francisco City and County, San Mateo County, and Santa Clara County. San Francisco's requirements applied to any chain restaurant within the city and county

offer[ing] for sale substantially the same Menu Items, in servings that are standardized for portion size and content, and is one of a group of 20 or more Restaurants in California that either: (1) operate under common ownership or control; or (2) operate as franchised outlets of a parent company, or (3) do business under the same name.¹⁹⁶

San Mateo's requirement, however, would have applied to chain food service establishments in the unincorporated county with fifteen or

¹⁹⁴ *Id.* at 117–18.

¹⁹⁵ See Brief for City and County of San Francisco et al. as Amici Curiae Supporting Respondents, at 2, *N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, 556 F.3d 114 (2d Cir. 2009) (No. 08-1892-cv.), 2008 WL 6513109 (stating that an adverse ruling in the New York menu labeling case “could undermine existing and pending legislation in state and local legislatures across the country”); Bernell, *supra* note 170, at 839–40 (stating that “New York City [menu labeling] law prompted numerous other cities, counties, and states to pass similar laws . . . and eventually led the restaurant industry to drop resistance to the idea and instead seek a unified, national standard for menu labeling”); Ashley Arthur, *Combating Obesity: Our Country's Need for a National Standard to Replace the Growing Patchwork of Local Menu Labeling Laws*, 7 *IND. HEALTH L. REV.* 305, 314 (2010) (noting that at the time “twenty-six states, Washington D.C., Puerto Rico and numerous cities and counties around the country ha[d] proposed menu labeling legislation”); see also Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 *Fed. Reg.* 19,192, 19,229 (proposed Apr. 6, 2011) (codified at 21 *C.F.R.* pts. 11, 101) (noting preexisting state and local menu labeling laws); Anthony J. Marks, *Menu Label Laws: A Survey*, 29 *FRANCHISE L.J.* 90, 93 (2009).

¹⁹⁶ *S.F., CAL., HEALTH CODE* § 468 (2008); see also *S.F., Cal. Ordinance* amending the San Francisco Health Code 260-80, File No. 081377 (Nov. 25, 2008) (suspending sections 468.3-468.8); see also Arthur, *supra* note 195, at 316 (discussing variations among the menu labeling laws of cities and counties within California).

more stores in California,¹⁹⁷ and Santa Clara County's requirement covered chain restaurants in the unincorporated area of the county with fourteen or more restaurants in California.¹⁹⁸ As a second example, the requirements among counties in different states also varied. Whereas the three California county requirements discussed above used the number of restaurants in the state to determine coverage, the menu labeling regulation in King County, Washington, "required chain restaurants with 15 or more locations nationwide to" provide nutrition information.¹⁹⁹

Second, these jurisdictions adopted menu labeling requirements in different ways. Whereas NYC Board of Health adopted menu labeling by a resolution amending the NYC Health Code,²⁰⁰ other jurisdictions used different mechanisms. For example, in Philadelphia, the city council passed and the mayor signed an ordinance to amend the city's Health Code.²⁰¹ In California, state legislators passed and the governor signed a bill to require menu labeling.²⁰²

Third, in October 2008, California became the first state to pass menu labeling legislation.²⁰³ The California menu labeling law expressly preempted local governments' menu labeling requirements.²⁰⁴ By preempting local menu labeling requirements, California took a significant step toward promoting more uniform menu labeling requirements. The inclusion of a preemption provision in the California bill may have been "key" in "overcoming restaurant industry opposition."²⁰⁵ California was the first state to pass menu labeling

¹⁹⁷ Michelle Durand, *Menu-Labeling Bill Yanked*, DAILY J. (Oct. 21, 2008), https://www.smdailyjournal.com/news/local/menu-labeling-bill-yanked/article_94764440-6c68-54a6-8b32-6654baad1e89.html.

¹⁹⁸ Press Release, Cty. of Santa Clara, County Adopts Menu Labeling Ordinance for Chain Restaurants with 14 or more Locations in California (June 3, 2008), https://www.sccgov.org/sites/opa/nr/Documents/Menu_Labeling_Ordinance_News_Release_FINAL.pdf; *see also* Press Release, Cty. of Santa Clara, County Repeals Local Menu Labeling Ordinance in Anticipation of State Law Taking Effect Jan. 1, 2009 (Nov. 4, 2008), <https://www.sccgov.org/sites/opa/nr/Documents/County-Menu-Labeling-Ord.pdf>.

¹⁹⁹ Donna B. Johnson et al., *Menu-Labeling Policy in King County, Washington*, 43 AM. J. PREVENTIVE MED. S130, S131 (2012).

²⁰⁰ NOTICE OF ADOPTION, *supra* note 184.

²⁰¹ Philadelphia, Pa., Ordinance 080167-A (Jan. 1, 2010).

²⁰² S. 1420, 2008 Leg., Reg. Sess. (Cal. 2008).

²⁰³ Arthur, *supra* note 195, at 316.

²⁰⁴ S. 1420.

²⁰⁵ KATE ARMSTRONG, PUB. HEALTH LAW CTR., MENU LABELING LEGISLATION: OPTIONS FOR REQUIRING THE DISCLOSURE OF NUTRITIONAL INFORMATION IN RESTAURANTS 9 (2008).

legislation,²⁰⁶ and other states, such as Oregon and New Jersey, followed suit.²⁰⁷ Like the California law, other state menu labeling laws expressly preempted local governments' menu labeling requirements.²⁰⁸

The state laws, however, did nothing to address differing menu labeling requirements such as differing requirements among states or among cities and counties in states that had not enacted menu labeling requirements. For example, "the California menu labeling law . . . require[d] restaurants with 20 or more locations *in the state* to post caloric content, carbohydrates, saturated fat, trans fat, and sodium content."²⁰⁹ By contrast, the New Jersey menu labeling law required chain restaurants with twenty or more locations *nationally* to provide calorie information for menu items listed on a menu, menu board, or similar signage.²¹⁰ Such variations were an impetus for federal menu labeling requirements.

B. Federal

1. Legislation

Less than four years after NYC's Health Department first proposed a menu labeling regulation and a little more than two years after NYC enacted a revised menu labeling rule, a national menu labeling requirement was signed into law by President Barack Obama as part of the Patient Protection and Affordable Care Act in 2010 (the ACA).²¹¹ This section discusses the ACA's menu labeling provisions and FDA's implementing regulations.

²⁰⁶ Arthur, *supra* note 195, at 316.

²⁰⁷ See, e.g., H.R. 2726, 75th Leg. Assemb., Reg. Sess. (Or. 2009); S. 3905, 213th Leg. (N.J. 2009); ME. STAT. tit. 22, § 2500-A (2012); 150 MASS. CODE REGS. § 590.002 (2009); VT. STAT. ANN. tit. 18, § 4086 (West 2011); see also BRETON PERMESLY & SUZANNE TRIGG, AM. BAR ASS'N, MENU LABELING—"CHEESE FRIES FOR 700 CALORIES, PLEASE" (2016).

²⁰⁸ See, e.g., OR. REV. STAT. § 616.585 (2017) (providing that "[a] local government may not adopt or enforce a local requirement for the determination or disclosure of nutritional information by a restaurant"); N.J. STAT. ANN. § 26:3E-17(k) (West 2012) (providing that the menu labeling law "shall occupy the entire field of regulation regarding the disclosure of caloric information by a retail food establishment").

²⁰⁹ AMALIA K. CORBY-EDWARDS, CONG. RESEARCH SERV., NUTRITION LABELING OF RESTAURANT MENUS 3 (2012).

²¹⁰ *Id.*; see also N.J. STAT. ANN. § 26:3E-17.

²¹¹ Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, § 4205, 124 Stat. 119 (2010) (codified as amended at Federal Food, Drug, and Cosmetic Act (FDCA) §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343, 343-1 (2012)).

Although Section 4205 of the ACA is the first federal menu labeling law, efforts to enact a federal menu labeling law began at least a decade earlier. In 2003, Representative Rosa DeLauro introduced legislation to create the Menu Education and Labeling Act (MEAL Act).²¹² In subsequent years, other legislators introduced additional menu labeling bills, including the Labeling Education and Nutrition Act (LEAN Act).²¹³ None of the menu labeling bills discussed above that preceded Section 4205 of the ACA, however, were enacted.

Nevertheless, there are some important similarities between these early bills, which focused on the provision of calorie information on menus and menu boards by chain restaurants, and NYC's menu labeling rules and Section 4205 of the ACA.²¹⁴ Similarly, the MEAL Act would have required restaurants that were part of a chain with twenty or more locations doing business under the same name to disclose calorie information and certain additional nutrition information on menus, menu boards, and other signs.²¹⁵ Dissimilarly, however, the MEAL Act—unlike Section 4205—would have established a federal floor for menu labeling, as it would not have preempted state and local requirements that covered establishments provide additional nutrition information.²¹⁶

The LEAN Act was similar to the MEAL Act in that it would have required chain food service establishments operating twenty or more establishments under the same name to disclose calorie information.²¹⁷ And, like section 4205 of the ACA, the LEAN Act would have preempted nonidentical state and local menu labeling requirements for

²¹² See Menu Education & Labeling Act (MEAL Act), H.R. 3444, 108th Cong. (2003); see also MEAL Act, S. 2108, 108th Cong. (2004).

²¹³ See, e.g., Labeling Education and Nutrition Act of 2008 (LEAN Act), H.R. 7187, 110th Cong. (2008); LEAN Act, S. 3575, 110th Cong. (2008); Howard M. Metzenbaum Menu Education and Labeling Act, S. 1048, 111th Cong. (2009).

²¹⁴ Compare N.Y.C., N.Y., HEALTH CODE § 81.50 (2006), N.Y.C., N.Y., HEALTH CODE (2008), and FDCA §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4), with H.R. 3444.

²¹⁵ H.R. 3444.

²¹⁶ See Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,249 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101) (stating that FDA “interpret[s] the provisions of section 4205 of the ACA related to preemption to mean that States and local governments may not impose nutrition labeling requirements for food sold in a covered establishment . . . unless the . . . requirements are identical to the Federal requirements”). Compare N.Y.C., N.Y., HEALTH CODE § 81.50 (2006), N.Y.C., N.Y., HEALTH CODE (2008), and FDCA §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4), with H.R. 3444.

²¹⁷ Compare H.R. 3444, with S. 3575.

covered establishments.²¹⁸ The NRA and other trade associations supported the LEAN Act.²¹⁹ Less than a month after bills to create the LEAN Act were introduced, the Coalition for Responsible Nutrition Information (CRNI), which includes the NRA, issued a press release announcing support for “[a] *uniform* national nutrition standard” that is “*efficient* and effective.”²²⁰

The NRA supported Section 4205 of the ACA. The NRA described Section 4205 as “a win for both consumers and restaurateurs,” noting that the law would replace the “confusing” patchwork of “regulations and laws a growing number of cities, counties and states have passed,” which posed burdens for restaurateurs.²²¹

Section 4205 amended the FDCA to require nutrition labeling of standard menu items at chain restaurants.²²² Specifically, a “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” must disclose calorie information for standard menu items as well as daily caloric intake information on menus and menu boards.²²³ Section 4205 also requires that specific, identified nutritional information be available to the consumer in a written form upon request.²²⁴ The required disclosures must be done “in a clear and conspicuous manner.”²²⁵ Section 4205 excludes certain foods from its requirements, including items not

²¹⁸ Compare FDCA §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4), with S. 3575; see also Food Labeling, 79 Fed. Reg. at 71,248.

²¹⁹ See Jodi Schuette Green, *Cheeseburger in Paradise? An Analysis of How New York State Restaurant Association v. New York City Board of Health May Reform Our Fast Food Nation*, 59 DEPAUL L. REV. 733, 744 (2010).

²²⁰ News Release, Nat’l Rest. Ass’n, New Coalition Advocates National Nutrition Standard for Chain Restaurants, (Oct. 22, 2008), <https://www.restaurant.org/Pressroom/Press-Releases/New-Coalition-Advocates-National-Nutrition-Standar> [<https://web.archive.org/web/20090125221110/http://restaurant.org:80/pressroom/pressrelease.cfm?ID=1702>] (emphasis added); see also Green, *supra* note 219, at 744.

²²¹ *Issue: Nutrition Disclosure, Overview: The National Restaurant Association Believes a New Federal Nutrition-Disclosure Standard for Restaurants is a Win for Both Restaurant Operators and Guests*, NRA, PUBLIC POLICY ISSUE BRIEFS, <https://web.archive.org/web/20100405191521/http://www.restaurant.org/advocacy/issues/issue/?Issue=menulabel> (accessing Internet Archive from Apr. 5, 2010). There has been, however, continuing opposition to Section 4205 and FDA’s menu labeling regulations. See, e.g., *infra* note 258.

²²² FDCA § 403(q)(5)(H), 21 U.S.C. § 343(q)(5)(H).

²²³ § 343(q)(5)(H)(i)–(ii). The Act also establishes requirements for self-service food and beverages and vending machines. § 343(q)(5)(H)(iii), (viii).

²²⁴ § 343(q)(5)(H)(ii)(III).

²²⁵ § 343(q)(5)(H)(ii)(I)–(IV).

identified on a menu or menu board, daily specials, custom orders, and certain temporary and test foods.²²⁶ If the required menu labeling is not provided, the food is “deemed to be misbranded.”²²⁷ A restaurant that is not required to have menu labeling can voluntarily opt into the menu labeling requirements.²²⁸ And, as noted earlier, the menu labeling law expressly preempts certain state and local laws.²²⁹

2. Regulations

Section 4205 directed the Secretary of Health and Human Services to promulgate proposed regulations to carry out its provisions.²³⁰ Accordingly in 2011, following a request for comments on the implementation of the ACA’s menu labeling provisions,²³¹ FDA proposed regulations.²³² A significant portion of FDA’s proposal focused on defining terms needed “[t]o establish the scope of establishments, labeling, and food covered by section 4205.”²³³ The proposal also discussed whether a “similar retail establishment” should include “grocery and convenience stores, as well as entities such as movie theaters, bowling alleys, bookstore cafes, and all establishments that sell restaurant-like food to consumers.”²³⁴ It also considered the definition of restaurant-type food and whether it should include “grab-and-go items.”²³⁵ The proposal further discussed how “the primary writing” in Section 4205’s definition of “menu or menu boards” should

²²⁶ § 343(q)(5)(H)(vii)(I)(aa)–(cc).

²²⁷ See § 343; see also Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Food Establishments, 76 Fed. Reg. 19,192, 19,193 (proposed Apr. 6, 2011) (codified at 21 C.F.R. pts. 11, 101).

²²⁸ § 343(q)(5)(H).

²²⁹ FDCA § 403A(a)(4), 21 U.S.C. § 343-1(a)(4).

²³⁰ § 343(q)(5)(H)(x).

²³¹ Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold from Vending Machines, 75 Fed. Reg. 39,026 (July 7, 2010); Notice of Meeting, 75 Fed. Reg. 43,182 (July 23, 2010).

²³² Food Labeling, 76 Fed. Reg. at 19,192. FDA published guidance on the preemptive effect of the federal menu labeling law on state and local laws and a draft guidance on the implementation of the menu labeling law, the latter of which was withdrawn. See Guidance for Industry: Questions and Answers Regarding the Effect of Section 4205 of the Patient Protection and Affordable Care Act of 2010 on State and Local Menu and Vending Machine Labeling Laws; Availability, 75 Fed. Reg. 52,426, 52,427 (Aug. 25, 2010); Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010; Withdrawal of Draft Guidance, 76 Fed. Reg. 4360-01 (Jan. 25, 2011).

²³³ Food Labeling, 76 Fed. Reg. at 19,195, 19,232.

²³⁴ See CORBY-EDWARDS, *supra* note 209, at 9.

²³⁵ See *id.* at 12.

be interpreted and whether it should be viewed from a customer's perspective.²³⁶

Congress did not define "restaurant or similar retail establishment,"²³⁷ despite the importance of this term in setting forth the scope of the covered establishments. FDA noted in the preamble to its final rule that the legislative history of Section 4205 is "very sparse" and that, on the few occasions Section 4205 was discussed, "few specifics were raised, including specifics about the scope of the law."²³⁸ In light of Congress's silence and the "ambiguity in the statute as to the breadth of the set of establishments covered," FDA defined a "restaurant or similar retail establishment" as "a retail establishment that offers for sale restaurant-type food, except if it is a school."²³⁹ This definition includes "bakeries, cafeterias, coffee shops, convenience stores, delicatessens, food service facilities located within entertainment venues . . . , food service vendors . . . , food take-out and/or delivery establishments . . . , grocery stores, retail confectionary stores, superstores, quick service restaurants, and table service restaurants . . . if they sell restaurant-type food."²⁴⁰ In explaining the inclusion of grocery stores that meet the other requirements of Section 4205, FDA favorably referenced comments that noted that grocery stores "sell a great deal of food for immediate consumption" and are "increasingly offering for sale restaurant-type food."²⁴¹

FDA defined "restaurant-type food," a term that does not appear in the statute,²⁴² as "food that is usually eaten on the premises, while walking away, or soon after arriving at another location."²⁴³ This food may be traditional restaurant food or bulk food used to prepare restaurant food.²⁴⁴ It may also be the aforementioned foods

²³⁶ *Id.* at 13.

²³⁷ See Food, Drug, and Cosmetic Act (FDCA) §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4) (2012); Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,165 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101).

²³⁸ Food Labeling, 79 Fed. Reg. at 71,166.

²³⁹ See FDCA §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4); Food Labeling, 79 Fed. Reg. at 71,165, 71,164, 71,168, 71,254 (defining "restaurant or similar retail food establishment").

²⁴⁰ *Id.* at 71,164.

²⁴¹ *Id.* at 71,166–68.

²⁴² See FDCA §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4).

²⁴³ Food Labeling, 79 Fed. Reg. at 71,254 (codified at 21 C.F.R. § 101.11(a)).

²⁴⁴ *Id.* (providing that restaurant-type food may be "[s]erved in restaurants or other establishments in which food is served for immediate human consumption or which is sold for use in such establishments").

“[p]rocessed and prepared primarily in a retail establishment, ready for human consumption, . . . and offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment.”²⁴⁵ Hence, FDA stated that the final definition of restaurant-type food “focuses on those establishments that offer for sale food that is most like food served in restaurants.”²⁴⁶

Congress defined “menu” and “menu board” as “the primary writing of the restaurant or other similar retail establishment from which a consumer makes an order selection”; however, it did not define the primary writing.²⁴⁷ FDA defined “menu or menu board” broadly in light of “the importance for all consumers to have access to nutrition information when making order selections.”²⁴⁸ It interpreted “‘primary writing’ . . . from a consumer’s vantage point” and concluded that this term “can include more than one form of written material.”²⁴⁹ In addition, it stated that “menu” and “menu board” include “any writing of the covered establishment that is the primary writing from which a consumer makes an order selection.”²⁵⁰

3. Compliance Date

After FDA finalized the menu labeling rule, FDA and Congress delayed the original January 1, 2015, compliance date.²⁵¹ Eventually

²⁴⁵ *Id.* The final rules also define other terms, including “doing business under the same name” and “offering for sale substantially the same menu items.” *Id.*

²⁴⁶ *Id.* at 71,166.

²⁴⁷ See FDCA § 403(q)(5)(H)(xi), 21 U.S.C. § 343(q)(5)(H)(xi).

²⁴⁸ Food Labeling, 79 Fed. Reg. at 71,177; see also *id.* at 71,209–10 (responding to comments expressing concerns about space constraints on menus and menu boards).

²⁴⁹ *Id.* at 71,176–77 (citing Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Food Establishments, 76 Fed. Reg. 19,192, 19,202 (proposed Apr. 6, 2011) (codified at 21 C.F.R. pts. 11, 101)).

²⁵⁰ *Id.* at 71,177.

²⁵¹ See *id.* at 71,241; Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, § 747, 129 Stat. 2242, 2282 (2015) (“None of the funds made available [by that] Act may be used to implement, administer, or enforce the final rule . . . until the later of—(1) December 1, 2016; or (2) the date that is one year after the date on which the Secretary of Health and Human Services publishes Level 1 guidance with respect to nutrition labeling”); Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date, 80 Fed. Reg. 39,675 (July 10, 2015) (extending compliance date to Dec. 1, 2016); A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II (Menu Labeling Requirements in Accordance With the Patient Protection Affordable Care Act of 2010); Guidance for Industry; Availability, 81 Fed. Reg. 27,067 (May 5, 2016) (announcing availability of guidance and that enforcement will begin on May 5, 2017); Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food

FDA set May 7, 2018, as the final compliance date.²⁵² FDA extended the compliance date once in response to “concerns that covered establishments [would] not have adequate time to fully implement the requirements of the rule by the compliance date.”²⁵³ Congress then further delayed the compliance date by prohibiting FDA from using any of the funds under the Consolidated Appropriations Act of 2016 to implement, administer, or enforce FDA’s final rule until one year after it published guidance on the rule.²⁵⁴

Following the change of administrations in January 2017, FDA further extended the compliance date for the rule to May 7, 2018.²⁵⁵ Although the interim final rule announcing the extension raised questions about the future of the final rule,²⁵⁶ in November 2017 FDA released draft guidance responding to comments on the implementation of the menu labeling regulation that indicated that FDA planned to finalize the guidance “to provide clarity to the industry on [the] remaining questions ahead of the [May 7, 2018, compliance date].”²⁵⁷ FDA Commissioner Scott Gottlieb stated that the draft guidance was intended “to make sure implementation of the new menu labeling requirements goes forward on [FDA’s] stated timeframe and succeeds for the long-term.”²⁵⁸

Establishments; Extension of Compliance Date, 81 Fed. Reg. 96,364 (Dec. 30, 2016) (formally extending the compliance date to May 5, 2017).

²⁵² Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments, 82 Fed. Reg. 20,825 (May 4, 2017).

²⁵³ Extension of Compliance Date, 80 Fed. Reg. at 39,676.

²⁵⁴ Extension of Compliance Date, 81 Fed. Reg. at 96,365; Consolidated Appropriations Act of 2016 § 747.

²⁵⁵ Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Request for Comments, 82 Fed. Reg. at 20,825.

²⁵⁶ *Id.* at 20,827 (stating that FDA was “reconsider[ing] the rule consistent with” several Executive Orders aimed at “reducing burdens, reducing costs, maintaining flexibility, and improving effectiveness”).

²⁵⁷ FDA, MENU LABELING: SUPPLEMENTAL GUIDANCE FOR INDUSTRY: DRAFT GUIDANCE 4 (Nov. 2017); *see also* FDA, MENU LABELING: SUPPLEMENTAL GUIDANCE FOR INDUSTRY (May 2018).

²⁵⁸ Statement from Scott Gottlieb, Comm’r, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on a Practical Approach to Ensuring Timely Implementation of FDA’s Menu Labeling Rule (Nov. 7, 2017), <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm584147.htm>. Efforts to repeal certain portions of the ACA have not generally included Section 4205, but since 2012, bills to create a “Common Sense Nutrition Disclosure Act” have been introduced in the United States House of Representatives and Senate. *See, e.g.*, Common Sense Nutrition Disclosure Act of 2012, H.R. 6174, 112th Cong. (2012). If enacted, the Common Sense Nutrition Disclosure Act

Despite the delays, the menu labeling law had an impact even before the final May 7, 2018, compliance date. Some restaurants announced that they would provide menu labeling in advance of FDA's enforcement of the menu labeling requirements.²⁵⁹ For example, in September 2012, McDonald's announced that it would start listing calorie information on menus that month.²⁶⁰ Subway announced that it would do the same in April 2016.²⁶¹ In addition, other restaurants implemented menu labeling in anticipation of an earlier compliance date.²⁶²

Section 4205 of the ACA, FDA's final menu labeling rule, and the debate about (and challenges to) menu labeling should inform the regulation of food allergen labeling and management in restaurants. This Article now turns to the regulation of food allergens.

III

CREATING A FRAMEWORK FOR THE REGULATION OF FOOD ALLERGEN LABELING AND MANAGEMENT IN RESTAURANTS

Although the existing literature describes the problem of food allergens in restaurants, it has not fully explored potential solutions.²⁶³

would amend the FDCA, among other things, to permit the calorie disclosure required under Section 4205 of the ACA to represent the calories in the whole menu item, per a serving, or per common unit division. Common Sense Nutrition Disclosure Act of 2017, H.R. 772, 115th Cong. (2018); Common Sense Nutrition Disclosure Act of 2017, S. 261, 115th Cong. (2017). It would also permit the calorie information to be provided solely by a menu on the internet where the majority of the restaurant's orders are placed by customers who are not on the premises at the time of order. H.R. 772 (passed House of Representatives Feb. 6, 2018); S. 261. And it would limit restaurants' liability for violations. H.R. 772; S. 261. Earlier versions of the bill contained a provision that would have limited the definition of "restaurant or similar retail establishment" to retail establishments that derive more than 50% of their total revenue from the sale of restaurant-type food. Common Sense Nutrition Disclosure Act of 2013, H.R. 1249, 113th Cong. (2013); Common Sense Nutrition Disclosure Act of 2013, S. 1756, 113th Cong. (2013).

²⁵⁹ See Helena Bottemiller Evich, *Trump's Delay of Calorie-Posting Rule Jolts Restaurants*, POLITICO (May 27, 2017, 6:49 AM), <https://www.politico.com/story/2017/05/27/trump-restaurant-calorie-posting-rule-238873>.

²⁶⁰ See Press Release, McDonald's, McDonald's USA Adding Calorie Counts to Menu Boards, Innovating with Recommended Food Groups, Publishes Nutrition Progress Report (Sept. 12, 2012), <https://www.prnewswire.com/news-releases/mcdonalds-usa-adding-calorie-counts-to-menu-boards-innovating-with-recommended-food-groups-publishes-nutrition-progress-report-169451836.html>.

²⁶¹ John Kell, *Subway to Add Calorie Information to All U.S. Menus*, FORTUNE (Apr. 5, 2016), <http://fortune.com/2016/04/05/subway-calories-us-menus/>.

²⁶² See Evich, *supra* note 259.

²⁶³ See, e.g., Brewer, *supra* note 123, at 312 (proposing "a state law . . . that is bifurcated into mandatory provisions for all Ohio restaurants and a voluntary provision creating an official designation of Food Allergy Friendly"); Derr, *supra* note 10 (discussing potential

There is no need to start from scratch in designing a regulatory framework to address food allergens in restaurants. Rather, lawmakers should look to menu labeling as a potential model for food allergen labeling and use menu labeling to inform both the substantive requirements and implementation of food allergen measures.

Using menu labeling as a guide, this Part argues that restaurants and similar retail establishments should be required to provide labeling and information about major food allergens and implement measures, including worker training, to prevent allergen cross contact and ensure accurate labeling.²⁶⁴ This Part also explores how menu labeling can help anticipate and respond to potential opposition to allergen requirements. It begins by setting forth a basic framework for food allergen labeling and accompanying measures and then considers potential benefits of this approach and responds to anticipated critiques. Part IV then considers how the implementation of menu labeling can inform the implementation of food allergen labeling and management measures.

A. A Proposed Framework for Food Allergen Regulation

1. Using Menu Labeling as a Model

There are several similarities between the menu labeling and allergen labeling contexts, which make the regulation of nutrition labeling an apt model for the regulation of allergen labeling.²⁶⁵ First, the growth in foods prepared outside the home that made the need for menu labeling more acute²⁶⁶ is the same growth that makes addressing

reforms including revision of the Food Code, ingredient or allergen disclosure, and training); Roses, *supra* note 64 (arguing for federal legislation giving FDA the power to regulate food allergen labeling in restaurants); Martin, *supra* note 64, at 85 (arguing for federal legislation “which requires training, open conversation between the allergy sufferer and the server, . . . the posting of information. . . . menu labeling, mandatory safety regulations for kitchens, and bolstering emergency response to allergic reactions”).

²⁶⁴ This Article uses the term restaurant in the discussion below to refer to restaurants and similar retail establishments unless discussing another source that uses the term differently.

²⁶⁵ There are of course limitations to this model, chief among them the need to prevent cross contact, which arises in the allergen but not the nutrition context. *See infra* Section III.A.3.

²⁶⁶ *See* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192, 19,192 (proposed Apr. 6, 2011) (codified at 21 C.F.R. pts. 11, 101) (“Americans now consume an estimated one-third of their total calories on foods prepared outside the home and now spend almost half of their annual food dollars on foods prepared outside the home.”) (internal citations omitted); Bernell, *supra* note 170, at 841–42.

food allergen labeling and management in restaurants so important.²⁶⁷

Second, current food allergen labeling regulation is similar to the regulation of nutrition labeling prior to the enactment of the Affordable Care Act (ACA) menu labeling provisions. Before the enactment of those provisions, labeling requirements were generally more stringent for foods in packaged form than for restaurant-type foods: calorie and certain other nutritional information was generally not required for restaurant-type foods. Specifically, before the ACA, the FDCA generally provided that food in packaged form is “misbranded unless its label or labeling bears nutrition information” but included exemptions for food sold in restaurants.²⁶⁸

Similarly, in the allergen context, the FDCA requires the labeling of major food allergens for packaged food, but there is no comparable requirement for restaurant-type food.²⁶⁹ As one United States Senator remarked in the menu labeling context, “It makes no sense that American consumers can go to a grocery store and find nutrition information on just about anything, but then they are totally in the dark when they go to a restaurant for dinner.”²⁷⁰ The same can be said regarding major food allergen information. Congress enacted menu labeling requirements for certain chain restaurants in the 2010 ACA and, in so doing, took a significant step toward making nutrition information available for standard menu items at these establishments.²⁷¹ The gap in allergy labeling for restaurant-type food, however, remains.²⁷²

Third, both the lack of menu labeling information pre-ACA and the current lack of allergen labeling create a situation where consumers may be unaware of certain characteristics of the food they are consuming—nutrition information in the menu labeling context and

²⁶⁷ See *supra* Section I.A.

²⁶⁸ Food, Drug, and Cosmetic Act (FDCA) § 403(q)(5)(A)(i)–(ii), 21 U.S.C. § 343(q)(5)(A)(i)–(ii) (2006). The ACA amended these exemptions. See FDCA 403(q)(5)(A)(i)–(ii), 21 U.S.C. § 343(q)(5)(A)(i)–(ii) (2012).

²⁶⁹ FDCA § 403(w), 21 U.S.C. § 343(w); see also *supra* Section I.B.

²⁷⁰ Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,167 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101) (quoting Senator Harkin, 155 CONG. REC. S5522 (May 14, 2009)).

²⁷¹ See Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, § 4205, 124 Stat. 119 (2010); see also Arthur, *supra* note 195, at 313 (drawing an analogy “between putting a restaurant’s nutrition information at the point of purchase and labeling food products sold in a grocery store”).

²⁷² See FDCA § 403(w), 21 U.S.C. § 343(w); see also FDA *Questions and Answers*, *supra* note 64.

food allergen information in the food allergen context.²⁷³ In both situations, the lack of information is linked to health risks. The overconsumption of calories is a risk factor for being overweight and obese, which in turn increase the risk of certain chronic health diseases, including coronary heart disease and type two diabetes.²⁷⁴ The consumption of a food containing an allergen puts people with food allergies at risk of an allergic reaction.²⁷⁵ Both menu labeling and allergen labeling aim to increase the amount of information available to consumers so they can make better-informed choices about which foods they eat to try to reduce negative health consequences.²⁷⁶

Although there are many similarities between the nutrition labeling and allergy labeling contexts, one of the primary objections to menu labeling—that it may not change people’s food choices and reduce the number of calories consumed—is unlikely to carry over to the food allergen context.²⁷⁷ This is because although a consumer might not change her food choices today to reduce the possibility of developing a chronic disease in the future,²⁷⁸ a consumer with a food allergy that is immediate and possibly life-threatening may go to great lengths to avoid the allergen.²⁷⁹

²⁷³ See Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192, 19,192 (Apr. 6, 2011) (codified at 21 C.F.R. pts. 11, 101) (“Consumers are generally unaware of, or inaccurately estimate, the number of calories in restaurant foods. In one survey of 193 adults, the participants underestimated the calorie content in foods prepared outside of the home they perceived to be “healthier” food choices by nearly half, an average of almost 650 calories per item.”) (internal citations omitted).

²⁷⁴ Food Labeling, 79 Fed. Reg. at 71,156.

²⁷⁵ See Section I.A.

²⁷⁶ See H.R. REP. NO. 111-299, pt. 1, at 738 (2009).

²⁷⁷ See, e.g., Lauren Slive, Note, *Closing the Kitchen? Digesting the Impact of the Federal Menu Labeling Law in the Affordable Care Act*, 22 U. FLA. J.L. & PUB. POL’Y 255, 263 (2011) (noting “[e]arly evidence regarding the effectiveness of calorie disclosures on menus to influence healthier choices has been mixed”); Bernell, *supra* note 170, at 868 (discussing studies on the impact of New York City’s Regulation 81.50). Other critiques of menu labeling are discussed in Section III.B.2 *infra*.

²⁷⁸ See David Orentlicher, *Health Care Reform and Efforts to Encourage Healthy Choices by Individuals*, 92 N.C. L. REV. 1637, 1643 (2014) (stating that “it often is difficult for people to exercise self-control when weighing present costs and benefits with future costs and benefits”).

²⁷⁹ See Boyce et al., *supra* note 1, at 63. *But see* Greenhawt et al., *supra* note 56, at 326 (noting the majority of the college students who responded to the survey “reported that they did not always avoid the food item to which they reported an allergy”); Sampson et al., *supra* note 56, at 1442 (noting that a majority of the adolescent and young adult respondents “admitted to eating at least a tiny amount of a food that was known to contain an allergen”).

In addition, although menu labeling has been the subject of much debate and criticism,²⁸⁰ this may be an asset for those seeking to create and implement allergen labeling and management requirements. Proponents of allergen labeling can look to menu labeling to help them anticipate and respond to arguments that are likely to arise in the allergen context. Indeed, the regulation of allergen labeling in restaurants is likely to raise questions similar to those already addressed in the menu labeling context. These questions include: What establishments should be covered? How should any disclosure requirements be made feasible for covered establishments? How should allergen information be made accessible and understandable to consumers?²⁸¹ This Article now turns to these questions.

2. Labeling Food Allergens

Although any allergen labeling requirements must comply with any applicable procedural requirements—such as those for legislation and notice-and-comment rulemaking—and these procedural requirements will likely improve any resulting framework, there is no need to reinvent the wheel. Congress and FDA have already considered the menu labeling requirements.²⁸² Accordingly, this Article proposes that, like 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.”²⁸³ In addition, like the menu labeling provisions

²⁸⁰ See, e.g., Slive, *supra* note 277, at 294; Christine Cusick, *Menu-Labeling Laws: A Move from Local to National Regulation*, 51 SANTA CLARA L. REV. 989, 1004 (2011); Kindel, *supra* note 171, at 264.

²⁸¹ See Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156 (Dec. 1, 2014) (codified at 21 C.F.R. pts 11, 101); Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192 (proposed Apr. 6, 2011) (codified at 21 C.F.R. pts 11, 101); Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold from Vending Machines, 75 Fed. Reg. 39,026 (July 7, 2010).

²⁸² See Food, Drug, and Cosmetic Act (FDCA) §§ 403(q)(5)(H), 403A(a)(4), 21 U.S.C. §§ 343(q)(5)(H), 343-1(a)(4) (2012); Food Labeling, 79 Fed. Reg. at 71,156 (final rule); Food Labeling, 76 Fed. Reg. at 19,192 (proposed rule); Disclosure of Nutrient Content Information, 75 Fed. Reg. at 39,026; see also Food Labeling, 79 Fed. Reg. at 71,167 (final rule) (noting the “very sparse” legislative history of section 4205).

²⁸³ See FDCA § 403(q)(5)(H)(i), 21 U.S.C. § 343(q)(5)(H)(i); see also Food Labeling, 79 Fed. Reg. at 71,253–54 (defining covered establishment) (codified at 21 C.F.R. § 101.11(a)).

which permit an establishment to voluntarily opt in to the menu labeling requirements,²⁸⁴ any allergen labeling and management requirements should permit establishments that do not meet the mandatory coverage requirements to opt in to become a covered establishment.²⁸⁵

Covered establishments should be prominently identified as such. In addition, covered establishments should indicate that written allergen information is available upon request and should be required to provide accurate labeling indicating whether or not a “major food allergen” is present in a given food upon request.²⁸⁶ The labeling requirement could apply to standard menu items, like the ACA menu labeling, or it could apply to all restaurant-type foods.²⁸⁷ Requiring labeling regarding major food allergens would cover a substantial portion of the documented food allergies in the United States and “the foods most likely to result in severe or life-threatening reactions.”²⁸⁸ It would also help to eliminate information deficit with respect to food allergens in restaurants and bring the requirements for nonpackaged foods in restaurants closer to those for packaged foods.

The notice and provision of information requirements also could be modeled on menu labeling, which requires that all forms of the menu and menu board include a clear and conspicuous statement about the availability of additional written nutrition information for standard menu items upon request and that such information be provided upon request.²⁸⁹ In addition, although the focus of this Article is on food

²⁸⁴ FDCA § 403(q)(5)(H)(ix), 21 U.S.C. § 343(q)(5)(H)(ix); Food Labeling, 79 Fed. Reg. at 71,258 (codified at 21 C.F.R. § 101.11(d)). In the preamble to the final menu labeling rule, FDA noted that it had not received any voluntary registrations from restaurants or similar retail food establishments opting in to menu labeling coverage. Food Labeling, 79 Fed. Reg. at 71,245.

²⁸⁵ See Food Labeling, 79 Fed. Reg. at 71,253 (codified at 21 C.F.R. § 101.11(a)) (defining covered establishment for menu labeling).

²⁸⁶ See FDCA §§ 201(qq), 403(q)(5)(H)(ii)(III)–(IV), 21 U.S.C. §§ 321(qq), 343(q)(5)(H)(ii)(III)–(IV).

²⁸⁷ FDCA § 403(q)(5)(H)(i), 21 U.S.C. § 343(q)(5)(H)(i). In the menu labeling context, FDA has defined “standard menu items” as “restaurant-type food that is routinely included on a menu or menu board or routinely offered as self-service food or food on display.” Food Labeling, 79 Fed. Reg. at 71,254. The preamble to the final menu labeling rule identifies “condiments, daily specials, temporary menu items, custom orders, . . . food that is part of a customary market test; and self-service food and food on display that is offered for sale for less than a total of 60 days per calendar year or fewer than 90 consecutive days in order to test consumer acceptance” as items that are not standard menu items. Food Labeling, 79 Fed. Reg. at 71,158.

²⁸⁸ *Id.*; FDA *Questions and Answers*, *supra* note 64.

²⁸⁹ 21 C.F.R. § 101.11(b)(2)(ii).

allergen labeling, foods should also be subject to measures to prevent allergen cross contact as discussed below.²⁹⁰

3. Preventing Cross Contact

One important limitation of nutrition menu labeling as a model for the regulation of food allergens in restaurants is that, in the food allergen context, labeling major food allergens alone is not sufficient to protect individuals with a food allergy.²⁹¹ In fact, requiring labeling of major food allergens without accompanying measures to prevent cross contact may increase the risk to allergic individuals. For example, if labeling indicates that a food does not contain peanuts (a major food allergen), but the food has had cross contact with peanuts, the labeling may give a person with a peanut allergy a false assurance of safety. Thus, it is important that any measure to address food allergens require science-based measures to prevent cross contact and ensure accurate labeling. Although preventing cross contact in restaurants may be difficult, and there are a number of decisions that must be made about how to prevent such contact, these difficulties and questions should not be a justification for continued inaction. Instead, existing lawmaking processes should be used to begin to address these challenges and uncertainties.

One possibility would be to require covered restaurants to implement an allergen control plan that uses HACCP principles to control the risks of major food allergens.²⁹² As noted in Section I.C.1, although the Food Code does incorporate HACCP principles and

²⁹⁰ The Author intends to consider more fully in future work the issue of allergen cross contact and management but includes here a brief discussion of one possible approach—the use of HACCP principles along with worker training and public education.

²⁹¹ Menu labeling does require some training. See CORBY-EDWARDS, *supra* note 209, at 16 (discussing costs for employee training in FDA's Preliminary Regulatory Impact Analysis).

²⁹² For a discussion of the components of an allergen control plan for food processing plants, see *Components of an Effective Allergen Control Plan: A Framework for Food Processors*, FOOD ALLERGY RES. & RESOURCE PROGRAM, <https://farrp.unl.edu/3fcc9e7c-9430-4988-99a0-96248e5a28f7.pdf> (last visited Oct. 7, 2018); see also FDA, GUIDANCE FOR INDUSTRY: JUICE HACCP HAZARDS AND CONTROLS GUIDANCE FIRST EDITION (Mar. 2004) (providing guidance regarding HACCP principles for juice processors, including controls for allergens). Principles drawn from HARPC could also inform any requirement. See Food, Drug, and Cosmetic Act §§ 301(uu), 418, 21 U.S.C. §§ 331(uu), 350g (2012); 21 C.F.R. pt. 117; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food, 80 Fed. Reg. 55,908 (Sep. 17, 2015) (codified at scattered sections of 21 C.F.R.).

identifies food allergens as hazards, for the most part, use of HACCP is currently voluntary at the retail level.²⁹³

Although HACCP, which focuses on preventing food safety problems,²⁹⁴ has faced resistance,²⁹⁵ it is “widely recognized as the best approach for improving food safety.”²⁹⁶ It is focused on identifying food safety hazards, identifying the steps to control them, and implementing those steps, including corrective action plans.²⁹⁷

HACCP is based on seven principles: First, conducting an analysis of hazards (i.e., “biological, chemical or physical agent[s] that [are] reasonably likely to cause illness or injury in the absence of [their] control”) such as major food allergens.²⁹⁸ Second, determining critical control points at which preventative measures can be applied to prevent, eliminate, or reduce to an acceptable level a food safety hazard.²⁹⁹ Third, establishing critical limits to which hazards must be controlled.³⁰⁰ Fourth, establishing monitoring procedures “to assess whether a CCP is under control and produce an accurate record for future use in verification.”³⁰¹ Fifth, establishing corrective actions for when a deviation from the HACCP plan occurs. Sixth, establishing verification procedures to “determine the validity of the HACCP plan and that the [HACCP] system is operating according to the plan.”³⁰² And seventh, establishing record-keeping and documentation

²⁹³ FOOD CODE annex 4, at 552, 559 (FDA 2017) (“Food Allergens As Food Safety Hazards”); *see also* FDA, MANAGING FOOD SAFETY: A MANUAL FOR THE VOLUNTARY USE OF HACCP PRINCIPLES FOR OPERATORS OF FOOD SERVICE AND RETAIL ESTABLISHMENTS 6–7 (2006).

²⁹⁴ FDA, HACCP PRINCIPLES & APPLICATION GUIDELINES (1997), <https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm> (last updated Dec. 19, 2017) [hereinafter HACCP GUIDELINES] (defining HACCP as “[a] systematic approach to the identification, evaluation, and control of food safety hazards”); Neal D. Fortin, *The Hang-Up with HACCP: The Resistance to Translating Science into Food Safety Law*, 58 FOOD & DRUG L.J. 565, 567 (2003) [hereinafter Fortin, *The Hang-Up with HACCP*].

²⁹⁵ For a discussion of some of the possible barriers to incorporating HACCP into food safety law, as well as suggestions for how to overcome them, *see also* Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 567, 571 (examining the resistance to HACCP and measures to create a more efficient food safety system).

²⁹⁶ *Id.* at 567. HACCP has been used for juice, fish, and fishery products. *See* 21 C.F.R. pts. 120, 123 (2017).

²⁹⁷ Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 566; HACCP GUIDELINES, *supra* note 294.

²⁹⁸ HACCP GUIDELINES, *supra* note 294; Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 566.

²⁹⁹ HACCP GUIDELINES, *supra* note 294.

³⁰⁰ *Id.*

³⁰¹ *Id.*

³⁰² *Id.*

procedures to document that the system is consistently working correctly.³⁰³ As Neal D. Fortin notes, HACCP as “a science-based, preventative, and risk control system” has several benefits—it “creates a complete system to ensure food safety,” recognizes the food industry’s responsibility for food safety, and represents a “continuous method” of food safety—but its “preventative nature may be its most significant design achievement.”³⁰⁴ Before implementing HACCP principles, restaurants should have systems in place to control their basic operational and sanitation conditions.³⁰⁵ Therefore, any HACCP requirement should include a requirement that appropriate prerequisite programs are in place.

4. *Training Employees*

As noted in Section I.A, servers may be overly confident that they know how, and are able to, safely serve a customer with a food allergy.³⁰⁶ In addition, despite the Food Code’s recommendations, as also noted in Section I.A, a study of restaurant food allergy practices in six cities found that only 44.4% of restaurant managers, 40.8% of food workers, and 33.3% of servers surveyed “reported that they had received training on food allergies while working at their respective restaurants.”³⁰⁷ These knowledge and training gaps underscore the need for required food allergy training for food workers. Any allergen labeling and management requirements should include empirically tested comprehensive food allergy training for workers as well as establishment-specific training on the restaurant’s policies, processes, and procedures.³⁰⁸

5. *Recognizing the Role of Consumers*

Consumers also have an important role to play with respect to food allergen safety in restaurants as studies have shown that people with food allergies may not inform restaurants of their allergies. For example, one study of registrants with seafood allergies reporting restaurant reactions found that “[o]nly 21% [of the participants] with a

³⁰³ *Id.*; Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 566.

³⁰⁴ Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 567–68.

³⁰⁵ HACCP GUIDELINES, *supra* note 294 (“The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs.”).

³⁰⁶ *See supra* Section I.A; Ahuja & Sicherer, *supra* note 51; Dupuis et al., *supra* note 33.

³⁰⁷ Radke et al., *supra* note 3, at 404.

³⁰⁸ *See* Dupuis, *supra* note 33, at 153.

known allergy disclosed their allergy to the restaurant.”³⁰⁹ A study of allergic reactions to peanuts and tree nuts in restaurants and other food establishments found that “[o]f 106 registrants with previously diagnosed allergy who ordered food specifically for ingestion by the allergic individual, only 45% gave prior notification about the allergy to the establishment.”³¹⁰ And a study of deaths from food-induced anaphylaxis noted that twelve of the thirty-one fatalities identified between 2001 and 2006 “were caused by individuals with [a] peanut or tree nut allergy consuming desserts . . . prepared away from home, and without having properly inquired about the ingredients.”³¹¹

Accordingly, consumers should be prompted to inform their server of their allergy. This could be done through a written notice on menus and menu boards. Again, menu labeling, which requires a notice of the significance of calorie information as well as the availability of additional nutritional information, may be instructive with respect to the placement of the notice.³¹² The Massachusetts allergy law could also inform any such requirement; it requires a notice on printed menus and menu boards stating, “Before placing your order, please inform your server if a person in your party has a food allergy.”³¹³

B. Discussion

1. Potential Benefits

Adopting food allergen labeling and management requirements may reduce injuries and deaths due to allergic reactions to restaurant

³⁰⁹ T.J. Furlong, *Seafood Allergic Reactions in Restaurants*, 117 J. ALLERGY & CLINICAL IMMUNOLOGY S41 (2006).

³¹⁰ Furlong et al., *supra* note 4, 867–68. Customers may not inform restaurants of their allergy because they are concerned about “the social implications of disclosing their nut-allergic status” and do not want to be seen as “simply being fussy or picky about what they ate.” Leftwich et al., *supra* note 31, at 248. In addition, customers with allergies may “fear[] a conservative reaction from restaurant staff that would inappropriately and unnecessarily further constrain an already restricted range of food choices.” *Id.*

³¹¹ Bock et al., *supra* note 33, at 1016; *see also* Furlong et al., *supra* note 4, at 868 (also noting that in 78% of the allergic reactions associated with a food establishment “the episode was caused by a food that was known by someone in the establishment to contain [peanut] or [tree nut] as an ingredient”).

³¹² Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,256 (Dec. 1, 2014) (codified at 21 C.F.R. § 101.11(b)(9)); *see also id.* at 71,254 (codified at 21 C.F.R. § 101.11(a)) (defining menu or menu board); *id.* at 71,209–10 (responding to comments expressing concerns about space constraints on menus and menu boards).

³¹³ 105 MASS. CODE REGS. 590.009 (2017).

food.³¹⁴ In addition to potentially advancing public health, these proposed changes would respect the autonomy of people with food allergies. This proposal may expand the food choices for people with food allergies by providing them access to information about major food allergens in many restaurant foods to enable them to make better-informed decisions about where and what to eat. Expanding access to information to facilitate more informed and hopefully better consumer choices is, similarly, a primary aim of menu labeling.³¹⁵ If the mandatory coverage of any food allergen requirements was identical to that of federal menu labeling, the requirements would cover approximately 298,600 establishments in 2130 chains.³¹⁶

Without these measures, people with food allergies may be unable to obtain accurate information about the risk that restaurant foods may pose.³¹⁷ Allergen labeling and management requirements may also enhance the ability of those with food allergies to participate in everyday life activities because restaurants do far more than simply provide food: they serve as locations for social and business activities, help facilitate travel, and affect culture.³¹⁸ Requiring restaurants to provide labeling and adopt measures to prevent cross contact may decrease the risks that restaurants pose for people with food allergies and reduce accidental allergen exposures and the concomitant costs.³¹⁹

³¹⁴ See Section I.A.

³¹⁵ See, e.g., Arthur, *supra* note 195, at 312; Bernell, *supra* note 170, at 843; Michelle I. Banker, *I Saw the Sign: The New Federal Menu-Labeling Law and Lessons from Local Experience*, 65 FOOD & DRUG L.J. 901, 916 (2010). Proponents of menu labeling also argued that “it may encourage restaurants to reduce the calories in standard menu items, reduce portion sizes, or offer new healthy alternatives.” See Banker, *supra*, at 917; see also ELISE GOLAN ET AL., U.S. DEP’T OF AGRIC., NO. 793, AGRICULTURAL ECONOMIC REPORT, ECONOMICS OF FOOD LABELING 16 (2000) (noting that one “type of benefit arising from government intervention in labeling could be those stemming from product reformulation”).

³¹⁶ See FDA, FDA-2011-F-0172, FOOD LABELING: NUTRITION LABELING OF STANDARD MENU ITEMS IN RESTAURANTS AND SIMILAR RETAIL ESTABLISHMENTS, FINAL REGULATORY IMPACT ANALYSIS 7 (2014) (discussing the 2014 Regulatory Impact Analysis for FDA’s final menu labeling rule and the estimated number of covered establishments).

³¹⁷ See *supra* Section I.A (discussing restaurant worker knowledge and confidence about food allergen safety). This is similar to the difficulties people experienced in getting accurate nutrition information about restaurant-type foods before menu labeling.

³¹⁸ See M.N. Primeau et al., *The Psychological Burden of Peanut Allergy As Perceived by Adults with Peanut Allergy and the Parents of Peanut-Allergic Children*, 30 CLINICAL & EXPERIMENTAL ALLERGY 1135 (2000) (finding that the parents of children with a peanut allergy reported considerable disruption in their daily activities); see also *supra* notes 42–50 and accompanying text.

³¹⁹ See Dipen A. Patel et al., *Estimating the Economic Burden of Food-Induced Allergic Reactions and Anaphylaxis in the United States*, 128 J. ALLERGY & CLINICAL IMMUNOLOGY 110 (2011) (estimating the economic costs of food allergy and anaphylaxis);

At the same time, however, it is important to acknowledge that even with robust and well-implemented food allergen labeling and management requirements, no restaurant would likely ever be entirely safe for those with food allergies. Accordingly, it is important for people with food allergies to be educated regarding this risk, so that they can make informed decisions about whether or not to accept it.³²⁰

Covered establishments may also benefit if they gain new customers. These customers may include people who did not eat at restaurants or who limited the restaurants that they ate at due to food allergy concerns. The new customers may also include friends, family, colleagues, and business associates of persons with food allergies. An increase in customers may help offset some of the compliance costs. Of course, no system is fail-safe, and some people with food allergies may still decide not to eat at restaurants due to the risk of an allergic reaction, even if food allergy labeling and management were regulated.

Restaurant workers may believe that their current knowledge and practices are sufficient to safely serve consumers with food allergies, which may dissuade restaurants from opting in to an allergen regulatory scheme. Nevertheless, a restaurant might decide to opt into a regulatory system. For example, establishments that are part of a smaller chain or not part of a chain at all may not have the resources or expertise to create a system for the labeling and management of food allergens from scratch, but they may be willing to opt in to an already established system if the benefits of doing so are less than the compliance costs. In addition, consumer demand for allergen labeling may increase as consumers become accustomed to having access to labeling at covered restaurants. Restaurants may also opt in to allergen requirements if they see that these measures are profitable for other restaurants. Thus, the

see also Ruchi Gupta et al., *The Economic Impact of Childhood Food Allergy in the United States*, 167 JAMA PEDIATRICS 1026, 1027 (2013) (examining “the overall economic impact of [childhood] food allergy”).

³²⁰ The risk of undeclared food allergens (e.g., due to mislabeling or cross contact) should not be a reason to not require restaurant food allergen labeling as this risk is not unique to the restaurant context. There is a risk that packaged foods required to have food allergen labeling under FALCPA may contain undeclared allergens or contain allergens as a result of cross contact. *See Recalls, Market Withdrawals, & Safety Alerts*, FDA (June 2, 2018), <https://www.fda.gov/Safety/Recalls/default.htm> (listing, among other things, recalls for undeclared allergens); Tiffany Maberry, *A Look Back at 2017 Food Recalls*, FOOD SAFETY MAGAZINE (Feb. 6, 2018), <https://www.foodsafetymagazine.com/enewsletter/a-look-back-at-2017-food-recalls/> (“Undeclared allergens still dominate when it comes to food products needing to be pulled from store shelves. Last year, 218 food products posed health risks to unknowing consumers because allergenic ingredients were not properly displayed on product labels.”).

regulation of food allergens in restaurants may create benefits for both consumers and restaurants.

2. *Response to Anticipated Critiques*

The aim of requiring food allergen labeling and management in certain restaurants is to advance public health. Several of the anticipated critiques addressed below prioritize goals, values, and concerns other than public health.³²¹

a. *Coverage*

Covered restaurants and advocates for people with food allergies may object under the Equal Protection Clause of the United States Constitution to allergen labeling requirements only applying to establishments that have standardized menus and are part of a larger chain. As the Supreme Court has stated, however, there is “no requirement of equal protection that all evils of the same genus be eradicated or none at all.”³²² Additionally, “[t]he legislature may select one phase of one field and apply a remedy there, neglecting the others.”³²³ Accordingly, allergen labeling and management requirements should survive an Equal Protection challenge. In the menu labeling context, commentators have considered whether the focus on large chain restaurants violates the Equal Protection Clause of the United States Constitution.³²⁴ They concluded that these laws should survive an equal protection challenge because the laws seem rationally related to a legitimate government interest.³²⁵ If allergen labeling and management requirements enable consumers with food allergies to make better food choices, then these requirements should

³²¹ See Jacqueline Fox, *Reforming Healthcare Reform*, 50 U. RICH. L. REV. 557, 599–600 (2016) (“It is likely true that the vast majority of people would agree that the goals of the public health system are to reduce morbidity and mortality. Methods for achieving these goals can be in conflict with other goals and values such as those related to the proper scope of government, allocation of scarce resources, and autonomy. But it does not seem extreme to assume that people generally would prefer, in the absence of other issues, for there to be less illness and injury. . . .”); see also Banker, *supra* note 315, at 919 (discussing opposition to menu labeling and stating that “loss of revenue to any company is not necessarily a legitimate ‘cost’ from a public health perspective”).

³²² *Ry. Express Agency v. New York*, 336 U.S. 106, 110 (1949).

³²³ *Williamson v. Lee Optical of Okla., Inc.*, 348 U.S. 483, 489 (1955).

³²⁴ Cusick, *supra* note 280, at 1010–11; Lainie Rutkow et al., *Preemption and the Obesity Epidemic: State and Local Menu Labeling Laws and the Nutrition Labeling and Education Act*, 36 J.L. MED. & ETHICS 772, 786 (2008) [hereinafter Rutkow et al., *Preemption and the Obesity Epidemic*]; Bernell, *supra* note 170, 863–64.

³²⁵ See, e.g., Bernell, *supra* note 170, at 863–64; Cusick, *supra* note 280, at 1011.

be rationally related to the government's legitimate interest in protecting and promoting health by reducing deaths and injuries from allergic reactions.

There are several potential benefits to having allergen labeling requirements cover the same establishments as the ACA menu labeling provisions.³²⁶ Large chain restaurants with menu standardization are likely to have a certain level of sophistication due to their size, chain status, and standardized menus,³²⁷ characteristics which may also carry over into their policies, processes, and procedures. Thus, these restaurants may be better equipped to implement the labeling requirements and thereby avoid giving people with food allergies a false sense of safety while actually increasing their risk.

Focusing on chain restaurants with substantially the same menu items across locations may also reduce the compliance costs for restaurants as they may be able to use economies of scale (e.g., in the creation of signs and other labeling).³²⁸ In addition, if the covered establishments are identical to those covered by Section 4205 of the ACA, it will simplify the coverage determination for establishments. Further, it may help reduce administration and enforcement costs. For example, it may reduce costs if compliance with both menu labeling and allergen requirements could be assessed during the course of a single inspection. Thus, allergen labeling requirements modeled on the coverage of the federal menu labeling requirements should survive an Equal Protection challenge and may have several benefits.

³²⁶ The current analysis uses the ACA menu labeling provisions and regulations as of January 2018 as a model, but if Congress or FDA changed these, whether it continues to make sense to use them as a model would need to be evaluated. *See, e.g.*, Common Sense Nutrition Disclosure Act of 2017, H.R. 772, 115th Cong. (2018) (proposing to amend the menu labeling requirements); Common Sense Nutrition Disclosure Act of 2017, S. 261, 115th Cong. (2017) (also proposing to amend).

³²⁷ *See* Derr, *supra* note 10, 154–55 (noting in passing that “[i]ngredient or allergen disclosure understandably may be more feasible—and beneficial (due to their prevalence and national scope)—for chain restaurants with standardized ingredients and menus than for independent restaurants”). This is not to say that there may not be some establishments that lack such sophistication or that all smaller nonchain restaurants lack such sophistication. Size has been used as an indicator of sophistication in other contexts. *See, e.g.*, Greg Oguss, Notes & Comments, *Should Size or Wealth Equal Sophistication in Federal Securities Laws?*, 107 NW. U. L. REV. 285 (2012) (critiquing the treatment of size as sophistication in securities law).

³²⁸ The recipes for standardized menu items, however, could vary between establishments with respect to inclusion of food allergens required to be labeled.

b. Market

Critics may also argue that the government should not interfere with the free market by requiring these measures. They may argue that if food allergen labeling and management measures were in sufficient demand, restaurants would take them voluntarily. Opponents of menu labeling have made similar arguments,³²⁹ arguing that (1) “compelled menu labeling . . . amounts to an unwarranted and paternalistic government intrusion into private decision-making and interferes with the free market” and (2) is “anticompetitive because requiring all restaurants to disclose nutrition information eliminates the competitive edge of those restaurants . . . that use voluntary provision of nutrition information as a marketing point for attracting health-conscious consumers.”³³⁰

Allergen labeling requirements, however, may strengthen the market by providing information so that consumers with food allergies can make better informed and more efficient choices. Similar to the menu labeling context, restaurants may not provide labeling without government intervention because they may not fully account for the costs of not providing labeling³³¹—specifically, allergic reactions.³³² Consumers failing to report allergic reactions to restaurants may contribute to this problem.³³³ If restaurants do not fully account for the costs of failing to prevent allergic reactions, then they may take inadequate precautions.³³⁴

Relatedly, restaurant workers may fail to recognize their shortcomings with respect to allergen management.³³⁵ These shortcomings may mean that information about the safety of food from an allergen management perspective is unavailable or unreliable.³³⁶ Thus,

³²⁹ See, e.g., Stephanie Rosenbloom, *Calorie Data to be Posted at Most Chains*, N.Y. TIMES (Mar. 23, 2010), <http://www.nytimes.com/2010/03/24/business/24menu.html?scp=1&sq=menu%20labeling&st=cse>; Slive, *supra* note 277, at 265.

³³⁰ Banker, *supra* note 315, at 919–20 (discussing arguments raised by opponents of menu labeling).

³³¹ In the menu labeling context, “obesity produces external costs to society by increasing health care costs.” *Id.* at 920.

³³² See Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 578 (discussing a law and economics analysis of food safety and arguing that the failure to communicate safety and risk creates inefficiencies); see also Section I.C.3 (discussing tort law).

³³³ Furlong, *supra* note 309, at S41.

³³⁴ See Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 578.

³³⁵ See *supra* Section I.A.

³³⁶ See Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 584 (“Market controls have proven inadequate to provide the level of safety that consumers desire largely because information on the safety of food generally is unavailable either before or after purchase.”).

providing consumers with accurate information about food allergens in restaurant food “may enhance economic efficiency by helping consumers identify and purchase products they want most”—food that will not trigger an allergic reaction.³³⁷

c. Information Access

Similar to the opponents of the menu labeling requirements, covered establishments may argue that allergen labeling requirements impose burdensome information production requirements requiring them to determine whether a food contains any major food allergen as an ingredient.³³⁸ Covered establishments, however, likely already have access to the food allergen information that they would need for allergen labeling, thus reducing this burden. First, many reported food allergy attacks occurred at establishments where someone in the establishment knew the food contained an allergen³³⁹ but this information was not communicated to the person with a food allergy. Second, FALCPA reduces the burden on restaurants to identify the allergens. Many foods that restaurants use are already required to be labeled for major food allergens under FALCPA, giving establishments an efficient way to determine if an ingredient contains an allergen.³⁴⁰ And for raw agricultural commodities, which are not subject to the food allergen labeling requirements under FALCPA, the identity of the product should be clear to the restaurant since the food is “in its raw or

³³⁷ Robin M. Nagele, *Keeping Consumers in the Dark: How the National Bioengineered Food Disclosure Standard Threatens Transparency and Food Security*, 57 *Jurimetrics J.* 529, 543 (2017); see GOLAN ET EL., *supra* note 315, at 12–13 (discussing mandatory labeling as a way to correct asymmetric or imperfect information and “provide consumers with greater access to information and . . . increase the efficiency of the market”); Jennifer L. Pomeranz, *Compelled Speech Under the Commercial Speech Doctrine: The Case of Menu Label Laws*, 12 *J. HEALTH CARE L. & POL’Y* 159, 193 (2009); see also 15 U.S.C. § 1451 (2012) (“Informed consumers are essential to the fair and efficient functioning of a free market economy.”).

³³⁸ See, e.g., Katherine Wilbur, *The Informed Consumer Is a Healthy Consumer? The American Obesity Epidemic and the Federal Menu Labeling Law*, 23 *LOY. CONSUMER L. REV.* 505, 522 (2011) (“Many restaurant and pro-business advocates are concerned that the burden of the law falls unfairly on restaurants because restaurants are now required to pay for the cost of determining the calorie content of each meal”); Slive, *supra* note 277, at 265.

³³⁹ Furlong et al., *supra* note 4, at 867–68 (finding that in 78% of 106 reactions of registrants “with previously diagnosed allergy who ordered food specifically for ingestion by the allergic individual [S]omeone in the establishment knew the food contained peanut or tree nut as an ingredient”).

³⁴⁰ See Food, Drug, and Cosmetic Act (FDCA) § 403(w), 21 U.S.C. § 343(w) (2012); see also *FDA Questions and Answers*, *supra* note 64; Derr, *supra* note 10, at 153.

natural state.”³⁴¹ Under current law, a restaurant that receives food labeled under FALCPA is not required to pass that allergen information on to the consumer whom it could benefit. By limiting allergen labeling requirements to major food allergens, covered restaurants would have the needed information about major food allergens in foods that they use and serve.

Restaurants may counter that even with FALCPA they may have difficulty obtaining accurate information about potential food allergens due to the use of advisory label warnings, such as “May Contain,” which FALCPA left “untouched.”³⁴² But restaurants, particularly large chains, are uniquely suited to help discourage overuse of advisory label warnings and shape the supply chain through their purchasing decisions³⁴³: restaurants could insist that their suppliers not use advisory labeling in place of good manufacturing practices (GMPs).³⁴⁴ This would be consistent with the requests of “the Grocery

³⁴¹ FDCA § 201(r), 21 U.S.C. § 321(r) (defining “raw agricultural commodity” as “any food in its raw or natural state”).

³⁴² Besnoff, *supra* note 77, at 1469, 1483–84; Derr, *supra* note 10, at 86–88. FALCPA did require that the Secretary of Health and Human Services (HHS) submit a report on advisory labeling. *See* FDCA § 201 note, 21 U.S.C. § 321 note (requiring HHS to submit a report to Congress on advisory labeling); FDA, FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT OF 2004 PUBLIC LAW 108-282 REPORT TO THE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS, UNITED STATES SENATE AND THE COMMITTEE ON ENERGY AND COMMERCE UNITED STATES HOUSE OF REPRESENTATIVES (2006), available at <https://web.archive.org/web/20060925225306/http://www.cfsan.fda.gov/~acrobot/alrgrep.pdf> (accessing Internet Archive from Sept. 25, 2006) (discussing cross contact and advisory labeling).

It remains to be seen how the Food Safety Modernization Act (FSMA) Hazard Analysis and Risk-Based Preventive Controls (HARPC) provisions and FDA’s regulations implementing these provisions will affect the use of these warnings on packaged foods, if at all. In the preamble to its final HARPC regulations, FDA indicated that its prior “guidance on the reasonable steps that should be taken to prevent allergens from being unintentionally incorporated into the food and the limited use of allergen advisory statements is still applicable.” Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food, 80 Fed. Reg. 55,908, 56,034–35 (Sept. 17, 2015) (codified at scattered sections of 21 C.F.R.) (stating that “establishing regulatory policy or requirements, such as a long-term strategy regarding use of allergen advisory labeling . . . is outside the scope of” the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule); *see also* FDCA § 418, 21 U.S.C. § 350g; 21 C.F.R. pt. 117.

³⁴³ *See, e.g.*, Graciela Ghezán et al., *Impact of Supermarkets and Fast-Food Chains on Horticulture Supply Chains in Argentina*, 20 DEV. POL’Y REV. 389, 399 (2002) (discussing how multinational supermarkets and fast-food chains have changed supply chains); Jaap van der Kloet & Tetty Havinga, *Private Food Regulation from a Regulatee’s Perspective* 9 (Nijmegen Sociology of Law Working Papers Series, Paper No. 2008/07) (stating that “purchasing power of supermarkets makes retail food safety standards in fact obligatory for many manufacturers”).

³⁴⁴ *See* 21 C.F.R. pt. 117.

Manufacturers of America (GMA) and the National Food Processors Association (NFPA), [which] have urged their members to not use advisory labeling in lieu of following GMPs.”³⁴⁵

Restaurants may also argue that required food allergen labeling would hinder their ability to substitute ingredients in a pinch. There is nothing in the proposal, however, that would prevent restaurants from updating their labeling as the major food allergen content of their foods changed. Changing the allergen labeling would be necessary only if the substituted ingredient had a major food allergen that the original ingredient did not or vice versa.

Although allergen information requirements would create additional responsibilities for covered establishments, it would be far less costly for establishments to obtain food allergen information than for consumers to do so. In fact, without restaurants’ participation, it may be virtually impossible for a consumer to obtain this information. This information asymmetry supports labeling.

d. Cost and Feasibility

Allergy labeling and management opponents may also argue that such measures will be too expensive. Although a full cost-benefit analysis would be needed to assess this argument—and is something that could be done during the enactment process—food allergen measures may be beneficial for restaurants.³⁴⁶ Again, the experience with menu labeling may be instructive. Opponents of menu labeling argued that “the cost of implementation to restaurants [would] be prohibitive.”³⁴⁷ Proponents countered that most restaurants affected by the menu-labeling laws had already incurred the costs of nutritional analyses of standard menu items.³⁴⁸ Similarly, in the food allergen labeling context, restaurants largely already have access to information about major food allergens in the foods that they purchase due to FALCPA.³⁴⁹

³⁴⁵ Derr, *supra* note 10, at 87.

³⁴⁶ See Section IV.A (discussing the federal rulemaking process); see also FDA, FINAL REGULATORY IMPACT ANALYSIS, *supra* note 316 (regulatory impact analysis for menu labeling).

³⁴⁷ See Banker, *supra* note 315, at 919; Ellen A. Black, *Menu Labeling: The Unintended Consequences to the Consumer*, 69 FOOD & DRUG L.J. 531, 546 (2014).

³⁴⁸ Banker, *supra* note 315, at 919; Black, *supra* note 347, at 546.

³⁴⁹ See Food, Drug, and Cosmetic Act (FDCA) § 403(w), 21 U.S.C. § 343(w) (2012); see also *supra* Section III.B.2.c.

It may be costlier for restaurants to comply with food allergen requirements than menu labeling requirements as the costs to prevent cross contact may be significant. This would need to be subject to a cost-benefit analysis again, this is something that could be assessed as part of the process of enacting any food allergen requirements. The costs and benefits would depend on the particular contours of the measurements to prevent cross contact and train workers. The benefits of preventing cross contact, however, may also be significant. For example, if fewer people are injured or killed by allergic reactions to restaurant food because of allergen labeling coupled with other allergen management measures, this not only benefits people with food allergies who avoid harm but may also lower liability for restaurants.³⁵⁰ In addition, covered restaurants may gain customers—both those with allergies to the major food allergens and those who dine with them.³⁵¹

Opponents may argue that regulating food allergens in restaurants would not be feasible for restaurants. The proposal to use menu labeling as a model for allergen labeling is a starting point in that it would need to be accompanied by measures to prevent cross contact, train restaurant workers, and educate the public. The proposed allergen labeling requirements and accompanying measures would need to be further fleshed out and refined—for example, through the legislative and regulatory processes with input from various stakeholders including restaurants and similar retail food establishments, public health professionals, and those with food allergies.³⁵² Stakeholders and other interested persons could provide feedback regarding what labeling control and management measures would be both effective from a public health perspective and feasible for restaurants. This may be particularly important with respect to measures to prevent cross contact as the menu labeling regulation does not provide a model for such measures.

The food allergen requirements could also be informed by the European Union's experience with its requirement that food businesses, such as restaurants, provide allergen information for non-prepacked foods that contain one or more of fourteen different allergens.³⁵³

³⁵⁰ Brewer, *supra* note 123, at 328.

³⁵¹ *Id.* at 326.

³⁵² See, e.g., *infra* Section IV.A (discussing notice-and-comment rulemaking process).

³⁵³ Regulation 1169/2011 of the European Parliament and of the Council of Oct. 25, 2011, on the provision of food information to consumers, 2011 O.J. (L 304/18); see also FOOD STANDARDS AGENCY, QUESTIONS AND ANSWERS ON THE EU FOOD INFORMATION FOR CONSUMERS REGULATION ALLERGEN PROVISIONS (2014); Liz Tucker, *New Food*

e. Potential Liability

Opponents may also argue that the proposed allergen labeling requirements will increase restaurants' liability. A restaurant may be liable if it provides labeling to a person that incorrectly indicates that a food does not contain a major food allergen, resulting in an allergic reaction. The doctrine of negligence per se may permit a person so injured to use a statutory or regulatory food allergen labeling and management requirement to establish a duty.³⁵⁴ Most courts would require that a plaintiff prove that she (1) "was injured by a type of risk the statute (or regulation) was intended to prevent" and (2) "was in the class of persons the statute (or regulation) was intended to protect."³⁵⁵ Even if negligence per se applied, the plaintiff would still have to prove the other elements of negligence.³⁵⁶ As another example, a person may have a claim for a breach of an express warranty if a restaurant provides labeling indicating that a food does not contain a major food allergen when it does.³⁵⁷

The end goal of the proposal, however, is to make restaurants safer for those with food allergies by reducing allergic reactions. If the proposal works as intended, the number of people who are injured by allergic reactions should be reduced, and with it restaurants' liability.³⁵⁸ But if a restaurant makes a mistake, and that mistake causes a person to be injured or to die, the restaurant should be liable.³⁵⁹ Such liability may help create a safer system for those with food allergies by acting as a means of regulatory enforcement³⁶⁰ and by providing feedback to restaurants that they should invest more in food allergen

Labeling Regulations for the Catering Industry, FOOD SAFETY MAGAZINE (Dec. 2, 2014), <https://www.foodsafetymagazine.com/enewsletter/new-food-labeling-regulations-for-the-catering-industry/?mobileFormat=false>.

³⁵⁴ David G. Owen, *Proving Negligence in Modern Products Liability Litigation*, 36 ARIZ. ST. L.J. 1003, 1006 (2004).

³⁵⁵ *Id.*

³⁵⁶ *Id.*; see also Leavitt, *supra* note 64 (discussing effect of the Massachusetts FAAA on common law causes of action).

³⁵⁷ See U.C.C. § 2-313(1)(a)–(b) (AM. LAW INST. & UNIF. LAW COMM'N 2002) (stating in part that "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise" and "[a]ny description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description").

³⁵⁸ See Martin, *supra* note 64, at 100–01.

³⁵⁹ *Id.*

³⁶⁰ *Id.*

safety.³⁶¹ In addition, “if restaurants seek liability insurance, the insurers will demand compliance with the law,” thereby further reinforcing its requirements.³⁶²

IV

IMPLEMENTING FOOD ALLERGEN LABELING AND MANAGEMENT REQUIREMENTS

This Part uses the experience with menu labeling to explore how the proposals from Part III might be implemented. It discusses the benefits and limitations of federal action as a means of enacting food allergen labeling and management requirements and argues that federal action, ultimately, may be the best way to advance public health and address food allergen labeling and management in restaurants. Because of the political and other challenges inherent in creating a federal regulatory framework for food allergens in restaurants, this Part also considers some of the benefits and limitations of state and local action. Like in the menu labeling context, local action may spur states and, ultimately, the federal government to regulate the labeling and management of food allergens in restaurants.

A. Federal Action

There is a strong argument that FDA has the authority to promulgate regulations requiring food allergen labeling and management in restaurants under the current law. FDA has jurisdiction over “food,” which the FDCA defines, in part, as “articles used for food or drink for man” and “articles used for components of any such article.”³⁶³ Restaurant food is “food” under the FDCA.³⁶⁴ The FDCA prohibits, among other things, the adulteration or misbranding of food “while such article is held for sale (whether or not the first sale) after shipment in interstate commerce.”³⁶⁵ The shipment of components of food (i.e., its ingredients) has been held to give FDA jurisdiction.³⁶⁶ Thus FDA

³⁶¹ Fortin, *The Hang-Up with HACCP*, *supra* note 294, at 574.

³⁶² *See* Martin, *supra* note 64, at 101.

³⁶³ Food, Drug, and Cosmetic Act (FDCA) § 201(f), 21 U.S.C. § 321(f) (2012).

³⁶⁴ *See id.*

³⁶⁵ FDCA § 301(k), 21 U.S.C. § 331(k). Interstate commerce is “commerce between any State or Territory and any place outside thereof” and “commerce within the District of Columbia or within any other Territory not organized with a legislative body.” FDCA § 201(b), 21 U.S.C. § 321(b).

³⁶⁶ *See, e.g.*, *United States v. An Article of Food*, 752 F.2d 11, 12 (1st Cir. 1985); *see also* *Baker v. United States*, 932 F.2d 813 (9th Cir. 1991); *United States v. 40 Cases*, 289 F.2d 343, 345 (2d Cir. 1961); PETER BARTON HUTT ET AL., *FOOD AND DRUG LAW: CASES*

would have jurisdiction over food held for sale in restaurants if the food or the ingredients used to make the food were shipped in interstate commerce.³⁶⁷ Many of the foods sold by large chain restaurants would likely meet this requirement.

Section 701(a) of the FDCA has been interpreted by courts as giving FDA the “authority to promulgate substantive regulations for the efficient enforcement of” the FDCA.³⁶⁸ The FDCA provides, in part, that a food is misbranded if “its labeling is false or misleading in any particular.”³⁶⁹ Section 201(n) provides that

determining whether the labeling . . . is misleading there shall be taken into account . . . the extent to which the labeling . . . fails to reveal facts . . . material with respect to consequences which may result from the use of the article to which the labeling . . . relates . . . under such conditions of use as are customary or usual.³⁷⁰

FDA has relied on FDCA 701(a) and 201(n) to promulgate regulations requiring mandatory warnings, such as those for certain foods packaged in self-pressurized containers and with certain propellants.³⁷¹ Furthermore, the FDCA provides, in part, that a food is

AND MATERIALS 284 (4th ed. 2014) (listing “cases holding that shipment of product ingredients in interstate commerce is sufficient to confer jurisdiction on FDA”).

Before the ACA, in the menu labeling context, commentators stated that FDA had the authority to promulgate regulations requiring restaurants to provide certain information. *See* Rebecca S. Fribush, *Putting Calorie and Fat Counts on the Table: Should Mandatory Nutritional Disclosure Laws Apply to Restaurant Foods?*, 73 GEO. WASH. L. REV. 377, 383 (2005) (stating that “[i]t is generally accepted that the FDCA gives the FDA jurisdiction to regulate restaurant food in ways that include menu labeling”); Sarah A. Kornblat, *Fat America: The Need for Regulation Under the Food, Drug, and Cosmetic Act*, 49 St. Louis U. L.J. 209, 243 (2004) (arguing that “the FDA may find fast food misbranded and its labeling insufficient to provide consumers with knowledge of what they are eating, and it may mandate some type of labeling either on a menu or posted in a restaurant”).

³⁶⁷ *See* HUTT ET AL., *supra* note 366, at 281.

³⁶⁸ *See* FDCA 701(a), 21 U.S.C. § 371; *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 617–18 (1973); *Nat’l Nutritional Foods Ass’n v. Weinberger*, 512 F.2d 688, 696 (2d Cir. 1975) (“Whatever doubts might have been entertained regarding the FDA’s power under § 701(a) to promulgate binding regulations were dispelled by the Supreme Court’s recent decisions in *Weinberger v. Hynson, Westcott & Dunning, Inc.* . . . and its companion cases . . .” (citations omitted)).

³⁶⁹ FDCA § 403(a), 21 U.S.C. § 343(a).

³⁷⁰ FDCA § 201(n), 21 U.S.C. § 321(n).

³⁷¹ *See, e.g.*, *Food, Drug & Cosmetic Products, Warning Statements*, 40 Fed. Reg. 8,912, 8,912 (Mar. 3, 1975) (explaining the Commissioner’s conclusion that there was “ample authority for the establishment of warning statements” for self-pressurized containers and those with certain propellants); *see also* HUTT ET AL., *supra* note 366, at 401 (providing examples of FDA regulations requiring warnings).

At one point before FALCP was enacted, FDA considered proposing regulations “to require that foods that contain certain protein ingredients include information on the label

adulterated “if it has been prepared, packed, or held under insanitary conditions . . . whereby it may have been rendered injurious to health.”³⁷² FDA has relied, in part, on sections 402(a)(4) and 701(a) of the FDCA in promulgating its current Good Manufacturing Practice regulations.³⁷³ In addition, in 1974, in the preamble to proposed food service sanitation regulations, FDA stated that the prohibition in section 301(k) of the FDCA on “adulteration of food while held for sale after interstate shipment . . . includes food service sanitation.”³⁷⁴ Because of the authority granted to FDA by the FDCA—and specifically sections 201(n), 301(k), 402(a), and 701(a)—there is a strong argument that FDA has the authority to promulgate regulations requiring food allergen labeling and management in restaurants.³⁷⁵

State and local governments, however, may strongly oppose any such action by FDA. For example, the Food and Drug Law casebook by Hutt, Merrill, and Grossman describes FDA as having “ceded the regulation of [restaurants, grocers, and food vending machines] to state and local governments.”³⁷⁶ The casebook authors note that when FDA proposed to make its model ordinance for the regulation of food service establishments mandatory in 1974 via regulation, “[s]tate officials opposed this action, primarily because ‘it abridged a long-term understanding between the States and the Federal government regarding the regulation of the food service industry . . .’” and that

in plain English terms that clearly identifies the presence of these ingredients” and “to require food allergen labeling on spices.” Unified Agenda, 68 Fed. Reg. 72,862, 72,890 (Dec. 22, 2003). Although the legal basis for those regulations is not identified in the Unified Agenda, it seems likely it could have been FDCA 701(a) and 201(n). *See* Unified Agenda, 68 Fed. Reg. at 72,890.

³⁷² FDCA § 402(a)(4), 21 U.S.C. § 342(a)(4).

³⁷³ *See, e.g.*, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food, 44 Fed. Reg. 33,238, 33,239 (proposed June 8, 1979) (codified at C.F.R. pts. 20, 101).

³⁷⁴ Food Service Sanitation, 39 Fed. Reg. 35,438, 35,438 (proposed Oct. 1, 1974). The proposed regulations were ultimately withdrawn. *See* Food Service Sanitation, 42 Fed. Reg. 15,428, 15,428 (Mar. 22, 1977); *see also infra* note 376 and accompanying text.

³⁷⁵ Courts will generally defer to agency interpretations of ambiguous statutes if the agency’s interpretation of the statute is permissible and Congress has “delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.” *See* *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 841, (1984); *United States v. Mead Corp.*, 533 U.S. 218, 227, (2001); *City of Arlington v. FCC*, 569 U.S. 290, 293 (2013) (holding that “an agency’s interpretation of a statutory ambiguity that concerns the scope of its regulatory authority (that is, its jurisdiction) is entitled to deference under *Chevron*”). *But see* *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (holding that “FDA’s assertion of jurisdiction [over tobacco products] is impermissible”).

³⁷⁶ *See* HUTT ET AL., *supra* note 366, at 281–82.

“FDA withdrew the proposal, declaring that ‘it was never [the agency’s] intention to supersede State and local regulation of food service sanitation.’”³⁷⁷ For similar reasons, states may oppose any allergen labeling and management requirements.

Although there is a strong argument that FDA has authority to promulgate food allergen labeling and management requirements for restaurants, Congress could enact legislation requiring restaurants to provide major food allergen labeling and implement allergen control measures.³⁷⁸ This would be similar to the approach Congress took with menu labeling in the ACA.³⁷⁹ Like it did with menu labeling, Congress could direct FDA to promulgate implementing regulations and issue guidance.³⁸⁰

The rulemaking process could help to improve any resulting regulatory system by providing interested persons an opportunity to provide feedback on proposed allergy labeling and management requirements. Even if allergy labeling requirements were modeled on the menu labeling requirements as this Article suggests, there would still be many questions and issues to be resolved regarding the labeling requirements as well as accompanying allergen management, worker training, and public education requirements. Questions would include how to best prevent allergen cross contact in covered establishments and the feasibility of different approaches. For example, although an in-depth analysis of the “informal” or notice-and-comment rulemaking process, its benefits, and limitations is beyond the scope of this Article,

³⁷⁷ *Id.* at 282 (internal citations omitted) (quoting 42 Fed. Reg. at 15,428; 39 Fed. Reg. at 35,438).

³⁷⁸ Several student commentators have argued for national labeling. *See, e.g.*, Roses, *supra* note 64, at 226; Martin, *supra* note 64, at 85.

³⁷⁹ *See* Food, Drug, and Cosmetic Act (FDCA) § 403(q)(5)(H), 21 U.S.C. § 343(q)(5)(H). As noted above, in the obesity context, before the federal menu labeling law, some commentators suggested that FDA promulgate restaurant labeling rules. Fribush, *supra* note 366, at 383; Kornblet, *supra* note 366, at 221.

³⁸⁰ *See* FDCA § 403(q)(5)(H)(x), 21 U.S.C. § 343(q)(5)(H)(x) (providing that within one year of enactment FDA must promulgate proposed regulations to carry out the menu labeling law); *see* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156 (Dec. 1, 2014) (codified at C.F.R. pts. 11, 101); Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, § 747, 129 Stat. 2242 (2015); FDA, MENU LABELING: SUPPLEMENTAL GUIDANCE FOR INDUSTRY: DRAFT GUIDANCE (Nov. 2017); FDA, A LABELING GUIDE FOR RESTAURANTS AND RETAIL ESTABLISHMENTS SELLING AWAY-FROM-HOME FOODS-PART II (MENU LABELING REQUIREMENTS IN ACCORDANCE WITH 21 CFR 101.11): GUIDANCE FOR INDUSTRY (Apr. 2016); FDA, GUIDANCE FOR INDUSTRY: NUTRITION LABELING OF STANDARD MENU ITEMS IN RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS: SMALL ENTITY COMPLIANCE GUIDE (Mar. 2015).

through this process interested persons—including those potentially affected by an allergy labeling and management rule—could provide feedback on a proposed rule.³⁸¹ In addition, the costs and benefits of any proposed rule and regulatory alternatives would be assessed and approached to maximize net benefits.³⁸²

The primary benefit of federal action as compared to state or local government action would be an increase in uniformity for both consumers and covered establishments if the federal law preempted any inconsistent state and local requirements.³⁸³ For consumers with food allergies, standardized labeling may help them better identify major food allergens. As one commentator noted in the menu labeling context, “[U]niform labeling formats may accelerate the beneficial effects of menu-labeling laws by increasing familiarity with nutrition

³⁸¹ See 5 U.S.C. § 553 (2012) (describing the “notice and comment” rulemaking process); see also Food Labeling, 79 Fed. Reg. at 71,156 (discussing comments on proposed menu labeling rule and publishing final menu labeling rule); Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Food Establishments, 76 Fed. Reg. 19,192 (proposed Apr. 6, 2011) (codified at 21 C.F.R. pts 11, 101). Generally, in notice and comment rulemaking, the agency must give notice of the proposed rule by publishing it in the Federal Register, “give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments,” and “[a]fter consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose.” 5 U.S.C. § 553(c). Courts, Congress, and Presidents have also imposed other requirements on rulemaking. See, e.g., Thomas O. McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 Duke L.J. 1385, 1400 (1992) (discussing judicially, congressionally, and presidentially imposed analytical requirements). This issue of food allergens labeling and management in restaurants and similar retail establishments may also be suited for negotiated rulemaking. See Marie Boyd, *Unequal Protection Under the Law: Why FDA Should Use Negotiated Rulemaking to Reform the Regulation of Generic Drugs*, 35 Cardozo L. Rev. 1525, 1554–68 (2014) (discussing negotiated rulemaking).

³⁸² See, e.g., Improving Regulation and Regulatory Review, Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 18, 2011); Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993); 5 U.S.C. §§ 601–612; Unfunded Mandate Reform Act of 1995, Pub. L. No. 104-4, 109 Stat. 48 (1995); see also Food Labeling, 79 Fed. Reg. at 71,244 (discussing Regulatory Impact Analysis for final menu labeling rule); FDA, FINAL REGULATORY IMPACT ANALYSIS, *supra* note 316.

³⁸³ See U.S. CONST. art. VI, cl. 2 (Supremacy Clause). For a discussion of the Supremacy Clause and preemption see Caleb Nelson, *Preemption*, 86 VA. L. REV. 225 (2000). Congress could expressly preempt inconsistent state and local requirements as it did with menu labeling. See FDCA § 403A(a)(4), 21 U.S.C. § 343-1(a)(4). Even if there was no express preemption, there still could be preemption. See, e.g., *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002) (“[A]n express pre-emption clause ‘does not bar the ordinary working of conflict pre-emption principles,’ that find implied pre-emption ‘where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’”) (internal citations omitted).

labels and facilitating comprehension of the information provided.”³⁸⁴ A nationwide law may also substantially expand the food choices of people allergic to a major food allergen.

For covered establishments that operate in more than one jurisdiction, it may be easier to comply with a single federal standard than a patchwork of state and local standards.³⁸⁵ Establishments that are not part of a chain with twenty or more locations doing business under the same name and offering substantially the same menu items may opt in to coverage, further increasing uniformity.³⁸⁶ For example, an establishment that does not meet the definition of a chain restaurant subject to menu labeling—perhaps because it is part of a chain with only fifteen locations—may prefer to be subject to a federal standard instead of potentially more burdensome differing state and local standards.

A federal food allergen law may also reduce administration and enforcement costs. For example, as noted earlier, if the coverage was coterminous with the coverage of the menu labeling law, a single inspection could be used to determine compliance with both laws, potentially reducing regulatory costs.

Opponents of allergen requirements, however, may argue that the nationwide costs of compliance for covered restaurants are too burdensome. Although the costs may be substantial, there may also be substantial benefits. A nationwide law may generate efficiencies due to economies of scale relative to measures with a narrower applicability. However, given the Trump administration’s “focus on deregulation and concerted opposition to new government regulation,”³⁸⁷ creation of a new federal framework for the labeling and management of food allergens in restaurant-type food may be unlikely in the near term.

³⁸⁴ Banker, *supra* note 315, at 928.

³⁸⁵ See Wilbur, *supra* note 338, at 522–23 (discussing argument “that the federal menu labeling law should preempt all state and local menu labeling rules”).

³⁸⁶ See Cusick, *supra* note 280, at 1003 (discussing the menu labeling voluntary opt-in provision); Kindel, *supra* note 171, at 255 (also discussing the opt-in provision).

³⁸⁷ Diana R. H. Winters, Essay, *Food Law at the Outset of the Trump Administration*, 65 UCLA L. REV. DISCOURSE 28, 41 (2017); see also Binyamin Appelbaum & Jim Tankersley, *The Trump Effect: Business, Anticipating Less Regulation, Loosens Purse Strings*, N.Y. TIMES (Jan. 1, 2018), <https://www.nytimes.com/2018/01/01/us/politics/trump-businesses-regulation-economic-growth.html>; Reducing Regulation and Controlling Regulatory Costs, Exec. Order No. 13,771, 82 Fed. Reg. 9339 (Jan. 30, 2017).

B. State and Local Action

Absent federal action, states and localities could help fill the gap by adopting allergen labeling and management requirements. Although such measures would not entirely eliminate the gap in the allergen labeling requirements, they would go further than the existing state and local requirements discussed earlier. Ultimately, state and local food allergen labeling requirements may make federal legislative action more likely. This section discusses the power of states and localities to enact food allergen labeling and management measures, considers potential benefits and limitations of state and local action, and concludes by addressing two potential challenges to these actions.

1. State and Local Powers

States have the power to help fill the gap in food allergen management in restaurants and similar retail food establishments in the absence of preemptive federal legislative and regulatory action.³⁸⁸ The regulation of food allergen labeling and management in restaurants falls within the states' broad police power for public health,³⁸⁹ as food allergens pose health and safety risks to allergic individuals.³⁹⁰

Although a detailed examination of the powers of political subdivisions of states, as well as the limits and variations of these powers, is beyond the scope of this Article, in many cases, local governments have "broad power to address local issues"³⁹¹ and could use this power to help fill the gap in the labeling and management of food allergens in restaurants.³⁹² Although in other cases the power of

³⁸⁸ See Brewer, *supra* note 123, at 306 (arguing that Ohio should enact legislation regarding food allergens in restaurants).

³⁸⁹ See U.S. CONST. amend. X ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."); *Jacobson v. Massachusetts*, 197 U.S. 11, 24–25, (1905) (describing "police power" as "a power which the state did not surrender when becoming a member of the Union under the Constitution" and stating that "[a]ccording to settled principles, the police power of a state must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health . . ."); see also Jacqueline Fox, *Zika and the Failure to Act Under the Police Power*, 49 CONN. L. REV. 1211 (2017).

³⁹⁰ See *supra* Section I.A.; see also NAT'L ACAD. SCI., ENG'G, & MED., *supra* note 22, at 10.

³⁹¹ Lainie Rutkow et al., *Local Governments and the Food System: Innovative Approaches to Public Health Law and Policy*, 22 ANNALS HEALTH L. 355, 358 (2013) [hereinafter Rutkow et al., *Local Governments and the Food System*].

³⁹² *Id.* at 370 (discussing the ability of local governments to enact policies relative to the food system and noting that although the powers of many localities in this area are broad, some are limited).

localities may be more limited and some may lack the power to regulate food allergen labeling at all. For example, Mississippi law expressly reserves the regulation of nutrition labeling for food, which is defined to include the “allergen content,” to the legislature.³⁹³ Illinois law provides that allergen awareness training is an exclusive state function and local regulation of allergen awareness training is prohibited.³⁹⁴

2. Potential Benefits and Limitations of State and Local Action

Although state and local laws are unlikely to create uniformity to the same extent as a federal law, these laws may nevertheless increase uniformity relative to the status quo by increasing it within a single jurisdiction. For example, “[a]s a response to pressure from the restaurant industry to have a more uniform law in California, the California legislature introduced statewide [menu labeling] legislation on January 22, 2007” and passed it in October 2008.³⁹⁵ Different laws among different jurisdictions, however, may generate consumer confusion if restaurants that were part of the same chain were subject to different requirements. Moreover, such variation may be burdensome for restaurants that must comply with different laws. For example, a chain that operates in three different jurisdictions might be subject to no food allergen labeling and management requirements in one jurisdiction and be subject to different requirements in the other two jurisdictions.

A lack of uniformity at the state and local levels, however, may ultimately make federal action more likely. Indeed, the lack of uniformity with respect to menu labeling requirements appears to have been a catalyst for the national menu labeling law. The variation in state and local menu labeling requirements was one of the reasons the NRA and others supported federal menu labeling legislation.

Even within the framework proposed in Part III, there may still be room for state and local experimentation. Such experimentation may lead to innovations that improve food allergen labeling and management in restaurants. For example, questions that remain to be answered within the framework include, among other things, how food allergen labeling should be formatted to effectively communicate food allergen information to consumers, the components of an effective plan to prevent allergen cross contact, and how best to train restaurant staff

³⁹³ MISS. CODE. ANN. § 75-29-901 (West 2016).

³⁹⁴ H.R. 2510, 100th Gen. Assemb., Reg. Sess. (Ill. 2017).

³⁹⁵ Arthur, *supra* note 195, at 316–17.

on food allergen management. Even if a federal allergy law were to preempt states and localities from acting—or a state allergy law were to preempt localities from acting—there may still be gaps left to fill. For example, in the menu labeling context, states or “localities may introduce menu-labeling regulations for restaurants that have fewer than twenty locations”³⁹⁶ or may petition for an exemption from the preemption requirements.³⁹⁷ In the context of combating obesity, Professor Paul A. Diller notes that “cities have enacted heightened, innovative regulations,” and he argues that they may be particularly well suited to taking such actions due to “the streamlined nature of local lawmaking, combined with the lower campaign and lobbying costs,” which “provide[] a more favorable venue for public health interest groups to push for heightened regulation.”³⁹⁸ In this way, states or localities may test reforms that federal officials then adopt.³⁹⁹ This is consistent with the idea of states and localities as “laboratories of democracy.”⁴⁰⁰

In addition, a single food allergen law may help pave the way for other laws, similar to how the 2008 NYC menu labeling regulation paved the way for other local and state menu labeling requirements.

³⁹⁶ See Rutkow et al., *Local Governments and the Food System*, *supra* note 391, at 368–69; Federal Food, Drug, and Cosmetic Act (FDCA) § 403A(a)(4), 21 U.S.C. § 343-1(a)(4) (2012); *see also* Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,249–51 (Dec. 1, 2014) (codified at 21 C.F.R. pts. 11, 101) (discussing FDA’s interpretation of the menu labeling preemption provisions).

³⁹⁷ See FDCA § 403A(b), 21 U.S.C. § 343-1(b).

³⁹⁸ Paul A. Diller, *Why Do Cities Innovate in Public Health? Implications of Scale and Structure*, 91 WASH. U. L. REV. 1219, 1224, 1265–66 (2014); Patrick M. Steel, *Obesity Regulation Under Home Rule: An Argument That Regulation by Local Governments Is Superior to Administrative Agencies*, 37 CARDOZO L. REV. 1127, 1128 (2016).

³⁹⁹ See Kristin Madison, *Building A Better Laboratory: The Federal Role in Promoting Health System Experimentation*, 41 PEPP. L. REV. 765, 770 (2014); Michael S. Sparer & Lawrence D. Brown, *States and the Health Care Crisis: Limits and Lessons of Laboratory Federalism*, in HEALTH POLICY, FEDERALISM, AND THE AMERICAN STATES 181–200 (Robert F. Rich & William D. White eds., 1996) (discussing states as laboratories and their limitations).

⁴⁰⁰ *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) (stating that “a single courageous state may . . . serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.”); Heather K. Gerken, *Foreword: Federalism All the Way Down*, 124 HARV. L. REV. 4, 9 (2010) (discussing “federalism-all-the-way-down”).

3. Anticipated Challenges to State and Local Action

a. Preemption

Like NYC's menu labeling laws,⁴⁰¹ a state or local food allergen labeling law may be challenged on preemption grounds. Although the existing law is somewhat ambiguous, there is a strong argument that, under current law, state and local food allergen labeling requirements for restaurant-type food are not expressly preempted.⁴⁰² Although section 403A of the FDCA contains an express preemption provision that references FALCPA's allergy labeling requirements,⁴⁰³ that provision should not be read to preempt state and local food allergen labeling requirements for restaurant-type food. And even if that provision is found to preempt such requirements, a state or subdivision of a state can request an exemption from preemption under the FDCA.⁴⁰⁴

Section 403A provides in relevant part that

no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . any requirement for the labeling of food of the type required by section . . . [403(w) of the FDCA] . . . that is not identical to the requirement of [that] section⁴⁰⁵

Section 403(w) sets forth the major food allergen labeling requirements.⁴⁰⁶

The express preemption provision in section 403A of the FDCA should not be read to preempt state and local food allergen labeling requirements for restaurant-type food. Specifically, the language "any requirement for the labeling of food of the type required by section . . . [403(w) of the FDCA] . . . that is not identical to the requirement of [that] section" can be read to exclude allergen labeling requirements for restaurant-type food.⁴⁰⁷ This is because the allergen labeling requirements in section 403(w) apply to foods required to have a list of ingredients under 403(g) and (i).⁴⁰⁸ Those subsections refer to

⁴⁰¹ See *supra* Section II.A.1.

⁴⁰² As noted above, even if there is no express preemption, state and local requirements could still be preempted. See *supra* note 383.

⁴⁰³ FDCA § 403A(a)(2), 21 U.S.C. § 343-1(a)(2).

⁴⁰⁴ § 343-1(a); 21 C.F.R. § 100.1 (2017).

⁴⁰⁵ FDCA § 403A, 21 U.S.C. § 343-1.

⁴⁰⁶ § 343(w).

⁴⁰⁷ See § 343-1(a)(2).

⁴⁰⁸ § 343(w).

requirements for a food “label”—“a written, printed, or graphic matter upon the immediate container of any article.”⁴⁰⁹ Accordingly, section 403(w) sets forth requirements for foods in a container (packaged foods) and not restaurant-type foods.⁴¹⁰ Thus, state and local allergen labeling requirements for restaurant-type foods should not be preempted under section 403A as there are no federal allergen labeling requirements for these foods and labeling for restaurant-type food would not be a “requirement for the labeling of food of the type required by section . . . [403(w) of the FDCA].”⁴¹¹

Even if the express preemption provision were held to apply to state or local food allergen labeling requirements for restaurant-type food,⁴¹² FDCA 403A(b) permits FDA to exempt any state or local requirement from preemption if certain conditions are met.⁴¹³ Thus, there is a process by which a state or a political subdivision of a state could

⁴⁰⁹ § 321(k).

⁴¹⁰ See Section I.B; see also *FDA Questions and Answers*, *supra* note 64 (What about food prepared in restaurants? How will I know that the food I ordered does not contain an ingredient to which I am allergic?).

⁴¹¹ See FDCA § 403A(a)(2), 21 U.S.C. § 343-1(a)(2).

⁴¹² In *Cline v. Publix Supermarkets*, Judge Aleta A. Trauger of the United States District Court for the Middle District of Tennessee, Nashville Division, held that the plaintiff’s state law claims, “to the extent that they are based on Publix’s failing to label the Cookie as containing pecans,” were preempted pursuant to FDCA § 403A(a)(2), 21 USC § 343-1(a)(2). No. 3:15-0275, 2017 WL 67945, at *4 (M.D. Tenn. Jan. 6, 2017) (stating that “[t]he preemption clause contained in the FALPCA provides that a party cannot be held liable under state law for allergen labeling activity that is *not* a FALCPA violation”). *But see* notes 406–409 and accompanying text.

The court read FDCA § 403(q)(5)(A)(ii) and FDA’s nutritional labeling regulations 21 C.F.R. § 101.9(j)(3) to exempt the cookie (which was baked from scratch in the store bakery, offered for sale, and sold through the store’s full-service bakery counter) from FALCPA’s allergy labeling requirement. Its interpretation was based on the exemption applying to the ingredient labeling requirements referenced in FALCPA, however, as the court acknowledged the exception in FDCA § 403(q)(5)(A)(ii) “and the corresponding regulations frame this exemption as applying solely to the nutritional labelling requirements laid out in [FDCA § 403(q)] and not to the *ingredient* labeling requirements” *Cline*, 2017 WL 67945, at *3 n.6. Nevertheless, the Court read the exemption to apply “to all FDCA labeling requirements” saying it is “[t]he only logical reading of the statute.” *Id.* *But see supra* Section I.B & notes 407–411 and accompanying text (discussing FALCPA). The District Court also noted that the parties did not address the preemption clause in their briefs. *Cline*, 2017 WL 67945, at *4.

⁴¹³ FDCA § 403A(b), 21 U.S.C. § 343-1(b); 21 C.F.R. § 100.1 (2017) (Petitions requesting exemption from preemption for state or local requirements). FDA must find that the requirement “would not cause any food to be in violation of any applicable requirement under Federal law,” “would not unduly burden interstate commerce,” and “is designed to address a particular need for information which is not met by the requirements of the sections referred to in subsection (a).” FDCA § 403A(b), 21 U.S.C. § 343-1(b); see also 21 C.F.R. § 100.1.

request exemption from the express preemption provision if it was found to apply.⁴¹⁴

b. Dormant Commerce Clause

Commentators examining menu labeling laws have raised the question of whether these laws violate the “dormant” Commerce Clause doctrine by improperly burdening interstate commerce.⁴¹⁵ A similar question may arise regarding allergen labeling laws. With respect to menu labeling, although one student commentator argued that local menu labeling laws would improperly burden interstate commerce in violation of the dormant Commerce Clause doctrine,⁴¹⁶ other commentators have concluded that these laws would not.⁴¹⁷ The dormant Commerce Clause “refers to the inference that the Interstate Commerce Clause of the U.S. Constitution . . . is not only a basis for affirmative federal lawmaking, but also precludes states from acting in certain ways that threaten trade among the states.”⁴¹⁸ The dormant Commerce Clause prohibits “*discrimination* against interstate or out-of-state interests; the imposition of *unreasonable burdens* upon interstate commerce; and (occasionally) *extraterritorial regulation*.”⁴¹⁹

Like the menu labeling laws, allergy laws should not discriminate against out-of-state restaurants on their face.⁴²⁰ It is possible however that a covered establishment could argue that any allergy labeling and management laws that apply only to larger chains are discriminatory in effect, as the most significant burden is placed on restaurants that operate in multiple states and, therefore, should be subject to strict scrutiny.⁴²¹ However, others have argued that a burden is not

⁴¹⁴ See 21 C.F.R. § 100.1.

⁴¹⁵ See, e.g., Lauren F. Gizzi, Comment, *State Menu-Labeling Legislation: A Dormant Giant Waiting to be Awoken by Commerce Clause Challenges*, 58 CATH. U.L. REV. 501, 504 (2009); Rutkow et al., *Preemption and the Obesity Epidemic*, *supra* note 324, at 780; Jennifer L. Pomeranz and Kelly D. Brownell, *Legal and Public Health Considerations Affecting the Success, Reach, and Impact of Menu-Labeling Laws*, 98 AM. J. PUB. HEALTH 1578, 1579 (2008).

⁴¹⁶ Gizzi, *supra* note 415, at 504.

⁴¹⁷ See Rutkow et al., *Preemption and the Obesity Epidemic*, *supra* note 324, at 780; Pomeranz & Brownell, *supra* note 415, at 1579.

⁴¹⁸ Daniel Francis, *The Decline of the Dormant Commerce Clause*, 94 DENV. L. REV. 255, 258 (2017).

⁴¹⁹ *Id.*

⁴²⁰ See *id.*; see also Gizzi, *supra* note 415, at 522–23 (arguing that menu labeling laws are not discriminatory on their face).

⁴²¹ See Gizzi, *supra* note 415, at 504.

“discriminatory in the proscribed sense just because it applies mainly or even solely to out-of-state or interstate regulatees” and that the Supreme Court has “ignored effect-based discrimination . . . in cases lacking evidence of some kind of undesirably ‘protectionist’ frame of mind.”⁴²² Furthermore, although a covered establishment could also argue that an allergen law is unlawful if its burdens are “clearly excessive in relation to the putative local benefits,”⁴²³ there is a strong argument that such laws would have substantial local benefits and states should lay out the public health rationales for any such laws.⁴²⁴ In addition, as one scholar has argued “the practice of ‘burden review’ . . . has dwindled dramatically.”⁴²⁵

CONCLUSION

There is a need to regulate food allergen labeling in restaurants as changing consumption patterns mean that an increasing proportion of food is not subject to allergen labeling requirements under current law. Although there are some important differences between the menu labeling and allergen labeling and management contexts, the regulation of food allergens in restaurants is likely to raise similar questions and issues as menu labeling and therefore elicit similar objections. Accordingly, this Article argues that menu labeling should inform both the substance and implementation of food allergen labeling requirements. Food allergen labeling requirements are a starting point. Any allergen labeling requirements also should be accompanied by measures to prevent allergen cross contact, train restaurant workers, and educate the public. As in the menu labeling context, local and state allergen measures may ultimately prompt the creation of a federal regulatory system for food allergens in restaurants. Ultimately, food allergen labeling may make it so that the availability of information on major food allergens does not hinge on whether or not a food is in package form, thus advancing public health by creating a safer food environment for people with food allergies.

⁴²² Francis, *supra* note 418, at 263, 278.

⁴²³ *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970) (internal citation omitted); *see also* Bernell, *supra* note 170, at 863 (stating that since “no menu labeling cases have been decided on this issue, there is no precedent for how a court would answer this question”).

⁴²⁴ A fuller analysis would depend on the final scope of the measures, including those to prevent cross contact.

⁴²⁵ Francis, *supra* note 418, at 292.