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

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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

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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.

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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

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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

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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

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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

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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

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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]

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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 acute[266] is the same growth that makes addressing

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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

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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]

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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

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[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

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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

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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

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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

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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]

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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 EL., 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

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see also Ruchi Gupta et el., *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

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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.

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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 labeling[331]—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,

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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 allergen[339] 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

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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 el., *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 decisions[343]: 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/~acrobat/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]

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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]

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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 enforcement[360] and by providing feedback to restaurants that they should invest more in food allergen

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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

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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. Kornblet, *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 EL., *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

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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,

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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

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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.

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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

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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

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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.

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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] section . . . .[405]

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

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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

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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.

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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.